

Who is Liable for Medicine Containing Toxic Chemicals Based on The Consumer Protection Law

Suwinto Johan ^{a,1,*}, Citra Rahayu ^b

^{ab} Faculty of Business, President University, Jl. Ki. Hajar Dewantara, Jababeka Education Park, Cikarang Baru, Kab. Bekasi, Indonesia

¹ suwintojohan@gmail.com;

* Korespondensi Penulis

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ABSTRACT

The relationship between producer and consumer is not limited to buying and selling transactions only. But the producer is responsible until the product usage by the consumer. The producer sells a variety of products. It might be anything from simple items to ones that risk the lives of consumers. The producer is responsible for the effects that will raise from consumption of the product. The purpose of this study is to examine the medical/medicine producer's responsibility for the impacts on consumer poisoning. The study used normative juridical research methods. The conclusion of the study is the producer must bear responsibility for contaminating manufactured medicines. The producer accountability is in the form of compensate the consumer. These things have been managed in the Consumer Protection Act. If the producer received contaminated raw materials from the suppliers, so the producer can send these raw materials back to the supplier. A fraud penalty may be imposed on the supplier if they mix or provide the incorrect kind of raw material that doesn't fit the order. However, the producer still got to send these raw materials back.

Hubungan antara produsen dan konsumen tidak hanya terbatas pada transaksi jual beli. Namun pertanggungjawaban produsen hingga pada pemakaian produk oleh konsumen. Produk yang dijual oleh produsen terdiri dari berbagai produk, produk dapat berupa produk yang sederhana hingga produk yang dapat mengakibatkan kehilangan nyawa konsumen. Pertanggungjawaban produsen hingga efek yang ditimbulkan akibat konsumsi produk tersebut. Penelitian ini bertujuan membahas pertanggungjawaban produsen obat yang mengakibatkan keracunan pada konsumen. Penelitian ini mempergunakan metode penelitian yuridis normatif. Penelitian ini menyimpulkan bahwa produsen harus bertanggungjawab atas pencemaran produk obat yang diproduksi. Bentuk pertanggungjawaban produsen adalah menggantikan kerugian konsumen. Hal ini telah diatur dalam Undang Undang Perlindungan Konsumen. Jika produsen menerima bahan baku yang tercemar dari pemasok, maka produsen dapat mengembalikan bahan bakunya kepada pemasok. Jika pemasok melakukan oplosan atau jenis bahan baku tidak sesuai dengan pesanan, maka pemasok dapat dikenakan sanksi penipuan. Namun demikian, produsen obat tetap dapat mengembalikan bahan bakunya.

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1. Introduction

Children in Gambia have developed renal ailments as a result of four different varieties of cough syrup made in India. These cough medicines include ethylene glycol (EG). In Indonesia, these four varieties of cough syrup are not common. In medicine, ethylene glycol is used as a solvent chemical (Pinandhita, 2022).

The Indonesian Ministry of Health has made 91 syrup medications that may be the root of cases of pediatric kidney disease publicly available. Cough syrup and paracetamol make up the majority of this syrup medication. The Ministry of Health claims that kidney illness developed as a result of taking certain medications. These medications contain a chemical composition that contains polyethylene glycol, according to the study. According to data as of October 21st, 2022, there have been 241 deaths (Magang Merdeka, 2022).

Two pharmaceutical businesses have been identified by Indonesia's food and drug monitoring agency (BPOM) as being investigated in criminal cases for the possible presence of hazardous substances in cases of acute renal illness. According to BPOM, those two pharmaceutical companies' medications contain ethylene glycol (EG) and diethylene glycol (DEG) (Noviansah, 2022a). These two pharmaceutical firms are allegedly using EG/DEG on purpose. The victim's blood and urine samples were both examined by the Criminal Investigation Agency and the associated agency (Noviansah, 2022b). A food or medication product has gone through several phases if we consider the distribution procedure from the raw material till it is obtained by the consumer.

According to the examination of the inquiry, the first raw material supplier of the pharmaceutical businesses with the initial CV B was where the raw materials for their PT YF came from. Contrarily, CV B's raw materials came from CV APG. Raw materials are obtained by CV APG from CV SC. Lab testing of the CV SC raw material revealed that propylene glycol was present in amounts ranging from 4.69 to 99.09 percent. According to CV B, it possesses a certificate of analysis (COA). Figure 1 provides an illustration of this.

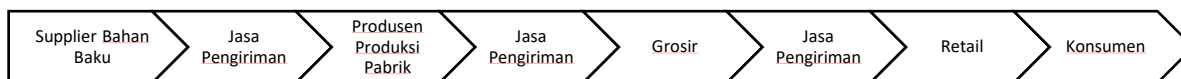


Figure 1 Value Chain of Product

Based on consumer protection laws, this investigation will go into specifics regarding the distribution of drugs containing harmful substances. Due to the rarity of this circumstance in Indonesia, there is currently a dearth of studies that explore medicine. Studies that examine the value chain from the origins of raw components to final pharmaceuticals are still quite rare.

Consumer protection aims to create a consumer protection system that contains an element of legal certainty and the open information also the access to get information. Besides that, consumer protection aims to build the businessmen awareness about the importance of consumer protection so it will be growing the honest and high responsibility attitude in business. (Nasution, Purba, Harianto, & Siregar, 2018) Consumer protection gives a safe feeling to the consumer in meeting the necessities of life (Fithri, Munthe, & Lubis, 2021).

Delivery services are included in the services involved in the value chain of food and medicine manufacturing as illustrated in figure 1. The delivery courier is responsible for loss, and damage to goods if caused by it. Couriers are not responsible for the risk of the goods they carry. The courier will replace lost or damaged goods with a maximum of 10 times the cost or shipping costs if not use insurance (Kevin Patria & Putra Ariana, 2020). Money that has the same value as the protection value contents of the goods sent (listed on the receipt) (Farkhan & Witasari, 2021). Consumer and courier or delivery services are a legal relationship (Ksatriagana & Utama, 2020).

Accountability mechanisms for providing compensation to consumers because of business errors, so PT. Go-Jek Indonesia gives the guarantee and or assurance of their services through the terms and conditions that has been stated in their official website that give the compensation with maximum IDR 10,000,000, -. The legal remedies that could be done by the consumer against the carriers for the damages they suffer are in accordance with the provisions of the consumer protection

law (Adi Putra, Putu Budiarta, & Sri Astiti, 2021). The delivery services are only responsible for the loss, and damage to goods that they carry. They are not responsible for the risk of using the goods.

The legal relationship between the service provider, business partner, and consumers is beginning when the consumer orders through the application, and after that, the service provider confirmed to their business partner/driver the goods delivery feature. After the price agreement then the goods delivery process happen, on there, electronic contract occurs between the parties with the applicable terms and conditions that has been explained on the application. Online transportation accountability is uncertain. Because the company/service provider, namely the transportation company, does not provide certainty of responsibility with the replacement/compensation for damages to consumer goods.(Abdulahanaa, 2021)

Grab, an online transportation provider is hesitant to report consumer products that have been damaged. This thing is also supported by the lack of response from online transportation provider consumer like Go-Jek and Grab in reporting damaged goods. The limitation of liability principle should be implemented by the application company of online transportation providers. Compensation arrangements have been regulated in the consumer protection law Article 4 letter h, Article 7 letter f, Article 19 paragraph (1), paragraph (2), paragraph (3), paragraph (4). These things also have been explained by the company/service provider on their apps that are subjected to the consumer protection law. Apart from that, the terms and conditions for filing the compensation are also explained by the service provider in the application, but in the fact, there are many customers do not report losses to service providers, customers only approach their business partners for compensation directly (Pernando, Azheri, & Fauzi, 2021).

Regulation of the Minister of Transportation No. 77 of 2011 concerning about the responsibility of air carriers and Regulation of the Minister of Transportation No. 49 of 2012. This rule is one of the legal protections for passengers against the carrier's negligence, however, if the carrier does not uphold its obligations, the passenger has the right to sue their rights (Yuliana, 2022). The focus of current regulations is still on carelessness or lateness. However, the law does not regulate if there is the contamination of the goods being delivered.

Airline companies are required to take the responsibility for airplane accidents based on the 1999 Montreal Convention. These responsibilities include the Air Asia QZ-8501 accident that claimed lives (Dwi, Njatrijani, & Saptono, 2019). The Convention of the Unification of Certain Rules for International Carriage by Air has ratified the protection of air transportation customers or better known as 1999 Montreal Convention. The ratification of the 1999 Montreal Convention has been adopted inside of the Indonesia national regulation through the President of Republic Indonesia Regulation No. 95 of 2016 with the date 21st November 2016 concerning ratification of the Convention on the Unification of Certain Rules Concerning International Air Transportation. Montreal Convention focuses on the transport accident, these rules do not discuss the effects caused by the transport.

That Presidential Regulation came into force on November 23rd, 2016, which aims to enforce these international agreements as a national legal defense in regulating the carriers' obligations in connection with international air transport and to ensure legal security for passengers, goods, baggage, and cargo. By limiting the amount of compensation that can be provided for international flights of passengers, goods, baggage, and cargo, this rule also provides protection to airline companies. Ratifying the international carrier responsibility law completes the Indonesian carrier responsibility law. Previously, Indonesia already had a carrier responsibility law for national flights, namely the Regulation of the Minister of Transportation No. 77 of 2011 that concerning about the responsibilities of air transport carriers, regarding lost, destroyed and damaged checked baggage is contained in Article 2 letter c. Meanwhile, the amount of compensation for passengers who have lost, destroyed or damaged their checked baggage as referred to in Article 2 letter c is contained in the provisions of Article 5, specific to compensation (Ferdian, 2020).

Based on the Indonesian Civil Code chapter 1320 and chapter 1338. Researchers can conclude that the producer give promises and information based on things that related to goods and/or services offered to consumers, rights and obligations the producer with retail goods consumer includes the responsibility of producer in maintaining product quality by limiting the risk of losses suffered by consumer In terms of consumer losses driven by product defects. Consumers have the right to sue producers under the consumer protection law. Meanwhile the compensation can be money

replacement or goods replacements and/or services or healthcare treatment (Faisal & Istiqamah, 2021). The losses that have been regulated by Civil Code are those that are related to products and/or services, not specifically discussing the consequences of using the goods produced.

Business actors have the responsibility to ensure the quality of goods and/or services produced and/or in accordance with the quality standards of goods and/or services that apply to transactions, also the legal consequences of consumer losses by the distribution service business actors are business actors who provide compensation, and/or replacement if the goods and/or services received or used do not meet the requirements (Siregar, Iriansyah, & Afrita, 2021). The explanation regarding the replacement is that the goods and/or services do not meet the requirements or agreements, and the producer's risks of causing the loss of life are not clearly regulated.

Buying and selling transactions through electronic media are regulated in Law Number 8 of 1999 concerning Consumer Protection, Law Number 7 of 2014 concerning Trade, and Law Number 19 of 2016 concerning Amendments to Law Number 11 of 2008 concerning about Information and Electronic Transactions (Ranto, 2019).

The following questions will be examined in this study: How does the sourcing process of raw materials up to the medicinal producers? Who should be liable for medicine containing toxic chemicals that cause casualties? How is the responsibility of the medicine producer in the case of medicine containing toxic chemicals?

2. Method

This study uses a normative juridical research method based on the background. This study examines the primary research materials, secondary research materials, and other research materials. This research focuses on legal norms and principles related to consumer protection. The research examines the vertical and horizontal synchronization of existing regulations. This research also examines the laws and regulations related to the relationship between consumers and producers. The study explored the industry overall, including both financial and non-financial aspects.

Normative research examines primary research materials, secondary research materials and other supporting research materials (Marzuki, 2017) The secondary research material consists of scientific research articles, books, proceedings, or research seminars. While other research materials are information from various communication media (Johan, 2022).

The study collects data on cases of drug poisoning from various sources. The study also conducted interviews with chemical business actors. The research examines the applicable regulations related to consumer protection.

3. Result and Discussion

3.1. The Process of Sourcing Raw Materials up to Medicinal Producers

Sources of basic raw materials for the manufacture of medicine consist of several types of raw materials, including water and chemicals. We know that chemicals are produced by chemical producers. One of the mixtures that we know is Ethylene Glycol. An overview of EG is explained in Figure 2.

Based on Figure 2, the mixed process to obtain EG undergoes a mixture of various chemical sources at the producer's manufacturer. This process carries the risk of mixing other substances into this process.

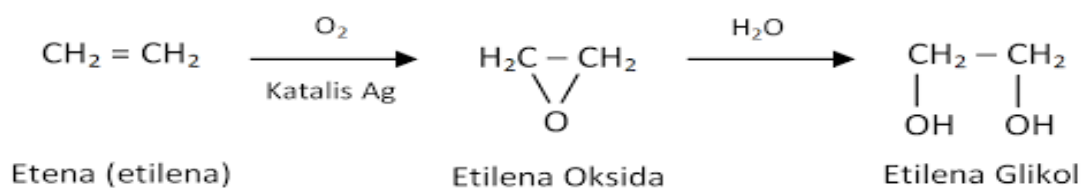


Figure 2 Source of Etilen

After the producer receives the chemicals, the pharmaceutical producer will carry out the production process by mixing the existing substances to produce medicine that is sold to consumers. There is a chance that raw materials used to make medicines could become contaminated during the delivery process by the delivery courier.

In accordance with the order, the parties receiving raw materials from other parties must check the raw materials' quality. The consumer may send back the goods to the supplier if the raw materials or orders received do not match the orders, so receiving unsuitable raw materials cannot be an excuse for fraud on the part of third parties.

3.2. Those who must be liable for Medicine Containing Toxic Chemicals that Cause Casualties

The products that have been passed from one chain to the next chain are at risk. To protect their customers from harm, medical producer must make sure that their goods follow to production standards. The producers of one stage will become producers of the next as the consumers. So that each stage should have good quality control for the product it produces.

The things that are essential for human life are food and medicine. Food and medicine consumption both have an effect on the human body. Therefore, it is crucial to control food and medicine. The Indonesia government has a special agency or institution, namely Food and Drug Supervisory Agency (BPOM). BPOM was formed based on Law Number 36 of 2009 concerning Health. In addition, Presidential Regulation Number 80 of 2017 specifically regulates the Food and Drug Supervisory Agency.

BPOM has the duties and functions as regulated in Article 3 paragraph 1 and paragraph 2 of Government Regulation (PP) No. 80/2017. In accordance with this regulation, BPOM oversees the food and medicines before. However, whether BPOM will monitor the types of medicine that have obtained approval for circulation, then experience contamination or changes from time to time. Before being distributed, medicines must first have BPOM approval, but not for every batch of medicines. Producers must inform BPOM and receive approval or distribution permission if they change the raw material used to make food or medicine.

It is a violation of the approval that has been given if the manufacturer changes the medication's raw material without informing BPOM and continues to use the same kind of food or medicine. If the producer uses the same raw materials but they are contaminated during delivery of materials or medicine products and food products, the courier who sent those must have responsibility. If this product is the final version. The courier for sending raw materials must take responsibility if there are problems with the delivery.

However, if the raw materials are contaminated and reach the medicine producer, The medicine producer should conduct an inspection before starting the production process or after completing the medicine production, it is very important in monitoring product quality. As a result, the producer must still be accountable for the quality of the medicine they produce.

Every producer has a Quality Control (QC) section, which allows for the detection of any product compliance issues. We are known that a shoe manufacturer has a QC division that examines the footwear made by its suppliers. If the shoes that are sent but do not meet the requirements will either be rejected or returned. The product quality including color quality is under QC's control. So, the medicine producer should have a QC section.

3.3. Accountability of the Medicine Producer in the Case of Medicine Containing Toxic Chemicals.

At the harmonization stage, there are 2 Medicine producers are required to obtain approval from BPOM. Before the medicine being distributed, medicines must first have BPOM approval, then the medicine producer will produce medicine according to the approved composition. Medicine producer will guide medicine production per batch as it should be with a composition that has been approved by BPOM.

Medicine producers get raw materials from suppliers. Before beginning production, it is appropriate for a medicine producer to examine the quality and composition of the raw materials in order to maintain the quality of the ingredients. The raw material producer has the right to return the raw material to the supplier if the quality of the raw material does not fulfil production requirements. Raw material producers are not required to accept goods delivered by the supplier.

In the case of EG and DEG, the producer of the medicine should return the raw material to the supplier after examining it. The process of making medicine starts with the raw materials being received by the producer and continues until consumers get poisoning. For this incident, the producer should be accountable to the consumers. A review of the received raw materials should be done by the producers.

In the meanwhile, if it is proven that the supplier purposefully mixed the raw materials in order to deceive the producer of the medicine, they must be held accountable. Upstream and downstream responsibilities are carried by both small and large suppliers. The related parties also will examine the supplier, and if the supplier can identify a source of the raw materials with the right composition, then the supplier has operated in line with the procedure. The supplier may be held liable for fraud against the buyer if the listed raw materials don't match the raw materials received.

This responsibility is in line with responsibilities in various other businesses, such as the problem with car air bags. Car manufacturers are still liable for any harm or flaws in air bag devices that cause a customer's fatality. This can demonstrate that consumers purchase vehicles from the car manufacturer, despite the fact that a supplier to a car manufacturer makes the air bag. Defective products are still the responsibility of the car manufacturer. Additionally, car manufacturers are recalling the vehicles they sell. This can serve as an illustration of the need for producers to take responsibility for their goods.

According to the article 7 Law No. 8 of 1999 concerning Consumer Protection (UUPK), business actors are expected to guarantee the quality of the goods and/or services they produce and/or trade based on the applicable product and/or service quality standards. Article 8 of the Consumer Protection Law (UUPK) prohibits business actors from producing and/or selling goods and services that do not adhere to the necessary requirements and statutory provisions. Business actors are prohibited from trading contaminated pharmaceutical/medicine and food preparations, as well as those that are damaged, defective, or used, without providing accurate and complete information in accordance with Article 8. According to Article 19, business actors are required to pay damages, clean-up costs, and/or customer losses resulting from the use of goods and/or services that were produced or traded. (Rusli, 2012)

4. Conclusion

According to the Consumer Protection Law (UUPK), producers are accountable for their products if it causes customers suffering. However, if a violation or misuse of the process for importing raw materials is discovered, other parties who have been involved as suppliers may also be made accountable. Distribution of raw materials from large suppliers to pharmaceutical/medicine producers passes through a lengthy stage. At this point, delivery services are also used by medicine producers and suppliers. So that there is a chance of contamination at every stage. Pharmaceutical/medicine producers have a responsibility to compensate consumers for losses as sellers and product providers. The accountability may take the form of compensation for consumer losses, in accordance with the consumer protection law (UUPK). This study has a weakness by only focusing on related regulations, specifically consumer protection laws. Another study can be developed by considering suggestions from business actors. The perspective of business actors may differ from that of consumers and regulators. Thorough control of all hazardous chemicals needs to be done. The government can issue regulations related to the control of hazardous chemicals. Chemicals can harm humans.

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