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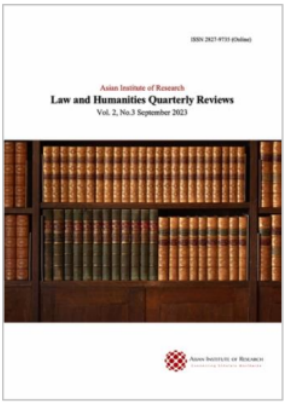

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Responsibility of a Pharmaceutical Company on Medicine Safety (Case Study on Paracetamol Syrup)

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Abstract
Cases of medicine poisoning derived from paracetamol syrup that is currently rampant have caused acute kidney failure in children. This is known because of the content of harmful substances contained in the medicine. The dangerous substances contained in the medicine are *Ethylene Glycol* and *Diethylene Glycol*. Paracetamol syrup poisoning cases have claimed many victims. Up to now, 269 victims have experienced acute kidney failure and 157 of them are declared dead. This article analyses the responsibility of pharmaceutical companies in securing medicine in cases that occur and how legal steps are to protect the interests of victims and their families. The research methods employed normative legal methods sourced from secondary data in the form of legal materials and non-legal materials. The qualitative approach is descriptive and the data collection is qualitative. Qualitative data analysis using the Miles and Huberman model where the narrative and secondary data are examined with analysis content. This case is caused by intentional or negligence on the part of the pharmaceutical company producing the medicine in the production process and carelessness in the packaging and distribution of these medicines. The Ministry of Health and the Food and medicine Supervisory Agency (BPOM) are also recognized for being careless in supervising and issuing proper distribution permits for these medicines. There must be a responsibility from the parties concerned to the victims and their families. The parties involved in this medicine poisoning case have absolute legal responsibility (strict liability) for the losses suffered by the victims.

Keywords: Poisoning, *Paracetamol*, *Ethylene Glycol*, *Diethylene Glycol*

1. Introduction

Along with the development of civilization that has been achieved by humans, human life in society is increasingly complex. The population growth throughout the world, including in Indonesia, continues to increase significantly so that the quality of public health continues to experience dynamics. On the one hand, the situation or condition that occurs at a certain time and in a certain place can be seen from two sides, some perceive it as an increase in health quality and on the other hand it can also be perceived as a decrease in health quality. The quality that is believed to be very dependent on the point of view and the school of thought held by a person or group of people at a certain place and time.

This happens because it is actually neutral and the increase in the number of people with the disease can be felt from various sides. For some people, an increase in the number of people who are sick can be interpreted as being successful in uncovering cases, while on the other hand, an increase in the number of people who are sick can be interpreted as not having/unsuccessfully competent institutions in the health sector have not worked optimally and so on. The increase in the number of hospitals and health facilities such as Puskesmas and clinics as well as the operation of pharmaceutical companies does not necessarily mean that the level of public health will improve.

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The substance Ethylene Glycol (EG) contained in paracetamol syrup is a chemical substance in the form of an odourless, colorless and sweet-tasting liquid. Ethylene Glycol is commonly used as an antifreeze in vehicle radiators. In addition, the substance can also be used as a solvent in industrial and household products. According to Indonesian Standards, the safe threshold is 0.5 mg/kg body weight per day for contamination from Ethylene Glycol and Diethylene Glycol (Agustin, 2022). If someone consumes more than the limit, it will be poisoned and can be fatal. According to UGM Pharmacy expert Prof. Zullies, the use of Ethylene Glycol as an additional substance has been regulated according to the level limit, it should not cause problems in its safety (Pinandhita, 2022). Meanwhile, according to PHARMACOPE, EG can actually be used but a maximum of 0.1%.

After you have introduced the problem and have developed the background material, explain your approach to solving the problem. In empirical studies, this usually involves stating your hypotheses or specific question and describing how these were derived from theory or are logically connected to previous data and argumentation. Clearly develop the rationale for each. Also, if you have some hypotheses or questions that are central to your purpose and others that are secondary or exploratory, state this prioritization. Explain how the research design permits the inferences needed to examine the hypothesis or provide estimates in answer to the question.

2. Method

The research uses normative legal methods based on secondary data in the form of legal materials (Primary, Secondary and Tertiary) and non-legal materials (Soekanto, Mamudji, 2022: page. 12-13). The qualitative

approach is descriptive and the data collection is qualitative. Qualitative data analysis uses the Miles and Huberman model where the narrative and secondary data are examined with analysis content (Ezmir, 2010: page.129-135).

3. Results

In the case of paracetamol syrup which causes acute kidney failure in children, *Ethylene Glycol* substance can help dissolve the paracetamol medicine into a liquid syrup for easy consumption by children. Regarding this matter, Penny Luquito, the head of BPOM, said that his party had carried out supervision in accordance with the provisions of medicine manufacture. The BPOM itself is conducting monitoring, but there is a possibility of an error. Substance EG is the result of imports from India (DataBooks, 2022), so it needs to be investigated further. Meanwhile, import and export supervision activities have not been optimal by the government (Mustakim, et.al, 2021: p. 120). According to Masteria Yunovilsan Putra, Head of BRIN's vaccine and medicine research center, there is a possibility that manufacturers may fraudulently mix EG syrup medicine solvents in order to make a lot of profit. However, this possibility has not been confirmed. Based on data from BBC Indonesia (2022), the problem has become more complicated because until now there has been no legal provision regarding the obligation to test solvents, so the process is not as strict as the testing of active ingredients. Supervision from pharmaceutical companies must be carried out to maintain medicine quality during the distribution process to the public (Deddy, *et.al*, 2022: 347).

When solvents enter Indonesia, scientific tests are not strictly carried out because there are no regulations that require it. Therefore, there is a lack of supervision, such as not detecting raw materials for medicine that exceed the maximum limit for consumption, as happened with paracetamol syrup which has a toxic impact on children. The lack of supervision occurs because the government puts trust in the importer, as seen with Indonesia being the world's 9th largest EG importer globally (Zahira, 2022). In addition, pharmaceutical companies also fail in monitoring so that there is an excess of EG content in *paracetamol* syrup.

Looking at this case, based on Article 19 of the UUPK concerning the responsibility of business actors which contains compensation for pollution, it does not eliminate the possibility of compensation in the form of criminal sanctions which are the responsibility of business actors covering all consumer losses. In Number 36 Article 14 of 2009 concerning Health, the government supervises the implementation of Health and Article 196 in conjunction with Article 201 Business actors who produce/distribute pharmaceutical preparations that do not meet the standards can be imprisoned for a maximum of 10 years and pay a maximum fine of one billion. Criminal sanctions can also be imposed on pharmaceutical companies if in pharmaceutical practice which includes manufacture, security and other processes are not carried out by pharmaceutical personnel who have expertise and authority (Article 108).

Observing the various explanations above, it can be seen that in terms of the use of *Ethylene Glycol* as a solvent for paracetamol syrup from a formal juridical point of view, the procedure has not been established. Specifically, regarding the level test to the contaminant test, therefore all parties who carry out the mandate of government duties, in this case especially in the pharmaceutical and health environment, need to build a strong commitment to develop high moral integrity to always refer to the moral message mandated by the founders of the country. As stated in the 4th Paragraph of the Preamble to the 1945 Constitution, the government protects the entire Indonesian nation and advances the general welfare. Article 28 of the 1945 Constitution states that anyone has the right to live in physical and spiritual prosperity and to live in a good and healthy environment.

The latest news, BPOM said it was processing criminal charges against two pharmaceutical companies that were not mentioned because of the alleged intentional process of producing medicines that did not comply with the requirements and set out 10. The Ministry of Health also recalled five syrup medicines containing EG that exceeded the threshold, namely cough and cold medicines. Unibebi flu Cough Syrup and Flurine DMP Syrup, while for fever medicine there are Termorex Syrup, Unibebi Fever Drops, and Unibebi Fever Syrup (Chaterine, 2022). The existence of illegal acts carried out by producers not only causes economic losses, but also harms

health and even threatens life safety as happened in the case of kidney failure which claimed many victims (Noviardi, 2021: p. 220).

Article 14 of the Health Law No.36/2009 states, anyone has the right to health. This is stated in the provisions that (1) Everyone has the right to obtain the same rights in the health sector. (2) Anyone has the right to obtain safe, affordable and quality health services. Pharmaceutical preparations in the form of medicinal ingredients that are produced and distributed in accordance with PHARMACOPEIA must meet the quality, usefulness and safety requirements as stated in Article 2 of PP Number 72 of 1998.

Comprehensive medicine management, including medicine distribution network, is needed to assure consumers of the quality, safety and efficacy of medicines. Considering the concept of Strict Liability, even though there are no strict rules regarding the testing of solvents, but with the discovery of many victims of kidney failure, it must be the responsibility of the BPOM who carry out supervision and the pharmaceutical company also carry out special supervision even though a medicine has passed the contaminant level test. So, a pharmaceutical company that produces paracetamol syrup whose solvent composition exceeds the threshold so that the resulting product does not meet the safety standards of pharmaceutical preparations. Where this happens intentionally or unintentionally can be subject to legal sanctions. If this is caused by negligence, of course, the sanctions that can be imposed on the pharmaceutical company concerned can be categorized as lighter. Meanwhile, if it is done intentionally, it can be subject to accumulative sanctions in the form of administrative, criminal, and civil sanctions.

BPOM's excuse stating that there are no regulations for testing raw materials for pharmaceutical preparations gives the impression that BPOM officials intend to avoid various demands for responsibility, both in terms of ethics, professional discipline (Siswati, 2015: pg. 213) and legal responsibility because they are actually guidelines, standards, guidelines. The measure of human behaviour in life in the nation and state is not only regulated by legal norms/rules. There are other rules that also apply at the same time, namely the rules of politeness, the rules of decency and the rules of religion. Rule-These non-legal rules also provide guidelines for humans and their lives, especially for those who carry public authority in which the duties of service, protection and protection are attached to the community.

Meanwhile, from the optical point of view of legal discipline, a legal norm is only a container in which it contains legal principles that contain various pairs of antinomical values, such as order and peace/freedom, legal certainty and legal comparability, and so on. Therefore, the absence of rules should not and should not be used as an excuse for the bearers of public authority to demand responsibility. For the case of kidney failure that claimed 269 victims if it happened in Japan, the relevant public officials would mobilize all resources and financial resources to deal with this case and after being handled they would resign and even commit seppuku out of shame.

As emphasized by Emmanuel Levinas "respondeo ergo sum" (Erwin, 2019), the existence of an official and the institution that oversees him will be determined by how much fundamental willingness to carry out the tasks inherent in his position so that its fulfilment depends on the belief in the willingness to accept and take responsibility and be aware of the consequences that will arise. People who do not have the authority and expertise in pharmaceutical preparations will cause harm to the community (Sompotan, 2016: page. 74).

4. Legal Measures to Protect the Interests of The Victims and Their Families

Consumer protection law is one of the interests of society. If there is no balanced legal protection between business actors and consumers, this can lead to the existence of consumers in a vulnerable position, because there are many cases of consumers who feel aggrieved and in the end the case ends with a dispute whose results cannot satisfy the consumer.

Therefore, the Consumer Protection Act (UUPK) was formed. The purpose of the establishment of this UUPK is to protect consumers so that consumers do not feel disadvantaged and their needs can be properly met, and

business actors can regulate business actions to run their business properly as well. Because business actors and consumers both need each other, so that later they will be able to create mutually beneficial relationships (Muthia, 2018).

In the case of poisoning with paracetamol syrup, if it is true that the content of EG and DEG is proven to be the cause, the victims and their families can sue for compensation, both material and immaterial, against the pharmaceutical company that produces the medicine and other related parties. The right to seek compensation is also stated in the UUPK. Because babies and children must strive for their health by doing maintenance in order to prepare a generation that is smart, healthy, and of good quality. Likewise, efforts to reduce cases of death that occur in infants and children. This maintenance lasts while in the womb until the age of 18 years. In this health care, from parents to the government, it is the responsibility to be involved in making efforts to maintain the health of infants and children.

According to Komariah Emong Sapardjaja, there are 4 elements of an act that can be called an act that violates the law, namely, there are those who commit the act, the act is against the law, the act is detrimental to others, and the act is caused by the negligence of the related party (Sutarno, 2014).

Initially this case of acute kidney failure was found in Indonesia in January 2022, with 1-2 confirmed cases of death due to acute kidney failure every month. Then, in August 2022 there was a very drastic increase in cases. With this increase in cases, it is necessary to conduct an examination related to the cause of this acute kidney failure. Muhammad Mufti Mubarok, Deputy Chairman of the National Consumer Protection Agency, said that the victims and their families can prosecute and seek compensation from pharmaceutical companies producing medicines and related parties by first identifying the cause of this acute kidney failure case. If the cause has been found, the victim and his family can file a lawsuit and ask for compensation from the pharmaceutical company that produces medicines and related parties if the medicines are proven to contain EG and DEG (Kompas, 2022).

Table 1: Increase in Cases

Adverb of time	**October 21, 2022**	**October 24, 2022**	**October 26, 2022**
Total Cases	241 Case	241 Case	251 Case
Death Case	133 Case (55%)	143 Case (56%)	157 Case (58%)

If the victims and their families want to file a claim or ask for compensation from the pharmaceutical company that produces the drug, YLKI or the Indonesian Consumers Foundation provides a place for complaints services for the victims and their families. YLKI is also ready to facilitate if the victims and their families want to file a public lawsuit. It can be seen that the drugs that are circulated should have met the requirements for quality, safety, and efficacy. However, these drugs containing DEG and EG apparently passed the marketing authorization for eligibility. The claim for responsibility for the case of mass kidney failure can be addressed to pharmaceutical companies producing drugs, the Ministry of Health, or BPOM.

As it is known that pharmaceutical products are known as adverse effects. Adverse effects are adverse effects that appear unexpectedly, caused by various things, such as hypersensitivity, drug interactions, excessive effects, inevitable side effects, and activation of the disease. Adverse effects can also be caused by product defects. These product defects are basically divided into 4 groups: (1) Defects at the time of production at the factory that occur due to deviations in product design, specifications, wrong labelling, contamination, and wrong doses, (2) Defects in product design, (3) Defects in storage, (4) defects in use (Sampurna, 2005: pg. 156-157). Information

from VOA Indonesia (2022) actually uses EG and DEG as solvents that have been used for a long time, but they are not used for the manufacture of pharmaceutical products. According to historical records, in 1937 in the United States there were cases of poisoning caused by EG and DEG because there are no rules for the use of these materials. In China, it was found to contain EG and DEG in cheap toothpaste. Then in Europe, EG and DEG was once used to give a good taste to wine.

According to the statement of Penny K Lukito, Head of BPOM, there will be 2 (two) pharmaceutical companies that will be followed up with criminal actions related to the use of EG and DEG. According to existing regulations, the use of EG and DEG is actually not allowed for ingredients in the process of making a medicine. However, if there are medicines that require EG and DEG as raw materials or additives, it must use the standard limits that have been set.

Based on the results of the investigation conducted by the Criminal Investigation Police of the two companies, namely PT. Yarindo Farmata and PT. Universal Pharmaceutical Industries. Evidence has been found in the form of syrup medicines that use excessive DEG and EG content, raw materials and packaging, as well as other documentary evidence owned by the two companies. The evidence will be confiscated and BPOM will impose sanctions on the two pharmaceutical companies that produce medicines in the form of administrative sanctions, namely in the form of product withdrawals and destruction of these products, as well as revocation of distribution permits and termination of distribution from these pharmaceutical companies (Bisnis.com, 2022).

As reported by Bisnis.com, the PT. Universal Pharmaceutical Industries believes that the blame in this case is the supplier who imported the hazardous substance. His party admitted that they had no particular intention and tried to cooperate with the policies set by BPOM. The government must move quickly to deal with cases of acute kidney failure so that cases of death in children do not continue to increase. If it is found that there is an element of intent or negligence on the part of a pharmaceutical company that produces medicines that causes the presence of hazardous substances in these medicines or there are product defects (defects), then the law enforcement process must be carried out and criminal penalties can be prosecuted. Pharmaceutical companies producing medicines can be subject to a criminal sentence of up to 10 years as well as a maximum fine of one billion. The Ministry of Health and BPOM can also be prosecuted if they are proven to have done or passively assisted the law because they have neglected to carry out supervision and failed to declare the distribution permit for the feasibility of these dangerous medicines.

In the Criminal Code Articles 359 to 361, as contained in the form of a threat, a person can be punished if it is proven that there has been negligence that has made a person injured, be it minor injuries, serious injuries, or death. Heavier criminal threats can be imposed on people who are proven to have committed the crime with the aim of carrying out their work/livelihood. Even those who are found guilty can be deprived of their rights in carrying out their work or activities.

This related party has absolute legal responsibility (strict liability) for the losses suffered by the victim, as regulated in Article 19 of the UUPK. From the article it is explained that if the related party is proven to have made a mistake, then they must take responsibility for the losses suffered and suffered by the victim. However, if not proven guilty, this related party must be able to prove that the error is not the result of his artificial production but comes from the consumer's fault (Muthia, 2018: page. 213).

In this way, it is hoped that there will be justice to protect the interests of the victims and their families so that they can be fulfilled as expected by them. Considering that until now there have not been any regulations regarding the testing of raw materials for hard medicines and there is no agreement on the level of solvents, in general the Indonesian people, especially infants and children who are susceptible to symptoms of fever, need preventive legal protection in the form of making related regulations and repressive protection. in the form of action as a law enforcement effort to provide preventive legal protection to the community, especially toddlers and children. Peparations will cause harm to the community (Sompotan, 2016: page. 74).

5. Discussion

In general, pharmaceutical companies can be held responsible for errors as long as the elements of intentional and negligence can be proven as well as liability without errors because they have caused losses. In particular, pharmaceutical companies can also be sued for absolute liability (Strict Liability) by referring to the provisions of Article 196 in conjunction with Article 201 of the Health Law. Protection of the interests of victims and their families in the form of preventive legal protection by enforcing the rules for testing solvents for pharmaceutical preparations contained in legislation or policy regulations as well as repressive legal protection in the form of legal action as a form of law enforcement by the police to courts or the imposition of administrative sanctions by the ministry of health. or civil lawsuits by the victim's family or legal representative.

Author Contributions: Yuwono Prianto is an Associate Professor for courses in philosophy of law and agrarian law at the Faculty of Law Tarumanagara Jakarta. Outside the campus, he does a lot of social preneurship for some urban marginalized groups as well as legal empowerment for rural communities in the use of natural resources, as well as community members who are victims of natural disasters in various parts of Java and South Sumatra. Currently, he is piloting a social preneurship project for seniors in the culinary and plant cultivation fields. On the sidelines of teaching and writing activities, it is often a structure in the training of certified mediators at the national level in collaboration with the Mahkamah Agung. Della Savelya is an undergraduate student at the Faculty of Law, Tarumanagara University and in the process of writing this article responsible for technical matters.

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