

Criminal Liability For Administering Drugs Causing Acute Kidney Disorders In Children Based On Government Regulation Number 51 Of 2009 Concerning Pharmaceutical Work

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Abstract.

This study aims to identify and analyze criminal responsibility for administering drugs that cause acute kidney problems in children. As well as knowing and analyzing law enforcement against Pharmaceutical Companies Regarding Contamination of Syrup Drugs. This research is a type of normative research. So that it can be seen that criminal responsibility for administering drugs that result in acute kidney disorders in children must be fully responsible. Especially companies that produce drugs that ultimately cause acute kidney problems in children. In addition, the Food and Drug Supervisory Agency (BPOM) as the drug and food supervisory agency has the right to recommend that law enforcement be carried out against pharmaceutical companies related to drug syrup contamination, strict action must be taken.

Keywords : Criminal Liability, Pharmaceuticals and Renal Disorders.

I. INTRODUCTION

When a human is born, he or she is born in a state of freedom and equality (Fuady, 2013) with various fundamental rights and protection for their rights and interests in a rule of law (Legal Precept) so that it is orderly so that crime does not occur (Mertokusumo, 2010). To achieve order, legal certainty is needed. Without legal certainty and order, realizing justice in social life cannot be separated from the function of law, namely creating an orderly social order and it is hoped that human interests will be protected. According to ethical theory, law solely aims at justice, the content of law is determined by our ethical beliefs about what is fair, according to this theory it aims to realize or realize justice (Mertokusumo, 2010). Realizing justice is inseparable from the function of law which regulates the creation and maintenance of public order. Law must have three elements. First, the legal structure is the part that persists, the part that gives form and limits to the whole. Second, legal substances are rules, norms and real human behavior patterns that are in the legal system. Third, legal culture is an atmosphere of social thought and social power that determines how law is used, avoided or abused (Friedman, 2001). To guarantee the function of law, coercive power is needed over the enforcement of laws that are in the State with its instruments. Indonesia as a rule of law state is contained in Article 1 paragraph (3) of the 1945 Constitution. Jimly Asshiddiqie (Salim and Nurbani, 2016), put forward thirteen basic principles of a rule of law state which includes one of them guaranteeing the protection of human rights.

The efforts of the Indonesian State to realize the human rights of its people were carried out by ratifying the Universal Declaration of Human Rights in 1948 and this can be seen from the politics of national law, including the right to health. According to WHO Health is a state of well-being of the body, soul and social that allows everyone to live productively socially and economically (Syaukani and Thohari, 2010). Health as a human rights issue is carried out based on non-discriminatory, participatory and sustainable principles in the framework of forming Indonesian human resources, as well as increasing the nation's resilience and competitiveness for national development. The government's role in protecting human rights can be seen in the issuance of Law Number 39 of 1999 concerning Human Rights (Elvandari, 2015). Law Number 9 of 1960 Concerning Health Principles, Law No. 23 of 1992 concerning health as revoked with the issuance of Law No. 36 of 2009 concerning Health Law No. 6 of 1963 concerning Health Workers

And revoked with the issuance of Law Number 36 of 2014 concerning Health Workers. National development aims to create a just and prosperous society that is evenly distributed materially and spiritually based on Pancasila and The 1945 Constitution which is carried out in a sustainable manner, including health. By paying attention to health services, especially the establishment of health centers. As one type of first level health service facility, it has an important role in the national health system. In particular, the health effort subsystem in the delivery of pharmaceutical services is carried out by health workers who have the competence and authority to carry out pharmaceutical work. (Article 18 of Regulation of the Minister of Health of the Republic of Indonesia Number 75 of 2014 Concerning Community Health Centers) consisting of pharmaceutical personnel (Pharmacists) and pharmaceutical technical personnel (Law No 36 of 2014 concerning Health Workers, State Gazette of the Republic of Indonesia Year 298 Number 10 and Supplement to the State Gazette of the Republic of Indonesia Number 5607, Article 11 paragraph (6)).

Pharmacy personnel must guarantee against Pharmaceutical companies related to contamination of syrup drugs which cause acute kidney problems which are currently viral in society. As stated in Government Regulation Number 51 of 2009 concerning Pharmaceutical Work, in order to suppress and supervise drug distribution from legal (official) channels to unofficial channels, especially syrupy drugs that cause acute kidney failure. The legal political efforts of the Government of Indonesia as a countermeasure against the distribution of drugs from legal (official) channels to especially unofficial channels syrupy drugs that cause acute kidney failure. Through the law enforcement system (Sunarso, 2005), namely "Actualizing the rule of law so that it is in accordance with legal ideals, namely realizing human behavior within the framework determined by law" (Sunarso, 2005). To overcome this, a penal policy is needed which concentrates on two things, the first is an applicable policy, namely how to apply the current criminal law laws and regulations in dealing with psychotropic problems. The second is a formulative policy that leads to the renewal of criminal law (Penal Law Reform), namely how to formulate criminal law legislation (Arief, 2005). There are 4 (four) institutions that always synergize in the Indonesian criminal justice system, namely the Police (in this case Investigators), Prosecutors, Courts and Correctional Institutions (Anwar and Adang, 2011). Investigators, in this case Civil Servant Investigators as stated in Article 6 Paragraph (1) letter b of the Criminal Procedure Code, and Article 56 of Law No. 5 of 1997 concerning Psychotropics with its Explanation Paragraph (1) Civil Servant Investigators referred to include Civil Servant Investigators department responsible for health.

The Food and Drug Supervisory Agency is a Non-Departmental Government Agency (LPND), namely according to the Decree of the President of the Republic of Indonesia Number 103 of 2001 concerning Position, duties, authorities, organizational structure of Non-Departmental Government Institutions as amended by Presidential Regulation of the Republic of Indonesia Number 64 of 2005. And finally amended Presidential Regulation of the Republic of Indonesia Number 80 of 2017 concerning the Food and Drug Supervisory Agency. BPOM carries out governmental tasks in the field of Drug and Food control consisting of: "Drugs, Medicinal Materials, Narcotics, Psychotropics, Precursors, Addictive Substances, Traditional Medicines, health supplements, cosmetics, and food processed food in accordance with the provisions of laws and regulations". BPOM has the function of overseeing drugs and food Supervision During Circulation to ensure that Drugs and Food in circulation meet the established standards and requirements for safety, efficacy/benefits, and product quality as well as law enforcement measures.

II. METHODS

The research method used in this research is normative legal research method. Normative legal research is legal research conducted by examining literature or secondary data (Soerjono Soekanto, et al. 2003: 13). According to Peter Mahmud Marzuki (Peter Mahmud Marzuki, 2010: 35), normative legal research is a process to find a rule of law, legal principles, and legal doctrines to answer the legal issues at hand. In this type of legal research, law is often conceptualized as what is written in laws and regulations or law is conceptualized as rules or norms which are benchmarks for human behavior that are considered appropriate (Amiruddin, et al. 2006: 118).

III. RESULTS AND DISCUSSION

a. Criminal Liability for Administration of Drugs Causing Acute Kidney Disorders in Children

Recently, we often encounter issues circulating about Children's Syrup Medicines that contain contaminants. In response to this issue,

The Food and Drug Supervisory Agency (BPOM) provides Description of the syrup.

Syrup medicine for children who are at risk of containing Ethylene Glycol (EG) and Diethylene Glycol (DEG) contaminants, BPOM informs the following (Data from the Food and Drug Supervisory Agency (BPOM)):

1. BPOM previously submitted an explanation regarding medicinal syrup for children contaminated with DEG and EG in Gambia, Africa, on Wednesday, 12 October 2022 which can be accessed via the link , and Saturday, 15 October 2022.
2. BPOM reiterates that the syrup medicines for children mentioned in the information from WHO consist of Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup, and Magrip N Cold Syrup. These four products are manufactured by Maiden Pharmaceuticals Limited, India.
3. The four products recalled in The Gambia are not registered and are not circulating in Indonesia and to date, none of the products from the producer Maiden Pharmaceutical Ltd, India have been registered with BPOM.
4. BPOM conducts comprehensive pre- and post-market supervision of drug products circulating in Indonesia. In accordance with regulations and drug product registration requirements, BPOM has stipulated requirements that all syrup drug products for children and adults are not allowed to use EG and DEG.
5. However, EG and DEG can be found as contaminants in glycerin or propylene glycol which are used as additional solvents. BPOM has set maximum limits for EG and DEG for these two additives according to international standards.
6. The Ministry of Health has explained that the cause of acute kidney failure or Acute Kidney Injury (AKI) is unknown and still requires further investigation with BPOM, the Indonesian Pediatrician Association (IDAI), and other related parties..
7. BPOM encourages health workers and the pharmaceutical industry to actively report drug side effects or unwanted events after drug use as part of preventing unwanted events that have a greater impact. BPOM also coordinates intensively with the Ministry of Health, health service facilities, and other related parties in the context of monitoring the safety of drugs (pharmacovigilance) that are circulating and used for treatment in Indonesia.
8. BPOM also conducts risk-based tracing, sampling and gradual sample testing of syrup drug products that have the potential to contain EG and DEG contaminants. The results of product testing containing EG and DEG contaminants still require further studies to ensure compliance with the safe threshold based on references.
Furthermore, for products that exceed the safe threshold, administrative sanctions will be immediately given in the form of warnings, severe warnings, temporary suspension of drug manufacturing activities, suspension of Good Manufacturing Practices (GMP) certificates, revocation of CPOB certificates, and temporary suspension of advertising activities, as well as suspension of permits. Distribution and/or revocation of Distribution Permit.
9. All pharmaceutical industries that have syrup drugs that have the potential to contain EG and DEG contaminants, are required to report the results of tests carried out independently as a form of responsibility for business actors. The pharmaceutical industry can also make other efforts such as changing drug formulas and/or raw materials if necessary.
10. BPOM invites the public to use drugs safely and always pay attention to the following:
 - Using drugs appropriately and not exceeding the rules for use;
 - Carefully read the warnings on the packaging;
 - Avoiding the use of leftover syrup that has been open and stored for a long time;

- Consult a doctor, pharmacist or other health worker if the symptoms do not decrease after 3 (three) days of using over-the-counter drugs and over-the-counter drugs are limited to self-medication efforts;
- Completely report the drugs used in self-medication to health workers;
- Report drug side effects to the nearest health worker or through the BPOM Mobile and e-MESO Mobile service applications.

BPOM also urges the public to be more vigilant and use drug products registered with BPOM which are obtained from pharmaceutical service facilities or official sources and always remember to Check CLICK (Check Packaging, Label, Distribution Permit and Expiration) before buying or using drugs.

Therefore, criminal liability for administering drugs that result in acute kidney disorders in children must be fully responsible. Especially companies that produce drugs that ultimately cause acute kidney problems in children.

b. Law Enforcement Against Pharmaceutical Companies Related to Syrup Contamination

Recently, Indonesia has been shocked by cases of acute kidney failure in children. Data shows that there were at least 325 cases of acute kidney failure throughout Indonesia and 178 of these cases died, mostly affecting children aged 0-5 years (as of Tuesday, 1 November 2022). The initial suspicion that the incident was caused by the presence of the syrup drug consumed. Therefore, to clarify and find out who should be responsible for this incident, the Consultation and Legal Aid Unit of the Faculty of Law, Airlangga University, again held an open discussion on Tuesday, November 1, 2022 with the title "Formulating Legal Responsibilities for Cases of Acute Kidney Failure". The discussion presented Sapta Aprilianto, SH, MH, LL.M. as a criminal law expert as well as Director of the Consultation and Legal Aid Unit at the Faculty of Law, Airlangga University and Prof. Junaidi Khotib S.Si., Apt., M.Kes., Ph.D. as an expert and Dean of the Faculty of Pharmacy, Airlangga University. The activity was opened directly by Iman Prihandono, SH, MH, LL.M. Ph. D. as the Dean of the Faculty of Law, Airlangga University. He explained that this discussion was the beginning of opening a complaint and advocacy post for the Consultation and Legal Aid Unit at the Faculty of Law, Universitas Airlangga. "Before opening, we must first find out from the expert, Prof. Junaidi Khotib. Mr. Sapta will also discuss the possibility of criminal responsibility. We will formulate all of that and use it for complaints and advocacy posts. This also proves that the law does not stand alone," he said opening the activity.

The discussion was continued with a brief presentation by Prof. Junaidi about the causes of acute kidney failure. He explained that when talking about medicines, quality is the main thing that must be considered, both in terms of safety and effectiveness. As for the occurrence of cases of massive acute kidney failure in children, until now the exact cause is not known. However, based on the results of the interim investigation, the probable cause is the quality of the drugs used due to the presence of ethyleneglycol and diethyleneglycol in the syrup preparations. "Even though these two compounds cannot be used for medicinal products, aliases are prohibited in various regions because they include toxic substances," he explained. Furthermore, these two compounds are not used as active ingredients or additives, but can be present in drug ingredients as contaminants from the four commonly used additives, namely propyleneglycol, polyethyleneglycol, sorbitol, and glycerol. The existence of these four additional ingredients was deliberately included in the pharmaceutical industry to form syrup drug preparations. "This is so that the pharmaceutical preparations can have a certain thickness, be easy to pour, easy to use, mix well, and will give consistency and an attractive appearance," he said. However, when the additional ingredients contain impurities or contaminants, they will also be included. The presence of these contaminants is suspected to be due to changes in the origin of the raw materials which are not properly monitored by the pharmaceutical industry and/or regulatory agencies. Sapta Aprilianto then continued the discussion by explaining criminal responsibility according to health law. According to him, if there is a criminal act, the cause must be sought. He then explained, a person could be held criminally responsible if there were criminal acts and criminal mistakes committed by that person.

When the elements of a criminal act have been fulfilled, it can be called a criminal act."In this case, the most important thing is to find out first whether there is causality between the act and intention, whether it is true that the liquid in the drug is the main cause of kidney failure or not," said Sapta. However, it is too early to determine whether there is a causal relationship as there has been no official investigation. In looking at this problem, at least there is a possibility that a crime has occurred so that only the commitment of law enforcers to resolve it remains. In closing, he then also committed to forming an acute kidney failure complaint post to defend people in need (<https://fh.unair.ac.id/menakar-peruntungan-Hukum-terhadap-cases-gagal-ginjal-akut-akibat-kandungan-cemaran-dalam-obat/>. Retrieved December 1, 2022). Therefore The Food and Drug Supervisory Agency (BPOM) is the drug and food supervisory agency has the right to recommend that law enforcement be carried out against pharmaceutical companies related to contamination of syrup drugs, they must be acted upon firmly, because it involves the lives of other people.

IV. CONCLUSION

Based on the explanation above, it can be concluded that criminal responsibility for administering drugs that cause acute kidney problems in children must be fully responsible. Especially companies that produce drugs that ultimately cause acute kidney problems in children. Besides that, The Food and Drug Supervisory Agency (BPOM) is the drug and food supervisory agency has the right to recommend that law enforcement be carried out against pharmaceutical companies related to contamination of syrup drugs, they must be acted upon firmly, because it involves the lives of other people.

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