

CONSUMER PROTECTION AGAINST THE PRODUCTION AND SALE OF SYRUP DRUGS SUSPECTED OF BEING CONTAMINATED WITH HAZARDOUS MATERIALS

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ABSTRACT

Recently, the Indonesian health world has been shocked by the alleged production and sale of syrup drugs suspected to be contaminated with Ethylene Glycol (EG)/Diethylene Glycol (DEG) which exceeds the safe threshold and triggers acute renal failure in children. This is very worrying because it is feared that the impact will be even wider. Based on the information cited by the author from the news article that the Food and Drug Supervisory Agency of the Republic of Indonesia (BPOM RI) released an updated list of ethylene glycol (EG)/Diethylene Glycol (DEG) tainted syrup drugs that exceed the safe threshold. The contamination is suspected of triggering acute renal failure in children. The method which was used in this Scholar Paper was the Qualitative Research Method, a kind of Normative Legal Writing which was based on prescriptive library research concerning the study of positive law. For the Primary Legal Materials, Scholar used references such as Act Number 8 Year 1999 regarding to Consumer Protection, etc. And for Secondary Legal Material, Scholar uses books, journals, papers, newspapers, and report of legal writing. Then, for Tertiary Legal Materials, Scholar used references such as legal dictionary, dictionary Indonesian-English dictionary and vice versa, etc. Consumer has rights that must be protected from legal perspectives. Law Number 8 of 1999 concerning Consumer Protection Article 1 point (2) states that consumers are every user of goods and or services available in society, whether for the benefit of themselves, family, others, or other living beings and not for trading. It is crystal clear as regulated by our legislation, Consumer Protection must have a guarantee of legal certainty given to consumers. In this case Consumer Protection must have a guarantee of legal certainty provided to consumers in this case is a guarantee of the safety of syrup drugs on the market so that they are safe for consumption by their buyers. Plus buyers who take the syrup medicine are in an unwell state. Of course they want what is called healing, instead of getting worse, conditions such as kidney failure or even death.

Keywords: *Legal Protection, Government Roles, consumer protection*

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INTRODUCTION

Recently, the Indonesian health world has been shocked by the alleged production and sale of syrup drugs suspected to be contaminated with Ethylene Glycol (EG)/Diethylene Glycol (DEG) which exceeds the safe threshold and triggers acute renal failure in children (DM et al., 2023). This is very worrying because it is feared that the impact will be even wider. Based on the information cited by the author from the news article that the Food and Drug Supervisory Agency of the Republic of Indonesia (BPOM RI) released an updated list of ethylene glycol (EG)/Diethylene Glycol (DEG) tainted syrup drugs that exceed the safe threshold. The contamination is suspected of triggering acute renal failure in children.

In its official statement, BPOM released a list of 32 drugs produced by PT Rama Emerald Multi Sukses (PT REMS) that are contaminated with EG-DEG. The test results of propylene glycol raw materials used in the pharmaceutical industry (IF) drug syrups showed EG levels of 33.46 percent and DEG of 5.94 percent which exceeded the threshold of EG / DEG contamination requirements.

"Based on further examination of PT REMS's production facilities, a discrepancy was found in the application of CPOB. For this reason, BPOM sets administrative sanctions by revoking the certificate of Good Manufacturing Practices (CPOB) of non-beta-lactam oral liquids and followed by the revocation of all distribution permits for medicinal syrup products (32 products) produced by PT REMS," wrote an official statement from BPOM (<https://Health.Detik.Com/Berita-Detikhealth/d-6447467/Terbaru-Bpom-Rilis-32-Obat-Tercemar-Eg-Deg-Dari-Pt-Rems-Izin-Edar-Dicabut>, n.d.).

The families of the victims who died in cases of acute kidney failure due to cough syrup with ethylene glycol (EG) and diethylene glycol (DEG) contamination were said to have suffered material losses estimated at Rp 2 billion per person. The victims who undergo treatment are estimated to cost Rp 1 billion 50 million per person. This was revealed by the lawyer of the family of the victim of acute renal failure due to a toxic syrup drug, Awan Puryadi. "We have formulated that there is IDR 2 billion for the dead, IDR 1 billion 50 million for the treated," Awan said when met by media crews at the Central Jakarta District Court (PN Jakpus), Tuesday (12/13/2022). Also read: Acute Renal Failure Victims Who Give the Power to Increase, Lawsuit to Ministry of Health and BPOM Revoked Awan said the amount of material loss will still be re-calculated, following the increase in victims' families who will join the lawsuit against the Ministry of Health (MoH), the Food and Drug Administration (BPOM), and a number of pharmaceutical companies. The cloud estimates that the amount of the loss will increase in value. According to him, the amount of loss refers to the index that is often used by the Central Statistics Agency (BPS) or the determination of the minimum wage. With this index, it is calculated the costs that a family must spend to raise a child up to five years old, starting from the time of pregnancy, childbirth, hospital care, and others. "If it is immaterial, we project until the child is of retirement age with minimal value. Neither do we put it all in. It's only a few percent," he said. Also read: Komnas HAM Will Dig Kidney Failure Cases to the Root, Including the Awan Drug Mafia question, said that when a class action lawsuit is won, the compensation money distribution scheme will be distributed based on a court ruling. However, before the lawsuit materials are later read, a panel of judges will determine whether the lawsuit is valid or not. If declared valid, the lawsuit will be declared to represent all victims, even if they do not give power of attorney. "If it has been passed following the trial process, it will be decided and it will cover everything," he said. Thus, later the defendant party must pay damages to all victims of syrup drugs tainted with EG and DEG. After the judge grants the lawsuit, the plaintiff must provide a statement through the mass media. "The plaintiff is asked to convey it to the national mass media so that other (victims) can join, later the verdict will be determined by how it is distributed," Awan said. A total of 199 children died as a result of liquid syrup drugs tainted with ethylene glycol (EG) and diethylene glycol (DG). The data refers to the Ministry of Health data as of November 16, 2022. The number of victims suffering from acute kidney failure was 324 children. A number of families of victims of toxic syrup drugs later sued nine parties deemed responsible. They are the Ministry of Health and BPOM. Then, PT Afi Farma Pharmaceutical Industry and PT Universal Pharmaceutical Industries as drug manufacturers. Furthermore, five companies supplying medicinal raw materials, namely PT Megasetia Agung Kimia, CV Budiarta, PT Logicom Solution, CV Mega Integra, and PT Tirta Buana Kemindo. The plaintiffs requested that the defendants pay material and immaterial damages. In addition, the judge was asked to

declare the defendants committed unlawful acts. However, the lawsuit was dismissed as the number of victims' families granting power of attorney increased. The lawsuit will later be revised and then re-filed. "It is likely that mid-January will be another hearing attended by all the victims' representatives." Awan said (<https://Nasional.Kompas.Com/Read/2022/12/13/16332981/Korban-Meninggal-Akibat-Obat-Sirup-Tercemar-Eg-Deg-Ditaksir-Alami-Kerugian>, n.d.).

This is what disturbs the author's mind to analyze further related to the alleged production and sale of syrup drugs suspected to be contaminated with Ethylene Glycol (EG)/Diethylene Glycol (DEG) which exceeds the safe threshold and triggers acute renal failure in children to be further analyzed from the perspective of Trade Law, especially in terms of Consumer Protection Law.

Consumer Definition

Law Number 8 of 1999 concerning Consumer Protection (n.d.) states that consumers are everyone who uses goods and or services available in society, both for the benefit of themselves, family, others, and other living beings and not to be traded.

Government Regulation Number 58 of 2001 concerning Guidance and Supervision of Consumer Protection Implementation (n.d.) states that consumers are everyone who uses goods and or services available in society, both for the benefit of themselves, family, others, and other living beings and not to be traded.

In addition, in accordance with Government Regulation Number 59 of 2001 concerning Non-Governmental Consumer Protection Institutions (n.d.) states that consumers are everyone who uses goods and or services available in society, both for the benefit of themselves, family, others, and other living beings and not to be traded.

Consumer Protection Definition

Law Number 8 of 1999 concerning Consumer Protection Article 1 point (1) states that consumer protection is any effort that guarantees legal certainty to provide protection to consumers.

Then as stated in Government Regulation Number 57 of 2001 concerning the National Consumer Protection Agency (n.d.) states that consumer protection is any effort that guarantees legal certainty to provide protection to consumers.

In addition, Government Regulation Number 58 of 2001 concerning Guidance and Supervision of the Implementation of Consumer Protection Article 1 point (1) states that consumer protection is any effort that guarantees legal certainty to provide protection to consumers. Government Regulation Number 59 of 2001 concerning Non-Governmental Consumer Protection Institutions Article 1 point 1 states that consumer protection is any effort that guarantees legal certainty to provide protection to consumers.

Consumer Protection Directives

As stated in Article 3 of Law Number 8 of 1999 concerning Consumer Protection, it aims to:

1. Increase consumer awareness, ability, and independence to protect themselves;
2. Raising the dignity and dignity of consumers by avoiding negative excesses of the use of goods or services;

3. Creating a consumer protection system that contains elements of legal certainty and information disclosure as well as access to information so that consumers can make alternative and selective choices in every purchase or use of a good or service;

4. Growing awareness of business actors regarding the importance of consumer protection so that an honest and responsible attitude in doing business grows;

5. Increase consumer empowerment in choosing, determining and demanding their rights as consumers;

6. Improving the quality of goods and or services that ensure the continuity of the business of producing goods and or services, health, comfort, security, and consumer safety.

METHOD

This paper is a Normative Legal Research. Normative Legal Research is a scientific procedure to find the truth based on the logic of the normative legal scientific. The scientific logic of normative Legal Research is developed by the scientific concentrate and ways of thinking of normative jurisprudence and their objects are regulation themselves. "Referring to Soerjono Soekanto's statement that legal writing is carried out by analyzing literature or secondary data called normative legal writing or library law writing." (Soekanto & Mamudji, 2003)

RESULTS AND DISCUSSION

1. Legal Protection to Consumers against suspected production and sale of syrup drugs suspected of being tainted with Ethylene Glycol (EG)/Diethylene Glycol (DEG) that exceeds the safe threshold and triggers acute renal failure in children

As we all know that Kosumen has rights that must be protected from a legal perspective. Law Number 8 of 1999 concerning Consumer Protection Article 1 point (2) states that consumers are everyone who uses goods and or services available in society, both for the benefit of themselves, family, others, and other living beings and not to be traded.

According to Government Regulation Number 58 of 2001 concerning The Development and Supervision of the Implementation of Consumer Protection Article 1 point (2) states that consumers are everyone who uses goods and or services available in society, both for the benefit of themselves, family, others and other living beings and not to be traded.

In addition, in accordance with Government Regulation Number 59 of 2001 concerning Non-Governmental Consumer Protection Institutions Article 1 point (2) states that consumers are everyone who uses goods and or services available in society, both for the benefit of themselves, their family, others and other living beings and not to be traded.

In this case, the Consumer is the buyer of a syrup drug suspected to be tainted with Ethylene Glycol (EG)/Diethylene Glycol (DEG) that exceeds the safe threshold and is suspected of triggering acute renal failure in a child. Moreover, according to the data obtained, there have been casualties due to this tainted syrup drug. Based on the news obtained above, as many as 199 children died due to liquid syrup drugs contaminated with ethylene glycol (EG) and diethylene glycol (DG). The data refers to the Ministry of Health data as of November 16, 2022. The number of victims suffering from acute kidney failure was 324 children.

In Law Number 8 of 1999 concerning Consumer Protection, Article 1 point (1) states that consumer protection is any effort that guarantees legal certainty to provide protection to consumers.

Then as stated in Government Regulation Number 57 of 2001 concerning the National Consumer Protection Agency Article 1 point (1) states that consumer protection is any effort that guarantees legal certainty to provide protection to consumers.

In addition, Government Regulation Number 58 of 2001 concerning Guidance and Supervision of the Implementation of Consumer Protection Article 1 point (1) states that consumer protection is any effort that guarantees legal certainty to provide protection to consumers. Government Regulation Number 59 of 2001 concerning Non-Governmental Consumer Protection Institutions Article 1 point (1) states that consumer protection is any effort that guarantees legal certainty to provide protection to consumers.

As stated in Article 3 of Law Number 8 of 1999 concerning Consumer Protection, it is very clear that according to laws and regulations, Consumer Protection must have a guarantee of legal certainty provided to consumers in this case is a guarantee of the safety of syrup drugs on the market so that they are safe for consumption by buyers. Plus buyers who take the syrup medicine are in an unwell state. Of course, they want what is called healing, instead of getting worse, conditions such as kidney failure or even death.

In addition, consumers should get their right to disclose information on the goods or services they consume. In this case, the suspected syrup drug tainted with Ethylene Glycol (EG)/Diethylene Glycol (DEG) exceeds the safe threshold and provokes acute renal failure in a child. In addition, based on the news obtained above, as many as 199 children died due to liquid syrup drugs contaminated with ethylene glycol (EG) and diethylene glycol (DG). The data refers to the Ministry of Health data as of November 16, 2022. The number of victims suffering from acute kidney failure was 324 children. This is certainly contrary to Article 3 letter (c) of Law Number 8 of 1999 concerning Consumer Protection.

In addition, the non-fulfillment of consumer rights as stated in Article 3 letter (d) of Law Number 8 of 1999 concerning Consumer Protection that "Growing awareness of business actors regarding the importance of consumer protection so that an honest and responsible attitude in doing business grows".

Attributed in this case, business actors who produce syrup drugs should say honestly about the content of the syrup drugs they produce and be fully responsible if it turns out that the syrup drugs actually have a bad impact on their consumers.

Principles regarding the position of consumers in relations with business actors based on doctrines or theories known in the historical development of consumer protection law, including:

1. Let the buyer beware (caveat emptor)

The doctrine of let the buyer beware or caveat emptor is the basis of the birth of disputes in the field of consumer transactions. This principle assumes that business actors and consumers are two very balanced parties, so consumers do not need protection. This principle contains weaknesses, that in the development of consumers do not get sufficient information to determine the choice of goods and / or services they consume. This can be caused by limited consumer knowledge or the inaccessibility of business actors to the products they offer. Thus,

if the consumer experiences a loss, the business actor can argue that the loss is the result of the consumer's own negligence.

According to the author's analysis, in this case the practice of producing and selling syrup drugs suspected to be contaminated with Ethylene Glycol (EG)/Diethylene Glycol (DEG) that exceeds the safe threshold and triggers acute renal failure in children is not in accordance with this principle has not been appropriately applied because the position of Business Actors and Consumers in this case is not balanced. As consumers, they should be protected by their rights, especially in terms of product safety and health by business actors.

2. The due care theory

This doctrine states that business actors have an obligation to be careful in marketing products, both goods and services. As long as the businessman is careful with his product, then he cannot be blamed. On this principle applies proof who postulates then he is the one who proves. This is in accordance with the spirit of proof in private law in Indonesia, namely proof is with the plaintiff, in accordance with Article 1865 of the Civil Code which expressly states that whoever postulates has a right or to affirm his rights or refute the rights of others, or point to an event, is required to prove the existence of such rights or events.

If analyzed using this principle, the Authorities can carry out an investigation and proof process on the practice of producing and selling syrup drugs suspected to be contaminated with Ethylene Glycol (EG)/Diethylene Glycol (DEG) which exceeds the safe threshold and triggers acute renal failure in children by collecting various evidence and requesting information from business actors and consumers who have used it. If all evidence has been collected then, the legal process can proceed as it should and is in accordance with Article 1865 of the Civil Code.

3. The privity of contract

This doctrine states that businesses have an obligation to protect consumers, but it can only be done if a contractual relationship has been established between them. Business actors cannot be blamed beyond the things promised. Thus consumers can sue on the basis of default. This is in accordance with the provisions in the Civil Code article 1340 which states that the scope of the agreement is only between the parties to the agreement (Shidarta, 2006).

In this case, the practice of producing and selling syrup drugs that are suspected to be contaminated with Ethylene Glycol (EG)/Diethylene Glycol (DEG) which exceeds the safe threshold and triggers acute renal failure in children, of course, there is no written agreement between the Business Actor and the Consumer before because the Consumer who requires services for a swab test alone is the one who pushes himself to be examined as a flight passenger before flying. So the agreement occurs when the Consumer makes a payment transaction for the swab test and the Business Actor checks the prospective passenger. So both parties are subject to the rules of Law Number 8 of 1999 concerning Consumer Protection.

2. The Government's role is related to the alleged production and sale of syrup drugs suspected to be tainted with Ethylene Glycol (EG)/Diethylene Glycol (DEG) that exceed the safe threshold and trigger acute renal failure in children

The role of the Government as a regulator and policyholder is very important. The importance of Government interference is based on several arguments, namely:

1. In modern society, manufacturers offer various types of new products resulting from technological advances and management en masse (mass production and consumption).

2. Mass production results and advanced technology, potential for the emergence of the risk of defective products that can harm consumers.

3. Unbalanced relationship between Consumers and Producers.

4. Perfect competition as a supporter of consumer sovereignty theory in practice is rare (Samsul, 2004).

Related in this case, the Government should intervene in the production and sale process of syrup drugs suspected to be contaminated with Ethylene Glycol (EG)/Diethylene Glycol (DEG) which exceeds the safe threshold and triggers acute renal failure in children, moreover, this product is distributed in very large quantities so that it must be extra supervised so that it is not misused by irresponsible parties so that it can be fulfilled as it should be.

CONCLUSION

Consumer Protection must have a guarantee of legal certainty given to consumers in this case are buyers of syrup medicines because they actually want to recover from the disease, instead of getting worse (experiencing acute kidney failure) or even to death.

Suggestion

The government should intervene in the production and sale process of syrup drugs suspected to be contaminated with Ethylene Glycol (EG)/Diethylene Glycol (DEG) which exceeds the safe threshold and triggers acute renal failure in children. Moreover, this product is distributed in very large quantities so that it must be extra supervised so that it is not misused by irresponsible parties so that it can be fulfilled as it should be.

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