
Criminal Liability in Case of Acute Kidney Failure in Indonesian Health Legal Perspective

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ABSTRACT

Cases of Atypical Progressive Acute Kidney Injury (AKI) have caused hundreds of children to die mysteriously, which has caused anxiety for all Indonesian people. The Ministry of Health noted that the number of cases of acute kidney failure as of November 7, 2022, had reached 324 cases, with a death rate of 195 children who had died. The high mortality rate due to acute kidney disease is thought to be caused by poisoning with the compounds Ethylene Glycol (EG) and Diethylene Glycol (DEG), which are commonly used as solvents in liquid medicines. It is necessary to know in advance whether there is causality between the act and intention, whether it is true that the active ingredient is the main cause of kidney failure, and the form of accountability from the parties involved as contained in Article 196 of Law Number 36 of 2009 concerning Health. In this case of acute kidney failure, it was found that several potential negligences led to death in this case, starting from the licensing process to drug control, maladministration by the Ministry of Health, pre-post market supervision regulations, and National Agency of Drug and Food Control's (BPOM) strategy in preventing unwanted events.

1. Introduction

Humans are perfect creations of God Almighty, have advantages over other creatures, and have rights attached to them from the moment they are born, even when they are still in the womb. The rights attached to him cannot be revoked or reduced by anyone. The first fundamental right is the right to life, which then brings consequences with the existence of other rights, one of which is the right to health. If studied philosophically, it is not humans who have life but the will of God Almighty. The presence of humans is also the will of God Almighty, which can be seen in human birth.

Health is an essential element for human life as one of the basic needs and is protected by the state and laws and regulations. Health is also the key to achieving progress in a country and is a capital for achieving the welfare of its people. As a large organization, Indonesia has an essential role in providing health services and providing health facilities and personnel. The 1945 Constitution outlines that health is a human right everyone must have. In article 34, paragraph (3), it has been explained in detail that the state is responsible for proper health services for every citizen.

Constitutional guarantees for the right to health have existed since the 1949 Constitution of the Republic of Indonesia (RIS). Article 40 of the RIS Constitution states, "The authorities have always made serious efforts to promote public hygiene and health." Still, after taking the form of a unitary state and coming into force, the 1950 UUDS (UUDS) provisions of Article 40 of the RIS Constitution were adopted into Article 42 of the UUDS. Article 28A of the 1945 Constitution states that every person has the right to live and defend his life and existence. It means that life is entrusted to God Almighty, who must be guarded, respected, and protected by the government and the state. Thus, it can be said that the Indonesian nation adheres to the principle of Pro-Life, not Pro-Choice.¹ Further explained in Article 28H paragraph (1), it is stated that everyone has the right to receive health services. In paragraph (3), it is explained that everyone has the right to social security that allows for the full development of himself as a dignified human being. This is why the right to health is included in Human Rights. Furthermore, in connection with the existence of Law no. 36 of 2009 concerning health has the following philosophical values:

1. Health is a human right and one of the elements of well-being that must be realized in the ideals of the Indonesian nation as stated in Pancasila and the 1945 Constitution;
2. Every activity to maintain and improve the highest degree of public health is carried out on a non-discriminatory, participatory, and sustainable basis in the framework of forming Indonesian human resources, as well as increasing the nation's resilience and competitiveness for national development;

¹ Siska Elvandari, *Hukum Penyelesaian Sengketa Medis Di Indonesia* (Depok: Rajawali Pers, 2021).

3. Everything that causes a disturbance to the health of the Indonesian people will cause a significant loss to the country's economy, and every effort to increase the degree of public health means an investment in the development of the nation;
4. Every development effort must be based on health insights because national development must pay attention to public health and is the responsibility of all parties, the government and the community.

The same thing is also stated in Article 25 of the UDHR paragraph (1), which says that "everyone has the right to a standard of living adequate for the health and welfare of himself and his family, including the right to food, clothing, housing and health care..." Likewise in, in the International Covenant on Civil and Political Rights (ICCPR) or the International Covenant on Civil and Political Rights, which Indonesia ratified on October 28, 2005, through Law no. 12 of 2005 concerning Ratification of the ICCPR, in Article 6 paragraph (1) it says, "every human being has the right to life which is inherent in him. This right must be protected by law. No one can be arbitrarily deprived of the right to life." This means that health and human rights are two things that are interconnected and influence each other. Often, when there is a problem with the right to health, the government sees it as a failure to fulfil its obligations. Although the state cannot guarantee good health because this goes back to its citizens' genetic factors and lifestyle, it plays a vital role in protecting and ensuring the right to life and obtaining proper health services.

The development of science and technology has made people more advanced in developing the pharmaceutical industry and producing drugs, food and medical devices. The variety of medications on the market is a helper and is essential as a public health service. Somebody can use drugs to save lives, restore health and maintain health. In health services, medicine is very important because medicine is needed in most health efforts.²

Modern technology can produce various medicinal products on a large scale and cover a wide range of products. The current increase in public consumption of medicines is not supported by the knowledge of the public to select and use products in an appropriate, correct and safe manner. Therefore, the Food and Drug Monitoring Agency (BPOM) was formed, with national and international networks, law enforcement, and professional authority.³

² Dwi Bagus Pambudi and Danang Raharjo, 'Perlindungan Hukum Bagi Konsumen Terhadap Obat Tradisional Tanpa Izin Edar Di Media Online', *Prosiding University Research Colloquium*, 2020, 21–25
<<http://repository.urecol.org/index.php/proceeding/article/view/984>>.

³ Muhammad Heru Hardianto, 'Peranan Balai Besar Pengawas Obat Dan Makanan (BBPOM) Terhadap Peredaran Produk Obat-Obatan Dalam Rangka Perlindungan Konsumen Di Kota Mataram', *Energies*, 6.1 (2018), 1–8
<<http://journals.sagepub.com/doi/10.1177/1120700020921110%0Ahttps://doi.org/10.1016/j.reuma.2018.06.001%0Ahttps://doi.org/10.1016/j.arth.2018.03.044%0Ahttps://reader.elsevier.com/reader/sd/pii/S1063458420300078?token=C039B8B13922A2079230DC9AF11A333E295FCD8>>.

In carrying out their business, pharmaceutical companies produce products called drugs, according to the law, are regulated in Article 1 number 8 of Law Number 36 of 2009 concerning health. Hard drugs are regulated in Article 1 Paragraph (1) of the Drug Law (St. Number 419 dated 22 December 1949).⁴ Somebody can trade the drugs from these pharmaceutical companies to trade freely to facilitate the supply of drugs and the healing of a person's illness, whether over-the-counter drugs or drugs given by a doctor's prescription.⁵ In fact, in the field, many drug dealers still sell drugs that are not by applicable regulations. For example, in selling drugs, sellers sell various complex medicines that somebody should purchase with a doctor's prescription, but in fact, somebody can buy these drugs freely. Things like this can cause multiple health problems that can severely impact society.

Based on Presidential Regulation No. 80 of 2017 concerning the Food and Drug Supervisory Agency, BPOM has duties in drug and food control before and after distribution. Drug and food control that is carried out before or after distribution functions as an action to guarantee that drugs and food that will be and have distribute have met the established standards and requirements for safety, benefits, and product quality so that they can become the first protector for the public to buy and use drugs and food is safe.

Some time ago, Indonesia was shocked by the news of the death of children caused by acute kidney failure. According to what was reported by Kompas.com, this case started with a report in January 2022 with two points of acute kidney problems. The Minister of Health, Budi Gunadi Sadikin, revealed an unusual graph of a spike in cases since August, with 36 cases. Then it increased in September and October to 110 cases. Usually, death in cases of kidney disorder or acute kidney injury (AKI) does not increase rapidly in a short time. According to Budi, the most significant suspicion, in this case, was that the drug syrup contaminates with chemical compounds, namely ethylene glycol (EG), diethylene glycol (DEG), and ethylene glycol butyl ether (EGBE).

Based on the case of acute kidney failure in Indonesia, there is a need for more supervision of drugs that pharmaceutical companies will distribute to the public. In this case, various parties must be involved in pre-checking, supervising, and preventing what will be circulated in the community so that negligence like this case does not occur again.

⁴ Evita Ariestiana, 'Analysis of Drugs and Certain Medicines Circulation Through Online Media', *Indonesia Private Law Review*, 1.2 (2020), 65–76 <<https://doi.org/10.25041/iplr.v1i2.2054>>.

⁵ Deo Andika Putra S, 'Pengawasan Penjualan Obat Keras Oleh Badan Pengawas Obat Dan Makanan Pekanbaru Berdasarkan Undang-Undang No 36 Tahun 2009 Tentang Kesehatan', *Journal of Chemical Information and Modeling*, 110.9 (2017), 1–15.

In public policy theory, various actors are involved in implementing public policy, namely: the bureaucracy, the private sector, and the role of society.⁶ So based on the description of the background above, this paper aims to examine who is responsible, what are the responsibilities of BPOM, and what are the responsibilities of pharmaceutical companies, which in this case are the first party responsible for the problems of cases of acute kidney failure that occur in children originating from drugs circulating in the community, so this is a form of protection for public health. Through the background that has been described, the author will include problems to find a legal solution as follows: 1). What is the criminal responsibility of pharmaceutical companies in cases of syrup contaminated with EG and DEG; 2). What is BPOM's responsibility in cases of syrup containing EG and DEG?

2. Method

This research is legal research with a normative approach, supported by various library materials, such as reading literature in the form of books, journals, online articles, media, and papers.

3. Criminal Responsibility of Pharmaceutical Companies

Health development is part of national development which is part of the efforts carried out by the Indonesian people, which aim to increase everyone's awareness, willingness, and ability to live healthily to realize the highest degree of public health. To ensure the success and continuity of health development, a Long-term Development Plan for the Health Sector (RPJP-K) for 2005-2025 has been prepared as an elaboration of the National Long-Term Development Plan (RPJP-N) for 2005-2025, of course, a National Health System (SKN) is needed. Each ministry needs to prepare a Strategic Plan (Renstra) by its primary tasks and functions, which are guided by the National Medium-Term Development Plan (RPJMN) as mandated in Law Number 25 of 2004 concerning the National Development Planning System (SPPN). The 2020-2024 period is the last stage of the 2005-2025 National Long-Term Development Plan (RPJPN), so the medium-term development period is crucial and strategic. For this reason, the development of the health sector is in line with the goals of National Development. The Ministry of Health's Strategic Plan for 2020-2024 has been prepared, which will be implemented directly by the Ministry of Health.

Health development must also be supported by development in the field of law by forming partnerships in the form of health law development planning. The development of national laws in the health sector is, in fact, increasingly important because, from the making of regulations to their implementation, health laws are always related to other fields. In other words, health law is multidisciplinary. With this

⁶ Rahmi Yuningsih, 'Pelindungan Kesehatan Masyarakat Terhadap Peredaran Obat Dan Makanan Daring', *Aspirasi: Jurnal Masalah-Masalah Sosial*, 12.1 (2021), 47–62 <<https://doi.org/10.46807/aspirasi.v12i1.2020>>.

cross-sectoral planning, it is hoped that development in health law can be aligned with national development planning. National legal planning in the health sector comprehensively and synergistically between development in the health sector and development planning in the health law sector so that medium and long-term legal development planning plans can be implemented.

Support development planning in the field of health law certainly requires health development first. As is well known, Indonesia still needs help in the health service sector. Various service facilities managed by other sectors besides health, including those operated by BPOM as the regulatory agency for drug circulation, have significantly contributed to health development. Still, this task has yet to be fully implemented. The existence of cases of drug syrup contaminated with ethylene glycol and diethylene glycol means that drug distribution without heeding the rules by Good Drug Manufacturing Practices (GMP) still occurs. For this reason, sanctions such as revocation of registration and product destruction must be applied consistently to deter violators because human life is at stake, in this case, children. Seeing these conditions, of course, health development, including development in health law covering planning, implementation, supervision, and accountability, needs to be renewed so that the mission in the pharmaceutical and medical device sector, as outlined by the President for 2020-2024 regarding increasing the drug raw material industry can be achieved to improve quality, just, and equitable public health degree.

3.1. History of Health Development

A nation with a high degree of health is one of the characteristics of an advanced country. Health development is an integrated part of human resource development in making a progressive, independent, and prosperous nation physically and spiritually. History related to the health system in Indonesia has existed since 1982 through the National Health System. For Indonesia, the boundaries of the National Health System (SKN) are determined by which the boundaries of the National Health System are determined by Decree of the Minister of Health of the Republic of Indonesia Number 131/Menkes/SK/II/2004 as a replacement SKN 1982 which was no longer relevant due to changes in the political climate in Indonesia at that time.⁷

Health development is oriented towards goals for physical fitness and health. The key factors are human/society, behavior, and environment. These three factors are interrelated so that the interaction between factors runs based on local socio-culture (Loedin, 1982:9; Corbin et al., 2004:5), namely values, norms, and the existence of social organizations supporting the achievement of health.⁸

⁷ Yussy A Mannas and Siska Elvandari, *Hukum Kesehatan Di Indonesia* (Depok: Rajawali Pers, 2022).

⁸ Rusmin Tumanggor, 'Masalah - Masalah Sosial Budaya Dalam Pembangunan Kesehatan Di Indonesia', *Jurnal Masyarakat Dan Budaya*, 12.2 (2010), 231-54.

Health development is related to all aspects of life, physical, mental, and socio-economic. In the development of health in the period before the birth of Law Number 23 of 1992 concerning Health, there had been a change in orientation, both in values and thoughts, especially regarding efforts to solve problems in the health sector, which were influenced by politics, economics, socio-culture, defense, and security as well as science and technology. A dynamic health legal instrument is needed to provide legal certainty and protection to improve, direct and provide a basis for health development. This legal instrument is expected to reach increasingly complex developments at that time. Therefore, Law Number 23 of 1992 concerning Health was born.

The new paradigm that is developing is the healthy paradigm, namely the health paradigm that prioritizes promotive and preventive efforts without neglecting curative and rehabilitative. In the context of implementing this healthy paradigm, laws that have a sick perspective are needed.

The health development strategy in Indonesia refers to the scope and quality of health that is coveted. The reference is the definition of healthy which has been established by the government as stated in RI Law No. 36 of 2009 concerning health. A healthy state includes physical, mental, spiritual, and social, which allows everyone to live productively, socially, and economically. Related to the quality of health to be achieved, it refers to a country's progress and capabilities. Indonesia is included in the category of developing countries that are actively involved in the process and flow of health development, appreciating the international commitment at the Alma Ata meeting in 1978 (SKN, 1982:19; Rukmono, 1982:24), namely "primary health care" (PHC) the main approach to achieve "health for all by 2000 (Health for All by the 2000 Year-HFA).

3.2. History of Health Development

Regulations related to this case of atypical progressive renal failure, namely:

1. Article 28H paragraph (1) and paragraph (3) 34 paragraph (3) of the 1945 Constitution;
2. Article 359 and Article 360 of the Criminal Code;
3. Article 52 and Article 62 of Law no. 39 of 1999 concerning Human Rights;
4. Article 6 paragraph (1) and Article 25 paragraph (1) of the Universal Declaration of Human Rights as ratified through Law no. 12 of 2005 concerning Ratification of the International Covenant on Civil and Political Rights;
5. Article 98 paragraph (2) and paragraph (3) in conjunction with Article 196, Article 105, Article 106, and Article 108 of Law no. 36 of 2009 concerning Health;
6. Article 8 in conjunction with Article 62, Article 19 paragraphs (1) and (2), and Article 46 of Law no. 8 of 1999 concerning Consumer Protection;

7. Article 2 paragraph (1) and Article 3 letter d Presidential Regulation No. 80 of 2017 concerning BPOM;
8. Regulation of the Minister of Health No. 73 of 2016 concerning Pharmaceutical Service Standards in Pharmacies;
9. Decree of the Director General of Health Services Number HK.02.02/I/3305/2022 concerning Management and Clinical Management of Atypical Progressive Acute Kidney Injury in Children in Health Service Facilities.

This Decree was issued on September 28, 2022, to increase awareness and be a reference for health facilities providing medical treatment to patients with acute kidney failure.

3.3. Duties, Functions, and Authorities of the National Agency of Drug and Food Control

Drugs and food significantly influence the needs of the Indonesian people, who consume food and medicine as basic needs. The importance of health for the community requires an institution that can protect and monitor various drugs and foods that will circulate in the community.⁹ Indonesia must have an effective and efficient drug and food control system (SISPOM) capable of detecting, preventing, and monitoring products, including protecting its consumers' security, safety, and health. For this reason, a Food and Drug Supervisory Agency was formed, with national and international networks and the authority to enforce the law.¹⁰

The real manifestation of eradicating and monitoring the distribution of medicines and food for the community's needs is carried out through supervision efforts by BPOM. BPOM was formed as a form of action to strengthen government services in supervising every product engaged in the medicine and food sector. Regarding the tasks that BPOM has, according to Presidential Regulation Number 80 of 2017 concerning the Food and Drug Supervisory Agency, they are as follows:

1. BPOM has the task of carrying out governmental functions in the field of Drug and food control field by the provisions of laws and regulations.
2. As referred to in paragraph (1), drugs and food consist of drugs, medicinal ingredients, narcotics, psychotropics, precursors, addictive substances, traditional medicines, health supplements, cosmetics, and processed food.

⁹ Bahmid Panjaitan, Junindra Martua, and Arbiah Arbiah, 'Peranan Badan Pengawas Obat Dan Makanan Dalam Memberikan Perlindungan Studi Di Kantor Cabang Badan Pengawas Obat Dan Makanan Badan Pengawas Obat Makanan (BPOM) Tanjungbalai', *DE LEGA LATA: Jurnal Ilmu Hukum*, 5.2 (2020), 183–92 <<https://doi.org/10.30596/dll.v5i2.3577>>.

¹⁰ Wahyu Simon Tampubolon, 'Peranan Dan Tanggung Jawab Badan Pengawas Obat Dan Makanan (Bpom) Terkait Kasus Albothyl Menurut Undang Undang Perlindungan Konsumen', *Jurnal Ilmiah Advokasi*, 6.1 (2018), 69–78 <<https://doi.org/10.36987/jiad.v6i1.266>>.

Regarding the functions that BPOM has in carrying out its duties in supervision according to Presidential Decree Number 80 of 2017, it is stated as follows:

1. In carrying out the task of supervising Drugs and Food, BPOM carries out the following functions:
 - a. preparation of national policies in the field of drug and food control;
 - b. implementing national policies in the field of drug and food control;
 - c. preparation and stipulation of norms, standards, procedures, and criteria in the field of Control Before Circulation and Supervision During Circulation;
 - d. implementation of Supervision before Circulation and Supervision During Circulation;
 - e. coordinating the implementation of Drug and Food control with central and regional government agencies;
 - f. provision of technical guidance and supervision in the field of drug and food control;
 - g. implementation of action against violations of statutory provisions in the field of drug and food control;
 - h. coordinating the implementation of tasks, coaching, and providing administrative support to all organizational elements within BPOM;
 - i. management of state property/wealth which is the responsibility of BPOM;
 - j. supervising the implementation of tasks within the BPOM; And
 - k. implementation of substantive support to all elements of the organization within BPOM.
2. Control before distribution, as referred to in paragraph (1), is control of Drugs and Food before distribution as a preventive measure to guarantee Drugs and Food in circulation meets the stipulated standards and requirements for safety, efficacy/benefits, and product quality.
3. Control During circulation, as referred to in paragraph (1), is control of Drugs and Food during distribution to ensure that Drugs and Food in circulation meet the stipulated standards and requirements for safety, efficacy/benefits, and product quality and law enforcement measures.

Furthermore, regarding the authority possessed by BPOM, according to Presidential Decree Number 80 of 2017 concerning the Food and Drug Supervisory Agency, which is as follows:

1. issue product distribution permits and certificates by standards and requirements for safety, efficacy/benefits, and quality, as well as drug and food testing by statutory provisions;

2. carry out intelligence and investigations in the field of drug and food control by the provisions of laws and regulations; And
3. the imposition of administrative sanctions by the provisions of laws and regulations.¹¹

3.4. Role of the Food and Drug Supervisory Agency

The importance of optimizing the role between BPOM and related institutions to supervise products circulating in the community. Institutions such as the police and the ministry of health must support and protect the community if there are losses or omissions in medicines and food circulating in the community. With various related institutions supporting the implementation of safety and comfort for the community regarding drugs and food in circulation, it makes people feel safe and comfortable to consume these as one of the basic needs for people's lives.

In protecting drugs and food that will circulate in the community, BPOM has procedures to protect this. One way that BPOM does this is:

- a. Preventive measures. Namely, actions were taken by creating a drug and food control system and establishing BPPOM in provinces across Indonesia.
- b. Repressive Measures. That is the action taken by making BPOM task force executors in the form of testing, investigation, research, and information on drugs and food, as well as UPLK (Consumer Service Complaints Unit). Through these task executors, BPOM can take decisive action when violations occur in medicine and food.¹²

3.5. Pharmaceutical Company Criminal Liability

A pharmaceutical or drug company is a commercial business in the health sector that is engaged and focused on researching, developing, and distributing drugs. Pharmaceutical companies are industries that utilize sizeable intellectual capital and intensively conduct research, innovative and balanced initiatives using human resources and technology (Shabarati et al., 2010). The pharmaceutical industry is a legal entity permitted to carry out production activities or utilize production resources, distribute drugs, medicinal ingredients, and phytopharmaca, and carry out education, training, and research and development.¹³ The information provided by the

¹¹ Peraturan Presiden Republik Indonesia Nomor 80 Tahun 2017 tentang Badan Pengawas Obat dan Makanan.

¹² Tyrsa Tesalonika Tambuwun, 'Peranan Badan Pengawas Obat Dan Makanan (Bpom) Dalam Perlindungan Konsumen Yang Mengandung Zat Berbahaya', *Lex Privatum*, 8.4 (2020), 96–106.

¹³ Peraturan Menteri Kesehatan Republik Indonesia Nomor 26 Tahun 2018 tentang Pelayanan Perizinan Berusaha Terintegrasi secara Elektronik Sektor Kesehatan

pharmaceutical industry is very influential for consumers in their decision to buy a product. According to Article 4 paragraph (1) of Drug and Food Control Agency Regulation Number 2 of 2021 concerning Guidelines for Drug Advertising Supervision, providing the information contained in advertisements must be objective, complete, and not misleading so as not to cause harm to consumers.¹⁴ Pharmaceutical companies act as business actors who are responsible as producers if consumers experience a loss.

In carrying out their business activities, business actors, in this case, pharmaceutical companies, may not commit acts contrary to the law. In Article 7 of Law Number 8 of 1999 concerning Consumer Protection, it is regulated regarding the obligations of business actors in running their business, namely as follows:

- a. good faith in carrying out its business activities;
- b. provide correct, clear, and honest information regarding the condition and guarantee of goods and/or services, as well as explain use, repair, and maintenance;
- c. treat or serve consumers properly and honestly and not discriminatory;
- d. guarantee the quality of goods and/or services produced and/or traded based on the provisions of the applicable standards for the quality of goods and/or services;
- e. provide opportunities for consumers to test and/or try certain goods and/or services as well as provide guarantees and/or guarantees for goods made and/or traded;
- f. provide compensation, compensation, and/or reimbursement for losses resulting from the use, use, and utilization of traded goods and/or services;
- g. provide compensation, compensation, and/or reimbursement if the goods and/or services received or used are not by the agreement

Based on Article 7, it is clear that business actors are obliged to provide correct, precise, honest information about the product's composition, guarantee the quality of the goods, and provide compensation if the product produced causes harm to consumers. In cases of atypical progressive acute kidney disease or acute kidney injury caused by syrup drugs, it has resulted in death in children caused by business actors or pharmaceutical companies who have not carried out their obligations in producing drugs according to the specified quality standards so that the drugs produced should not be harmful consumer health. Symptoms that lead to acute kidney failure include diarrhea, nausea, vomiting, fever for 3 to 5 days, coughing, runny nose, frequent drowsiness, less and less urine, and even the inability to urinate.

¹⁴ Peraturan Badan Pengawas Obat dan Makanan Nomor 2 Tahun 2021 tentang Pedoman Pengawasan Periklanan Obat.

The legal responsibility that pharmaceutical companies can account for in the production of children's syrup is absolute responsibility or entire strict liability for information, advertising, and the drugs produced. A pharmaceutical company can bear criminal liability if the evidence is found that the business actor deliberately makes drugs using hazardous substances, the composition on the label does not match the actual one, or mixes ingredients that exceed the safe threshold, thereby endangering the health of consumers. In this case, the business actor pharmaceutical companies can be held criminally responsible.

Criminal acts in the health sector are regulated in Law Number 36 of 2009. This law also regulates the investigative process and the investigator's authority. Criminal liability arises when there is a professional error. Suppose it is related to this case of acute kidney failure. In that case, the pharmaceutical company has made mistakes or omissions in producing or distributing pharmaceutical preparations that do not meet safety standards and/or requirements, namely by producing and distributing syrup drugs containing ethylene glycol (EG) and diethylene glycol (EG) contaminants. DEG). According to the Head of BPOM, Penny K. Lukito, on November 17, 2022, two pharmaceutical companies were named suspects after the investigation process was carried out, and three other pharmaceutical companies are still in the stage of further investigation. In addition to criminal sanctions, the five pharmaceutical companies also received administrative sanctions by revoking other drug manufacturing methods (GMP) and distribution permits.

Based on Article 196 of the Health Law, any person who deliberately produces or distributes pharmaceutical preparations and/or medical devices that do not meet the standards and/or requirements for safety, efficacy or benefits, and quality as referred to in Article 98 paragraph (2) and paragraph (3) shall be subject to imprisonment for a maximum of 10 (ten) years and a fine of a maximum of Rp. 1,000,000,000.00 (one billion rupiah). In Article 98, paragraph (2), the subject to punishment is any person who does not have expertise and authority and is prohibited from procuring, storing, processing, promoting, and distributing drugs and substances with medicinal properties. Meanwhile, in Article 98, paragraph (3), pharmaceutical companies can be held accountable in terms of provisions regarding the procurement, storage, processing, promotion, and distribution of pharmaceutical preparations and medical devices must meet pharmaceutical service quality standards stipulated by Government Regulations. With the existence of health law provisions, it intends to provide legal protection to drug consumers, in this case, children. However, what is meant by everyone in the health Law is not explicitly stated, whether those who can be held criminally responsible are individuals or legal entities.

4. BPOM's responsibility in cases of syrup containing EG and DEG

The Food and Drug Supervisory Agency, abbreviated as BPOM, is a non-ministerial government agency that carries out government affairs in drug and food control.¹⁵ BPOM is an agency at the forefront of supervising and protecting drugs and food that will distribute to the public. BPOM is currently under and responsible to the President through the minister who administers government affairs in the health sector.

In carrying out its duties, BPOM has the task of carrying out government duties in the field of Drug and Food control by statutory provisions. Article 3 of Presidential Regulation Number 8 of 2017 concerning the Food and Drug Supervisory Agency regulates BPOM's functions in carrying out its duties, namely as follows:

- a. preparation of national policies in the field of drug and food control;
- b. implementing national policies in the field of drug and food control;
- c. preparation and stipulation of norms, standards, procedures, and criteria in the field of Control Before Circulation and Supervision During Circulation;
- d. implementation of Supervision before Circulation and Supervision During Circulation;
- e. coordinating the implementation of Drug and Food control with central and regional government agencies;
- f. provision of technical guidance and supervision in the field of drug and food control;
- g. implementation of action against violations of statutory provisions in the field of drug and food control;
- h. coordinating the implementation of tasks, coaching, and providing administrative support to all organizational elements within BPOM;
- i. management of state property/wealth which is the responsibility of BPOM;
- j. supervising the implementation of tasks within the BPOM; And
- k. implementation of substantive support to all elements of the organization within BPOM.

Based on Article 3, it is clear that BPOM has the function of being able to supervise drugs and food both before and during their distribution and take action against individuals who violate BPOM statutory provisions. In cases of atypical progressive acute kidney failure or acute kidney injury caused by syrup drugs, it has resulted in death in children caused by negligence or negligence on the part of BPOM, which does not carry out its functions properly in maintaining and supervising the distribution of drugs according to the standards and quality that have been established and

¹⁵ Peraturan Presiden Republik Indonesia Nomor 80 Tahun 2017 tentang Badan Pengawas Obat dan Makanan

determined so that drugs circulating in the community should no longer cause death in the community, especially in children.

In carrying out supervision of drugs circulating in the market, BPOM has full responsibility for this matter. Can See that in carrying out supervision of drugs that are considered not by applicable regulations, BPOM will conduct investigations in the field of drug and food control by statutory provisions. BPOM will also provide administrative sanctions such as being banned from distribution and withdrawn from circulation, canceling the approval letter, revoking the distribution permit, and confiscating it for destruction to the pharmaceutical company distributing the drug or food. The drug and food violators can be processed based on the applicable criminal law if the violation enters the criminal realm. This is what shows BPOM's firmness and responsibility in following up on cases of drug distribution that are not by procedures and regulations so that it is hoped that there will be no further losses, both material and non-material, for the community.

In addition to the strict steps taken by BPOM to distribution companies, if consumers experience losses after consuming certain drugs on the market, BPOM, as a fully responsible party, has provided an Information and Complaint Service Unit (ULPK) that consumers can use to make complaints, regarding the losses experienced after consuming a drug. After a complaint is received, the BPOM inspection team will follow up on the complaint. The existence of this Information and Complaint Service Unit (ULPK) provides clear evidence of the responsibility that BPOM has in carrying out supervision and protection for people who feel disadvantaged due to consuming drugs on the market.¹⁶ This is the right step so that the medicines to be distributed can be checked and monitored regularly so that can reduce the negative impact of these drugs.

Suppose it is related to problems related to drugs containing EG and DEG on the market. That case will have a severe impact if the authorities do not investigate and investigate this case properly and thoroughly because this will cause kidney damage in children who consume more and more drugs. In addition, if BPOM does not have severe intentions in dealing with this matter, the role of BPOM in carrying out supervision in the field of medicine and food will have an impact on reducing public trust in the BPOM institution. Therefore, BPOM must act quickly and be responsible later in handling this case so that cases like this cannot happen again in the future.

¹⁶ Aulia Putri Andhini, 'Tanggung Jawab Badan Pengawas Obat Dan Makanan Terhadap Peredaran Obat-Obatan (Studi Kasus Crystal X)' (Universitas Islam Indonesia, 2018).

5. Conclusion

1. Based on cases of atypical progressive acute kidney disease or acute kidney injury caused by syrup drugs that have caused death in children caused by business actors or pharmaceutical companies that do not carry out their obligations in producing drugs according to the specified quality standards so that the drugs produced should not endanger consumer health. Apart from being subject to administrative sanctions, pharmaceutical companies are also subject to criminal liability by Article 196 of the health Law.
2. In addition, if you look at the cases of acute kidney failure, the causes of problems like this cannot be separated from good supervision by BPOM. Supervision and proper procedure implementation must be applied to drug and food control because this is the main thing for the community. Suppose this kind of thing happens more seriously. In that case, BPOM, the Government, and the community must jointly guard and protect the things circulating. It is also hope that BPOM can provide firm steps in overcoming severe problems like this.

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