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# Legal Protection for Consumers of Syrup Drugs Causing Atypical Progressive Acute Kidney Failure (GGGAPA) in Children: Analysis Based on Law Number 8 of 1999

Ahmad Muchlasin Nur Ihsan<sup>1</sup>, Diana Setiawati<sup>2</sup> <sup>1</sup>Muhammadiyah University of Surakarta (C100190282@student.ums.ac.id) <sup>2</sup> Muhammadiyah University of Surakarta (<u>Ds170@ums.ac.id</u>)

#### **ABSTRACT**

Human life from ancient times until now will never be separated from health products to help accelerate the healing of illnesses experienced by humans. Many kinds of medicinal products are made by manufacturers from traditional medicines that use natural ingredients and drugs that use chemicals as a mixture. Drugs that use chemicals if their use is not in accordance with existing requirements will cause health problems ranging from kidney failure to death. So consumer protection here is very important, so that people who feel their rights and interests are harmed by consuming these products, and ensure legal certainty for consumers to get legal protection. The purpose of this study is to determine consumer protection in cases of acute kidney failure in children who are suspected of consuming syrup medicine in accordance with Law Number 8 of 1999 concerning Consumer Protection, and to analyze the government's role in handling this case. This study uses normative research methods. Sources of data in this study used primary and secondary data, through interviews, and literature studies. This study aims to determine the government's role in protecting consumers in cases of acute kidney failure caused by syrup drugs, namely by imposing penalties on business actors to provide compensation to victims who experience acute kidney failure, as well as withdrawing drugs identified as the cause. acute kidney disease.

Keywords: Consumer Protection, Kidney Failure, Syrup Medicine, Children

## **INTRODUCTION**

Technology in the world has experienced quite significant developments, such as in the health sector which has experienced changes in terms of materials and methods of manufacture.. In the past, especially in Indonesia, traditional medicines were still used which were made using natural ingredients and were relatively simple, whereas in modern times like now medicines already use chemicals as a mixture and the process of making medicines has to go through several stages before they can be made. marketed and consumed by consumers(Wa Ode Lilis Wahid And La Ode Ali Basri, 2016).

Health is very important for every human being. Medicines are needed to treat patients, but it is not uncommon to find many medicines that contain ingredients that are harmful to the human body, while medicines are not only consumed by adults but also children.

We need to know that children are an asset for the family and the country to be able to continue the destiny of the nation in the future. So the growth and development of children in Indonesia still needs to be taken seriously from an early age(Sugeng et al., 2019). Children must have all their needs met, especially in terms of health. Children's health is one of the important things so that children's growth and development can be fulfilled properly, but it is not uncommon for children whose health is disturbed, there will be obstacles to their development, so children need more attention from their parents. (Karimah et al., 2015).

Currently, many pharmaceutical business products marketed in the community are still not in accordance with what has been determined by the Food and Drug Monitoring Agency (BPOM). The public has recently been shocked by the news on social media and mass media about the alleged existence of





Volume 2, Issue 1, September 2023 (icrtlaw@ums.ac.id)

dangerous chemicals in the composition of paracetamol syrup for children, where this syrup is one of the drugs commonly consumed by the public, especially in children, to reduce fever. (Husni Mubaraq et al., 2021)

Many people trust syrup medicine to be consumed when children have a fever in the hope that it can provide a healing effect. However, there is information circulating about syrup drugs that cause acute kidney failure. This is because the syrup medicine that causes kidney failure contains ingredients that are dangerous if consumed by the public. With the news circulating about this case, parents became alert, if their child had a fever, they had to take medicine for first aid(Tarigan et al., 2022).

The number of cases of acute kidney failure in children in Indonesia according to data obtained in the field was 352 cases of children experiencing acute kidney failure, 179 others died. The number of cases is spread across 28 provinces in Indonesia. DKI Jakarta, the province that contributed the most cases of kidney failure, was 142 cases, followed by West Java province, which contributed 41 cases of kidney failure, then in third place was the province of Aceh, which contributed 31 cases of kidney failure (Ministry of Health of the Republic of Indonesia, 2022).

Seeing cases of kidney failure caused by drinking syrup containing dangerous ingredients, consumer protection is important to provide legal certainty and provide legal protection to consumers. This protection is important because the average consumer is in a weaker position compared to producers. Even though there are regulations that regulate the rights and obligations of consumers and producers, there are still many producers who make goods and/or services that do not comply with existing regulations.(Sindy, 2014)

The level of awareness among the public is that many people still do not pay much attention to the composition of the ingredients used in making these drugs, this can lead to dangers that can be experienced by people if they consume drugs if the composition contains ingredients that are harmful to the body. In this case, consumer protection is needed to improve the welfare of the citizens of the Republic of Indonesia (Rizka Annisa Ilham, 2015).

Based on the background above, this research is important in analyzing the factors that cause acute kidney failure in children, what ingredients are contained in medicines, and how the government is responding to current events. This refers to article 4 of Law Number 8 of 1999 concerning Consumer Protection.

## RESEARCH METHODS

This research uses normative empirical research methods, namely by using legal materials based on primary data through observation and interview stages as well as secondary data using statutory regulations in accordance with the problems in this research (Kelik Wardiono, 2004). This type of research uses a descriptive type, namely by explaining and depicting an event or fact concretely according to what has been experienced by the community. The data collection method in this research uses observation, interviews and literature study, while data analysis uses qualitative methods based on deductive logic with stages of drawing conclusions from general to specific. (Sugiyono, 2013).

# **RESULTS AND DISCUSSION**

# 4) Labor welfare level

Legal protection is very important so that the rights and obligations of consumers can be protected and fulfilled properly, so that business actors do not arbitrarily make goods and/or services without paying attention to consumers' rights and obligations. business actors themselves. The rights of consumers are regulated in Article 4 of Law Number 8 of 1999 concerning Consumer Protection which states that:

a. The right to comfort, security and safety in consuming goods and/or services;





Volume 2, Issue 1, September 2023 (icrtlaw@ums.ac.id)

- b. The right to choose goods and/or services and obtain said goods and/or services in accordance with the exchange rate and conditions and guarantees promised;
- c. The right to correct, clear and honest information regarding the condition and guarantee of goods and/or services;
- d. The right to have opinions and complaints heard regarding the goods and/or services used;
- e. The right to receive advocacy, protection and efforts to resolve consumer protection disputes appropriately;
- f. The right to receive consumer guidance and education;
- g. The right to be treated and served correctly and honestly and not discriminated against;
- h. The right to receive compensation, compensation and/or replacement, if the goods and/or services received are not in accordance with the agreement or are not as they should be;
- Rights regulated in other statutory provisions.

As a business actor or producer, you must pay attention to the rights of consumers in accordance with the regulations made in article 4 of the UUPK above. However, in the case of kidney failure with the suspected cause being fever-reducing syrup, the business actor has violated consumer rights in article 4 letter a which does not provide comfort, security and safety in consuming goods and/or services.

This case of acute kidney failure in a child according to an interview with Apt. Ahmad Novian Nur Anas S.Farm said that this could happen because the syrup medicine contains dangerous chemicals, namely Ethylene Glycol and Diethylene Glycol which are contained in fever-reducing syrup medicines that are used excessively. If these substances or chemicals enter the human body, they can cause health problems and can lead to loss of life if you consume drugs containing EG and DEG chemicals whose levels exceed safe limits.

Why can this chemical be said to be dangerous for those who consume it because the chemical Ethylene Glycol is a compound that has the characteristics of being odorless, colorless, and tends to have a sweet taste (Elin Herlina. et al. 2023). This compound is commonly used in the antifreeze, plastics and explosives industries. However, this compound is also used as a mixture in syrup medicines, but it is very rarely used because the nature of this compound is dangerous if the mixture exceeds the safe limit permitted by the Ministry of Health, which is 0.5 mg/kg BW per day.(Dasopang et al., 2023).

The chemical compounds or ingredients Ethylene Glycol and Diethylene Glycol have the function of being an emulsifying agent or substance. The emulsifying agent in the syrup medicine itself is useful to help maintain the stability of the syrup medicine and prevent the separation of the ingredients in the syrup medicine content, so that it can be consumed by consumers more easily.

Meanwhile, the chemical Diethylene Glycol is a compound that is not much different from the chemical Ethylene Glycol in that Diethylene Glycol has a distinctive odor. This chemical is more dangerous than the chemical Ethylene Glycol because this compound can enter through the skin, inhalation, or ingestion. and can cause damage to human organs such as the kidneys, liver, brain and even the heart.

Due to the dangers posed by these two chemicals, BPOM has determined that it is not permissible to use the chemicals Ethylene Glycol and Diethylene Glycol in the mixture of all syrup medicines for children and adults (CNN Indonesia, 2022). However, it is likely that these two chemicals were found to be contained in four additional ingredients such as propylene glycol, polyethylene glycol, sorbitol, and glycerin/glycerol (Dr. Nurul Fajriah Afiatunnisa. 2022). Basically, these four additional ingredients are harmless chemicals and are not prohibited for use in mixtures for making syrup medicines.

From this case, business actors have violated article 4 letter c UUPK which states that consumers have the right to correct, clear and honest information regarding the condition of goods and guarantees for goods and/or services. And in article 7 letter b UUPK regarding the obligations of business actors which must provide correct, clear and honest information regarding the condition and





Volume 2, Issue 1, September 2023 (icrtlaw@ums.ac.id)

guarantee of goods and/or services as well as providing explanations of use, repair and maintenance. Because business actors do not provide clear and honest information about the composition used in making the syrup.

The government as the decision maker in this case must provide demands to business actors who produce medicines that do not comply with the provisions of Article 4 UUPK concerning the rights of consumers and also business actors must provide compensation in the form of all costs for treatment borne by the business actor, and If the victim experiences loss of life, the business actor must provide compensation to the victim's family in accordance with the statutory regulations of Article 19 paragraph (1) UUPK which states that the business actor is responsible for providing compensation for damage, pollution and/or consumer losses. as a result of consuming goods and/or services produced or traded. This is a form of the government to provide legal protection for consumers who experience losses due to consuming medicines produced by business actors which contain EG and DEG chemicals.

5) The Government's Role in Cases of Kidney Failure in Children Suspected of Consuming Fever Reducing Syrup

Seeing this case phenomenon which can cause concern for all aspects of society, the government must take action as soon as possible in order to provide a decision on how to follow up on cases of acute kidney failure in children caused by this fever-reducing syrup drug.

Then the Ministry of Health gave an appeal or warning to every level of society that several drugs were found from the pharmaceutical industry which were proven to produce syrup containing the chemicals Ethylene Glycol and Diethylene Glycol (Rindi Salsabilla, 2022).

In testing these medicines, it was found that there were 5 types of medicines that contained Ethylene Glycol and Diethylene Glycol at levels that exceeded the safe threshold (Febrian. 2022). The five medicines are Termorex Syrup (fever medicine), Flurin DMP Syrup (cough and flu medicine), Unibebi Cough Syrup (cough and flu medicine), Unibebi Fever Syrup (fever medicine), and Unibebi Fever Drops (fever medicine). Then the government ordered the distribution of the five drugs that cause kidney failure from the market.

The government here must also think about replacement drugs during the withdrawal of this syrup drug. There is an option to avoid consuming syrup medicine to help reduce fever in children, namely by giving medicine in the form of powders or what are called pulvares, tablets and capsules. This headache medicine is paracetamol in powder form which was used by parents in ancient times to relieve fever in the body before there were medicines in syrup form.

This medicine is the same as a fever-reducing syrup medicine in liquid form which has the function of helping to relieve fever in the body, however, this medicine for fever, in determining the dose which is done manually by the pharmacist, is different from the syrup medicine whose dosage has been determined.(Arianto, 2016). And this type of powder medicine has a relatively affordable price compared to syrup medicine, but in terms of practicality, this type of powder medicine is said to be quite difficult because this medicine is in powder form and must be stored in a refrigerated machine. And the expiration period is quite short compared to syrup medicine.

Apart from providing drug options, the government is also taking several steps to overcome cases of kidney failure by providing antidotes to patients who experience kidney failure. Antidote itself is an antidote to toxic substances in the body(Anggraini et al., 2014). This antidote was purchased by the government from Singapore and Australia in large quantities. Giving this antidote to these patients can improve the patient's condition and some may even stabilize it (Rico Afrido Simanjutak, 2022).

The government is also carrying out surveillance activities to anticipate a spike in kidney failure. Surveillance activities themselves are activities in monitoring disease routinely or continuously and systematically regarding the occurrence and distribution of disease as well as factors that influence society, prevention will become more effective by carrying out these activities(Ipa et al., 2014). Apart from that, the government also recommends to all levels of society to pay more attention to the





Volume 2, Issue 1, September 2023 (icrtlaw@ums.ac.id)

composition written on medicine labels first and check whether the medicine is safe for consumption and does not harm health by buying medicines in official places, secondly consuming medicines in accordance with recommended, thirdly, keep up to date on medicines, fourthly ask the pharmacist for an opinion about medicines that are safe to consume, and finally check the composition of each medicine.(Walean et al., 2018). Then people must always maintain their health by adopting a clean lifestyle

#### CONCLUSION

Cases of atypical progressive acute kidney failure occurred because the syrup contains the chemicals Ethylene Glycol and Diethylene Glycol which exceed the safe limit. So it is important to provide consumer protection to the public with Article 4 UUPK which regulates the rights that consumers must obtain. However, in this case, the business actor has violated the provisions of article 4 letter a and article 4 letter c of the UUPK, where the business actor has made drugs that can threaten the security, comfort and safety of consumers, and the business actor has not provided an explanation or information about what ingredients are used. contained in the syrup clearly and does not carry out its obligations as a good business actor in accordance with article 7 UUPK. With the actions that have been carried out by these business actors, the government has imposed sanctions, namely that they must provide responsibility to victims who experience the effects of drugs containing EG and DEG in the form of providing financing during treatment and if the victim experiences loss of life, the business actor must provide compensation to the victim's family, as stipulated in article 19 paragraph (1) UUPK.

With this incident, the government, after conducting an investigation and finding that there were 5 drugs containing the chemicals Ethylene Glycol and Diethylene Glycol which could cause health problems such as kidney failure and even death, the Ministry of Health gave an order to withdraw the distribution of these 5 drugs from market. The government also provides atidotum purchased from Singapore and Australia to patients suffering from kidney failure so that the patient's condition improves. Apart from providing antidotes, the Government is also carrying out surveillance activities aimed at anticipating a spike in cases of atypical progressive acute kidney failure. Apart from these activities, there are suggestions not to consume syrup medicines first and replace them with medicines in the form of tablets, capsules and pulvares or powders. Apart from that, people are required to pay more attention to the safety conditions of the goods they want to buy and maintain body health by maintaining their lifestyle.

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Volume 2, Issue 1, September 2023 (icrtlaw@ums.ac.id)

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