
Legal Responsibility by the Government Regarding Liquid Medicines That Cause Kidney Failure

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ABSTRACT

Ensuring public health is the duty of all human beings in the country. Providing legal certainty and protection is the government's duty, including providing safe and comfortable health services. The case of syrup drugs that cause kidney failure in children presents the latest challenge for the government regarding its failure to supervise operating permits and distribution permits for drugs in Indonesia. This turned out to result in several children dying after several times consuming syrup drugs containing ingredients that can trigger kidney failure. The state should be able to protect the public through the Consumer Protection Law, and the victims are children, so the Child Protection Law is then targeted. Even though as we know, that this country has a state institution that focuses on taking care of this, namely the Food and Drug Supervisory Agency (BPOM). So through this study, researchers will convey the analysis of accountability from BPOM and the role of UUPK in this problem. This research uses Juridical-Normative research methods by testing the Law.

Keywords: BPOM, Kidney Failure, Syrup Medicine, UUPK

INTRODUCTION

The 1945 Constitution firmly states that the Republic of Indonesia is a State of Law (rechstaat), not a state of power. This means that the law belongs to all Indonesian citizens, not to a few people, let alone the authorities. This situation also means that the supremacy of law must be upheld fairly and correctly, accountable, transparent, non-discriminatory and not arbitrary. (Simamora, 2014).

As we know, Indonesian society and the world cannot be separated from drugs. Medicines are one thing that is mandatory for all people because currently there are so many types of diseases faced by all people so that medicines can now be said to be one of the basic needs for humans, these medicines also play a very important role as help medical personnel to overcome all diseases faced by the community.

Nowadays, there are also a lot of people who need medical personnel to overcome or deal with all kinds of diseases caused by viruses or other things that cannot be detected by the general public, so people really need help from medical personnel and with the existence of these medicines, it is very important. can reduce the number of patients treated in hospitals and simplify the performance of medical personnel or doctors.

A drug is a substance including a biological product that is used to influence or investigate physiological systems or pathological conditions in order to determine diagnosis, prevention, healing, recovery, health improvement and contraception, for humans. (Farmalkes, 2011). Diagnosis is a determination of the health condition that a person is experiencing as a basis for making medical decisions for treatment. Diagnosis is also carried out to explain the symptoms and clinical signs experienced by a patient and differentiate them from other similar conditions.

Drugs are usually grouped based on their similarities, one of which is their shape or form in pharmaceutical terms, the form of onate is referred to as a dosage form. The form of this drug can be solid, semi-solid, liquid or gas. The following types of drugs are based on dosage form:

1. Tablet

Tablets are the most common type of preparation that you encounter, generally round in shape. Tablets are a mixture of active drug ingredients and additional substances to support their benefits, and also this drug is generally given orally or taken by mouth and there are also several types of tablets,

some of which are differentiated based on the method of administration. Medicines can be chewed, sucked or placed under the tongue.

2. Capsule

Another type of solid dosage form of medicine that is quite often used by the general public is a capsule. This capsule is packaged in a hard or soft tube-shaped shell made of gelatin or starch. This medicine contains the active ingredients of the medicine that have been crushed.

3. Caplet

Caplets are a combination of capsule and tablet forms. In this case, caplets are tablets covered in a layer of sugar and attractive coloring to maintain moisture and contamination when ingested.

4. Pill

Unlike tablets, pills are round and small in size. Granules are one form of pill variation.

5. Powder or powder

Powder or powder is a dry mixture of medicine and chemical substances that have been crushed. Unlike capsules which are coated with a shell, powder medicine can usually be taken immediately after dissolving it in water and is safe for the stomach and also for people who find it difficult to take medication. This medication is usually more makes it easier.

6. Suppositories

It is a type of semisolid drug that can dissolve or soften at body temperature and is usually given through the anus, vagina or urethra.

7. Topical medication

It is a semisolid drug and as the name suggests, this drug is generally given topically or applied to the surface of the skin or mucous membranes. That's why topical medicines are included in the topical medicine group and several types of topical medicines are creams, lotions, ointments, gels.

8. Liquid medication

Liquid medicine contains various dissolved chemicals. This type of medicine is usually given orally or topically. Several types of liquid medicines include solutions, elixirs, syrups, emulsions.

9. Suspension

Suspension is included in the liquid medicine group. The suspension contains a mixture of drugs in the form of a solid substance that has melted in a liquid. This type of medicine usually states "shake well before drinking" on the medicine packaging.

10. Injection

Injection is a sterile preparation in the form of a solution, emulsion, suspension or powder that is ready to use and needs to be dissolved first. The injection is given through body tissue with the aim of making the drug work more quickly.

11. Drops

Drops, also known as guttae, are preparations in the form of solutions, emulsions or suspensions that are given by drip.

12. Inhalers

Inhalers are a type of medicinal preparation in the form of gas or steam, this medicine is usually used to treat respiratory disorders or diseases and also this medicine has smaller drug particles so it is more easily absorbed through the respiratory tract, apart from inhalers several types of gas or steam medicine preparations include nebulizers and vaporizer(Sari, SehatQ, 2021).

Every citizen is obliged to uphold the law in every aspect of life. Citizens who deliberately/negligently carry out their obligations and harm other people can be said to have violated the law. In the current development of social conditions, accompanied by an increasingly dynamic society, it is very possible that actions that lead to criminal liability will also become increasingly diverse. One of the criminal acts committed by the public, in this case drug producers, is intentionally selling drugs does not meet the standards so that the action harms other people, especially those in the age category who are not allowed to consume medicines containing ingredients outside the required quality guarantee. Medicines are a

human need to fulfill the use of medicines for the purposes of treatment, prevention, reducing, eliminating and curing diseases in humans as stated in the Regulation of the Food and Drug Supervisory Agency Number 4 of 2018. Medicines can be useful for their users if the composition contained therein is raw material, which is safe and meets standards, but drugs cause harm to users if they contain dangerous substances.

Therefore, the author is interested in discussing further the Government's Legal Responsibility regarding Liquid Medicines that cause Kidney Failure.

RESEARCH METHODS

The type of research method used by researchers in this research is normative legal research with an approach to legislation and legal principles, specifically in this research the focus is on discussing the existence of law in society in the context of legal accountability by the government regarding drugs that can cause kidney failure. Normative legal research is defined as research that refers to legal norms contained in statutory regulations and court decisions. Normative legal research can also be called doctrinal legal research. This research method is used to study and analyze the government's legal accountability regarding drugs that cause kidney failure.

The procedure in this research was carried out in stages, namely collecting library data, reading, taking notes, analyzing, collecting concepts or texts, then elaborating and explaining the collected data or texts related to the main discussion topic in this research. This is in accordance with Zed's opinion (Zed, 2008) which says that library research is not just a matter of reading and taking notes on literature or books but rather a series of activities using library data collection methods, reading, recording and processing research material.

RESULTS AND DISCUSSION

1. Analysis of Consumer Protection Law on Use of Syrup Medication Which Causes Kidney Failure

A state's obligation is to ensure that every citizen receives legal protection and certainty. In terms of buying and selling, there is a Consumer Protection Law (UUPK) which functions to protect consumers when carrying out buying and selling transactions. In this case, consumers are considered weaker legal subjects than business actors, so the state's obligation is to protect and provide legal certainty.

If we depart from UUPK in article 7, there are several obligations that must be fulfilled by a business actor, namely providing clear, correct information, and providing compensation if there is a default when using the goods in accordance with the provisions of the business actor. During the ongoing investigation process, it was discovered that the manufacturer of the syrup medicine which can cause kidney failure in children was actually making medicine that did not comply with the standards given and set by the government to ensure the safety of its use. So in this case, the syrup maker must be responsible for what he has done. The syrup maker could be subject to criminal or civil penalties. So if you sue the UUPK, the syrup medicine maker as a business actor must take responsibility for what he has done and is obliged to make compensation. (Diyatmika, 2020)

In an investigation carried out by BPOM, it was proven that the business actors who produced syrup medicine were negligent by making syrup medicine with a mixture that was above average so it was declared unsafe. So in this case, the pharmaceutical business actor can be prosecuted with civil charges in the form of compensation to the victim, and because there was forgery, negligence and fraud on the part of the business actor, the business actor can also be prosecuted under criminal charges. And then they will receive administrative sanctions by having their business license revoked.

If we look closely at Article 4 of the UUPK, then the actions of business actors who have sold syrup drugs which have resulted in kidney failure and death in children, then the pharmaceutical company has violated the provisions in letters a and c by not providing a sense of security, comfort and not

providing information. which is clear and good so that it gives the impression that the pharmaceutical company has committed a criminal act of fraud which resulted in death. When conducting business, business actors should not only pursue benefits, but also prioritize the safety of consumers. (Sudjana, 2016) So in this case, victims of the syrup drug are obliged to receive compensation for health services and receive compensation if someone dies. Business actors are not only responsible for matters that are violated in the UUPK, but are also responsible for other laws that they have violated as business actors.

In terms of liability in the form of compensation carried out by business actors, in accordance with UUPK provisions, the compensation given must be given within a period of seven days, and this compensation process does not prevent a business actor from being free from criminal liability. The things that need to be paid attention to when a business actor provides responsibility are as regulated in Article 19 UUPK:

- a. Damage and loss caused by business actors
- b. Regarding pollution and losses caused by business actors.
- c. For material and immaterial losses that the business actor must be responsible for. (Miru, 2016)

A business actor not only prioritizes his interests in the business world, he is also responsible for progress and prosperity in the nation and state. He must also be present in the legal traffic that applies in the legal system in Indonesia by being responsible for what he does for the sake of prosperity and progress in Indonesia. (Sidabalok, 2006)

2. BPOM's accountability according to the law

Legal liability is a form of obligation that must be carried out for the emergence of a legal act. Legal accountability is carried out both in criminal and civil legal actions. Legal accountability in criminal cases is regulated in Article 2 of the Criminal Code, which states that criminal provisions are imposed on every Indonesian citizen. (Hasibuan, 2019) Meanwhile, civil responsibility is regulated in the Civil Code Article 1365 which states that every person who makes a mistake must be responsible for what they have done. (Hadi, 2018) Hans Kelsen said that every person who commits a criminal act must be held accountable for his actions in the sanctions given. (Kelsen, 2019)

Legal liability can only be carried out by legal subjects who carry out legal acts, namely humans and legal entities. (Kelsen, 2019) A legal entity itself can be said to be like a human being, who has wealth, has rights and is obliged to carry out obligations, so a legal entity can also be sued in court, and participate in carrying out legal traffic. (Mada, 2022) The legal subjects of legal entities include Limited Liability Companies (PT), Limited Partnerships (CV), and State Institutions. State institutions are legal subjects because they have authority and therefore the principle of no authority without accountability applies. (Michael, 2020)

And in the concept of state institutions, according to the constitution, the government is obliged to provide state services and administration with the aim of prospering the life of the nation and state. Therefore, the government is also given an authority to regulate this under the name of the authority of the directors to carry it out.

BPOM RI is a non-ministerial government institution which was formed based on presidential decree number 103 of 2001, where inam article 67 states that "BPOM has the task of carrying out government duties in the field of drug and food control in accordance with the provisions of applicable laws and regulations."

In article 2 of the Regulation of the Head of BPOM Number 14 of 2014 concerning the Organization and Work Procedures of the Technical Implementation Unit within the Food and Drug Supervisory Agency, it regulates the duties of the BPOM which reads "The Technical Implementation Unit within the Drug and Food Supervisory Agency has the task of implementing policies in the field of supervision medicine and food, which includes supervision of therapeutic products, narcotics, psychotropics, addictive substances, traditional medicines, cosmetics, complementary products as well as supervision of food safety and dangerous substances." In this article it is clear that the duties

and authority of BPOM are to supervise all types of food, including dangerous substances which should not be contained in food, both medicines and food circulating in the community.(Khusnu & D, 2021).

BPOM found a case of kidney failure in a child that caused death, this was allegedly a form of negligence and weak monitoring function of BPOM regarding medicines and food.including raw materials, production and circulation in society. Medicines that are suspected of causing Atypical Progressive Kidney Disorders (AKI) are liquid medicines in the form of syrup. Syrup is a concentrated preparation in water from sugar or sugar substitute with fragrance and medicinal substances. Syrup is a type of medicine that is easy and effective to give to children because it tends to taste sweet, so children are not afraid to take medicine.

In BPOM's findings, there were five syrup medicines that were declared to contain contamination from dangerous chemicals, where the five syrups were fever and cough syrups which were commonly consumed by children. The finding of dangerous substances in the syrup is dangerous chemicals Ethylene Glycol (EG), Diethylene glycol (DEG) and Ethylene Glycol Butyl Ether EGBE(Kurnia.ekaptiningrum, 2022)

Negligence on the part of BPOM itself carries quite a big risk for the community. Because in this case it causes kidney failure in children and can lead to death. This is then linked to the Consumer Protection Law which focuses on paragraph 4, which states that consumers receive comfort and security in using goods or services and receive compensation if an incident occurs that is detrimental to the consumer. BPOM was also then sued for obtaining guarantees in the form of certainty and legal protection, which it felt was still nil and far from certainty and protection. (Tempo, 2022)

As BPOM's responsibility for negligence committed by them, there are several things that BPOM must do in this case, namely:

1. Carry out regular and periodic retesting by not only focusing on the syrup medication but also as a whole.
2. Conduct studies with pharmacology experts to test the safety content of drug use.
3. Blocking the circulation of syrup drugs containing EG and DEG.
4. Order the company that distributes the syrup drug after issuing a letter to freeze the distribution permit.
5. Conduct outreach to the public to prevent the use of syrup drugs containing EG and EDG so that undesirable things do not happen again.

So in this case, people who are victims of actions in the form of negligence carried out by BPOM to the point of experiencing losses up to the level of loss of life, people can take the litigation route, namely by making a report to the police which will be continued in the legal realm. And the suspects in this case are BPOM and institutions affiliated with it. In civil cases, the community can also apply for compensation in the form of compensation for the amount of loss suffered by the community.

CONCLUSION

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