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BPOM Supervision Negligence Review Results in Child Victims of Acute Kidney Failure

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Abstract: In 2022, the Indonesian Pediatrician Association (IDAI) through the Ministry of Health conveyed to the public that there were 324 cases of atypical progressive acute kidney failure of unknown cause in children spread across 27 provinces in Indonesia. The method used in this study is the normative research method by collecting secondary data which is then analyzed qualitatively to obtain conclusions about the circulation of syrup drugs that cause acute kidney failure in children, which is certainly not in accordance with the provisions in the Health Law and also violates the guidelines for Good Manufacturing Practices. The form of legal responsibility that can be carried out by BPOM is to strengthen the pre-market and post-market supervision function of drugs in circulation and conduct independent drug tests. In addition, it is hoped that the government will immediately ratify the Drug and Food Supervision Bill to strengthen the supervisory function, authority and sanctions that can be imposed on BPOM if they are negligent.

Keyword: BPOM, Negligence, Supervision.

INTRODUCTION

Supervision of circulation has broad problems, tends to be complex, and is a joint responsibility between the government, society as consumers, and business actors. The role of the community and business actors in supervision is important and needs to be increased. One form of effort made by the government to monitor and protect public health was the formation of the Food and Drug Monitoring Agency (BPOM). BPOM is tasked with monitoring drugs and food in accordance with applicable laws and regulations. BPOM was formed to detect, prevent and supervise products, including to protect the safety and security and health of consumers.

BPOM is a Non-Ministerial Government Institution (LPNK) which is tasked with carrying out government duties in the field of drug and food supervision in accordance with statutory provisions. An effective and efficient Food and Drug Monitoring System (SisPOM) that is capable of detecting, preventing and supervising products with the aim of protecting the security, safety and health of the public both at home and abroad. For this reason, BPOM has

been formed which has national and international networks as well as law enforcement authority and has high professional credibility.

These duties and functions are inherent in BPOM as a government institution which is at the forefront in protecting the public regarding medicine and food. In the organizational structure of BPOM, the person who has the task of carrying out the preparation and implementation of policies in the field of supervision of traditional medicines, health supplements and cosmetics is the Deputy for Supervision of Traditional Medicines, Health Supplements and Cosmetics as stated in Article 17 of Regulation No. 80 of 2017 concerning Supervisory Bodies Medicine and Food. The existence of BPOM licensing itself functions for regulation, regulation and standardization, licensing and industrial certification in the pharmaceutical sector based on "good production methods, product evaluation before circulation, post marketing vigilance including sampling and laboratory testing, inspection of production and distribution facilities, investigations and law enforcement, pre-audit and post-audit advertising and product promotion, research on the implementation of drug and food control policies, as well as communication, information and public education including public warnings.

In order to protect the public from the distribution of drugs that do not meet the requirements for efficacy, safety and quality, it is necessary to register drugs before they are distributed, the government through the BPOM of the Republic of Indonesia so that drugs before being distributed/traded must go through an assessment process, especially an assessment of the quality and safety of drugs. An assessment is carried out on the medicinal ingredients used including other medicinal additives, an assessment of the packaging used and assessment of the production process, as well as assessment of the quality and side effects of drugs, so that if a drug has been given registration or registration approval, then the drug is of good quality and has benefits for the health of the person who uses the drug.

Even though this is the reality in the field, it is known that in October 2022, the Indonesian Pediatrician Association (IDAI) through the Ministry of Health conveyed to the public that from January to December 5 2022 there were 324 cases of atypical progressive acute kidney failure (GGAPA) whose cause was unknown. children spread across 27 provinces in Indonesia. This case is not only disturbing parents but also all Indonesian society.

The cause of cases of acute kidney failure in children is due to the presence of dangerous contaminants Ethylene Glycol (EG) and Diethylene Glycol (DEG) which exceed the safe threshold, resulting in dangerous contaminants which, if consumed, can cause acute kidney failure in children. This medicine is obtained freely in the community without having to have a prescription from a doctor. Medicines containing dangerous contaminants are well-known medicines that often circulate in the mass media. There are 6 pharmaceutical industries (IF) which are suspected of producing syrup medicines containing dangerous contaminants, including Pharmaceutical Industry. PT Yarindo Farmatama, Pharmaceutical Industry. PT Universal Pharmaceutical Industry, Pharmaceutical Industry. PT Ciubros Farma, Pharmaceutical Industry. PT Samco Farma, Pharmaceutical Industry. PT Afi Farma and the Pharmaceutical Industry. CV Samudera Chemical.

The legal facts mentioned above provide an explanation that the importance of good governance is that it is implemented or used by public resources and problems that are managed effectively and efficiently and are a response to the needs of the community, thereby enabling the interests of the community to be well guaranteed. With the aim of providing information transparency in response to the needs of the community which has provided maximum results, the distribution and use of products supervised by BBPOM include medicines, biological products, narcotics and psychotropic substances, traditional medicines, food and drinks, food supplements, cosmetics, substances. additives/cigarettes, as well as hazardous materials tend to decrease.

The problem in this research is the responsibility of the Food and Drug Monitoring Agency (BPOM) regarding the legal consequences of BPOM's negligence in supervision resulting in acute kidney failure in children and legal protection for victims due to negligence in supervision in the pharmaceutical industry which resulted in acute kidney failure in children.

METHOD

Research is a scientific activity based on certain methods, systematics and thinking which aims to study one or several particular legal phenomena by analyzing them. This type of research is divided into three, namely normative legal research. Normative legal research (normative law research) using normative legal case studies in the form of legal behavioral products, for example reviewing draft laws.

This research uses legal material analysis techniques with deductive logic. According to Peter Mahmud Marzuki who quoted the opinion of Philipus M. Hadjon explaining the deduction method as the syllogism taught by Aristotle, the use of the deduction method stems from submitting a major premise (general statement) then submitting a minor premise (specific in nature), from the two premises then a conclusion is drawn. conclusion or conclusion. So what is meant by processing legal materials in a deductive manner is explaining something from things that are general in nature, then drawing conclusions from things that are more specific in nature.

RESULTS AND DISCUSSION

The Consequences of BPOM'S Negligence Law Resulting in Acute Kidney Failure in Children

This BPOM institution was formed to carry out certain government tasks from the President. So his position is below and directly responsible to the President. In carrying out their duties, they must coordinate with the Minister of Health of the Republic of Indonesia. So it can be understood that the Head of BPOM is under the coordination of the Minister of Health as the highest person responsible for government affairs in the Health sector.

In this case, BPOM has the authority to carry out monitoring actions on drugs circulating in the community, but this function is not running well. This can be proven by The widespread circulation of syrup medicine which causes acute kidney failure in children which attacks children from various provinces in Indonesia. In accordance with this authority, BPOM is the only agency authorized to issue a distribution permit for a medicinal or food product if the product complies with applicable requirements and safety.

The existence of BPOM's authority over the function of drug and food supervision as well as the drug and food testing process, in practice does not run optimally. This can be proven by the large number of child victims due to the distribution of syrup drugs which cause acute kidney failure in children. The increase in the phenomenon of acute kidney failure in children due to syrup medication can be seen in the graph below, that cases of acute kidney failure in children have been occurring since January, but BPOM itself only carried out an investigation into this phenomenon in October, which is the peak month for the phenomenon of acute kidney failure. in children with the largest number of pediatric patients spread across various provinces in Indonesia.

In practice, BPOM's work procedures are carried out by the Technical Implementation Unit (hereinafter referred to as UPT) in accordance with Regulation of the Head of BPOM Number 12 of 2018 concerning the Organization and Work Procedures of Technical Implementation Units within the Food and Drug Supervisory Agency (hereinafter referred to as Perka BPOM concerning the organization and work procedures of UPT BPOM). This explains that the UPT is responsible to the head of BPOM and has the authority to carry out drug and food testing as investigation material, test drug and food labels and advertisements, take drug and food

sampling, carry out preventive measures, intelligence and investigations into violations of provisions. laws and regulations in the field of medicine and food, monitoring the circulation of medicine and food via cyber and so on.

There is negligence in BPOM supervision based on the description above, because currently BPOM does not carry out its own testing but asks producers to test and then report the test results to BPOM. Then, related to post market supervision, BPOM is also not carried out optimally, this is because BPOM only carries out post market supervision for special cases such as cosmetics and supervision during holidays and New Year. 32 Quality control, including qualitative and quantitative analysis, is always important to ensure safety and efficacy of a drug. For quantitative analysis, three aspects, namely quality markers, reference compounds and approaches, must be properly considered.33

As is known, based on Minister of Health Regulation Number 33 of 2016 concerning the Implementation of Drug Quality Testing at Government Pharmaceutical Installations (hereinafter referred to as Minister of Health Regulation concerning Drug Quality Testing). In Article 3 paragraph (1) of this Minister of Health Regulation as well as the Presidential Decree regarding BPOM, it is stated that BPOM is the organizer of drug quality testing by means of sampling, laboratory testing and reporting test results. 34 So based on this regulation BPOM should be able to carry out drug testing independently without relying on pharmaceutical industry so that test results can be more accurate.

Thus, it should be the obligation of the head of BPOM to be held accountable because the phenomenon of acute kidney failure is also a result of the lack of supervisory function of BPOM itself. Apart from that, this is also in accordance with the theory of legal responsibility put forward by Hans Kelsen which states that a person is legally responsible for a certain act or that he bears legal responsibility, subject means that he is responsible for a sanction in a contrary act.

The legal event that occurs when acute kidney failure in children is due to the presence of dangerous contaminants Ethylene Glycol (EG) and Diethylene Glycol (DEG) which exceed this safe limit, the Head of BPOM gave a statement at a press conference held on Thursday 27 October 2022 that it is not BPOM's responsibility but delegates it to the Pharmaceutical Industry, “BPOM has carried out its duties in accordance with the Pharmacopoeia standard guidelines issued by the Ministry of Health. So BPOM has no obligation to supervise finished medicinal products. "So, don't ask the POM Agency for responsibility because the POM Agency has done its job as well as possible."

Furthermore, BPOM also issued an explanation from BPOM RI regarding the issue of syrup medicine which is at risk of containing ethylene glycol (eg) and diethylene glycol (deg) contamination, informing the following:

1. BPOM previously provided an explanation regarding medicinal syrups for children contaminated with DEG and EG in Gambia, Africa, on Wednesday, October 12 2022, which can be accessed via the link https://www.pom.go.id/penjauhan-publik/penjualan -bpom-ri-about-medicinal-syrup-for-children-in-the-gambia-africa-contaminated-with-diethylene-glycol-and-ethylene-glycol, and Saturday, October 15 2022 via the link https://www.pom.go.id/penjelasan-publik/penjelasan-bpom-ri-tentang-sirup-obat-untuk-anak-di-gambia-afrika-yang-terkontaminasi-dietilen-glikol-dan-etilen-glikol-2.
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. The four products recalled in Gambia are not registered and are not circulating in Indonesia and to date, none of the products from the manufacturer Maiden Pharmaceutical Ltd, India are registered with BPOM.

3. BPOM carries out comprehensive pre- and post-market supervision of medicinal products circulating in Indonesia. In accordance with regulations and registration requirements for medicinal products, BPOM has stipulated requirements that all syrup medicinal products for children and adults are not permitted to use EG and DEG. However, EG and DEG can be found as contamination in glycerin or propylene glycol which are used as additional solvents, BPOM has set maximum limits for EG and DEG in these two additional materials according to international standards.
4. The Ministry of Health has explained that the cause of acute kidney failure or Acute Kidney Injury (AKI) is not yet known and still requires further investigation with BPOM, the Indonesian Pediatrician Association (IDAI), and other related parties.
5. BPOM encourages health workers and the pharmaceutical industry to actively report drug side effects or undesirable 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) circulating and used for treatment in Indonesia.
6. BPOM also carries out risk-based tracing, sampling and gradual sample testing of syrup medicinal products that have the potential to contain EG and DEG contamination. The test results for products containing EG and DEG contamination still require further study to ensure that safe thresholds are met based on references. Furthermore, products that exceed the safe threshold will immediately be given administrative sanctions in the form of warnings, strong warnings, temporary suspension of drug manufacturing activities, suspension of Good Medicine Manufacturing Practices (CPOB) certificates, revocation of CPOB certificates, temporary suspension of advertising activities, as well as suspension of permits. Distribution and/or revocation of Marketing Permit.
7. All pharmaceutical industries that have syrup drugs that have the potential to contain EG and DEG contamination are asked to report the results of tests carried out independently as a form of business actor responsibility. The pharmaceutical industry can also make other efforts such as changing drug formulas and/or raw materials if necessary.
8. BPOM invites the public to use medicines safely and always pay attention to the following matters:
9. Use medication appropriately and do not exceed the instructions for use;
a. Read carefully the warnings on the packaging;
b. Avoid using leftover syrup medication that has been opened and stored for a long time;
c. Consult a doctor, pharmacist or other health worker if symptoms do not decrease after 3 (three) days of using over-the-counter medication and over-the-counter medication is limited to self-medication efforts (self-medication);
d. Completely report the drugs used in self-medication to health workers;
e. Report drug side effects to the nearest health worker or via the BPOM Mobile and e-MESO Mobile service applications.
BPOM also urges the public to be more alert and use medicinal products registered with BPOM obtained from pharmaceutical service facilities or official sources and always remember to Check KLIK (Check Packaging, Label, Marketing Permit and Expiration) before buying or using medicine.

Legal Protection For Victims Due to Negligence of BPOM Supervision Which Results in Acute Kidney Failure in Children

Business activities supported by technology have the impact of expanding the circulation of goods across a country's borders indefinitely. The entry and exit of goods will provide benefits to the public in choosing and owning goods offered by business actors. The entry and exit of goods across a country's territorial borders can have negative effects that can cause harm to

consumers. Circulation of goods in the community must be quality products, quality, in accordance with predetermined quality standards and have undergone inspection by BPOM. Legal protection must be given to consumers when the product consumed endangers the consumer, such as the case of children's syrup being traded in the community causing acute kidney failure in children which results in death.

As explained previously, liquid medicine that causes acute kidney failure in children contains three chemicals that are dangerous to health, namely ethylene glycol (EG), diethylene glycol (DEG), and ethylene glycol butyl ether (EGBE). EG and DEG are medicinal raw materials which are used as solvent raw materials in syrup medicines. Use that is within reasonable limits is still safe for health. Unreasonable use exceeding the threshold poses a risk of causing acute kidney failure.

Regarding this, legal protection is needed for people who use syrup medicine and people who have experienced material losses and casualties. Legal protection can be defined as a form of effort that is given or can be done by someone to provide a sense of security and meet the misfortune or loss they experience. Indonesia itself has emphasized that every community has the right to have or obtain appropriate legal protection, which is explained in Article 28D paragraph (1) of the 1945 Constitution. If you look at the sound of this article, it can be seen that every human being has the right to obtain protection.

The concept of legal protection by Philipus M. Hadjon is divided into two forms, namely preventive protection and repressive protection. The efforts made by BPOM regarding the children's syrup case in protecting child consumers are taking preventive measures to prevent the emergence of new cases of victims.

The preventive legal protection carried out by BPOM to prevent new victims is to withdraw syrup medicine from circulation, appeal to the public not to buy syrup medicine in liquid form but to buy medicine in liquid form and consult a doctor before consuming the medicine. BPOM announces the list of syrup medicines through the public service room, electronic media and print media and deploys a field team to check the place where the medicine is sold and take samples of the medicine for examination in the laboratory and inform the drug dealers that they are temporarily not selling the medicine. liquid syrup to consumers. Carrying out inspections of raw materials, production processes, laboratory inspections, packaging and procedures Another thing that BPOM does before the distribution permit is issued is a form of legal protection carried out by BPOM and BPOM must be able to guarantee that liquid medicines before they are circulated do not harm the public.

Apart from that, it is the obligation of the head of BPOM to be held accountable because the phenomenon of acute kidney failure is also a result of the lack of supervisory function of BPOM itself. Apart from that, this is also in accordance with the theory of legal responsibility put forward by Hans Kelsen which states that a person is legally responsible for a certain act or that he bears legal responsibility, subject means that he is responsible for a sanction in a contrary act.

BPOM's actions are against the law, namely not carrying out comprehensive testing of syrup drugs, BPOM's inconsistent attitude in providing announcements regarding the number of syrup drugs contaminated with Ethylene Glycol (EG), Diethylene Glycol (DEG) and Ethylene Glycol Butyl Ether (EGBE), and BPOM's actions to monitor syrup drugs seem hasty and BPOM's actions to delegate testing of syrup drugs to the pharmaceutical industry is a violation of the general principles of good governance, namely the principle of professionalism. Where BPOM should carry out the duties and authority to carry out its own testing.

Other legal protection concepts such as the need to immediately inaugurate the Draft Law on Drug and Food Control (hereinafter referred to as the POM Bill) which is currently included in the National Legislative Program where this Bill will regulate in detail the authority and responsibilities of BPOM as well as the existence of regulations regarding the provision of

sanctions against BPOM which grants distribution permits for medicines and food that are dangerous to public health. 39 As well as strengthening the technical implementation of randomized clinical trials which have become the gold standard in producing clinical evidence of the efficacy of medical interventions before they can be marketed by pharmaceutical companies.

CONCLUSION

The phenomenon of circulating syrup medicine which is the cause of acute kidney failure in children is certainly not in accordance with the provisions in the Health Law and also violates the guidelines for Good Medicine Manufacturing Practices. The form of legal responsibility that can be carried out by BPOM is strengthening the function of pre-market and post-market supervision of circulating drugs and carrying out independent drug testing. Apart from that, it is hoped that the government will immediately ratify the Food and Drug Control Bill to strengthen the supervisory function, authority and sanctions that can be imposed on BPOM if it is negligent.

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