



EXAMINING THE CRIMINAL RESPONSIBILITY OF THE INDONESIAN FOOD AND DRUG AUTHORITY REGARDING THE DISTRIBUTION LICENSE OF SYRUP MEDICINES IN CASES OF ACUTE KIDNEY FAILURE

Eliska Vioni¹, Salma Agustina², Putri Nabila Sahwahita³

Universitas Pembangunan Nasional Veteran Jakarta

¹e-mail: eliskavioni@gmail.com

²e-mail: salmaagustina312@gmail.com

³e-mail: gehorenbil@gmail.com

Keywords: *Abstract*

Badan Pengawas Obat dan Makanan; Kidney Disorders; Syrup medicines. In 2022, there was a phenomenon of cases of Atypical Progressive Acute Kidney Disorders in Children. After laboratory examinations were carried out by The Indonesian Food and Drug Authority together with other institutions, it was found that the compounds Ethylene Glycol (EG), Diethylene Glycol (DEG), and Ethylene Glycol Butyl Ether (EGBE) exceeded the limits in syrup medicines consumed by children. Based on this, this research aims to determine criminal responsibility by BPOM as the party that supervises all distribution of medicines and food regarding the distribution of syrup medicines which cause acute kidney failure in children and indications of the application of the murder article in the Criminal Code as BPOM's responsibility. The object of study in regulating legitimate composing is the disclosure of law in concreto using statutory and conceptual approaches. The research results show that in this case BPOM can be held criminally liable because it essentially fulfills the elements of error due to negligence. Apart from that, if we examine the Criminal Code, the legal basis that can accommodate BPOM's actions is Article 205 of the Criminal Code because in this case BPOM was negligent in granting a distribution permit for the syrup medicine which resulted in MMR and resulted in the death of the child.

Submit : 2024-03-25

Review : 2024-04-01

Received : 2024-04-15



A. Introduction

Since the end of August 2022, the Ministry of Health (Kemenkes) and the Indonesian Pediatrician Association (IDAI) have received reports of increasing cases of Atypical Progressive Acute Kidney Disorders in Children (GGAPA), especially in children under 5 years of age (Setkab, 2022). Then, as of the report obtained in February 2023, there were 326 cases of GGAPA and one suspect spread across 27 provinces in Indonesia. From these cases, it is known that 204 children died (BBC News, 2023).

How to cite

Vioni, Eliska, dkk., Examining The Criminal Responsibility Of The Indonesian Food And Drug Authority Regarding The Distribution License Of Syrup Medicines In Cases Of Acute Kidney Failure, Volume 01, Issue 02 March 2024

Published by

Zhata Institut

Based on the spike in cases, the Ministry of Health together with the Food and Medicine Monitoring Agency (BPOM) and other institutions conducted laboratory examinations to prove the cause and determine preventive measures for GGAPA cases.

The results of laboratory examinations taken from samples of syrup consumed by one of the patients showed that traces of excessive compounds were found which could potentially cause acute kidney problems, including Ethylene Glycol (EG), Diethylene Glycol (DEG), and Ethylene Glycol Butyl Ether (EGBE). It is known that these ingredients are compounds that do not meet medicine standards which can cause acute kidney problems and have been determined to have a serious impact on public health, especially children (Kusuma, 2022). With the increasing number of ADD cases caused by the presence of dangerous ingredients in syrup medicines being distributed and resulting in death, in this case legal consequences arise in the form of criminal liability for the parties concerned.

The National Police's Criminal Investigation Agency (Bareskrim) named several suspects who were held accountable, namely, PT Afi Farma, CV Chemical Samudera, PT Tirta Buana Kemindo, CV Anugrah Perdana Gemilang, as well as PT Fari Jaya Pratama, PT Yarindo Farmatama and PT Universal Pharmaceutical Industries. The laws and regulations applied to arrest the suspects are the Health Law and the Consumer Protection Law (Catherine et al., 2023). However, in this research, we want to examine the possibility of imposing criminal liability on the government, in this case BPOM as the supervisor of the distribution of medicines and food throughout Indonesia. So that all permits regarding the legalization of the distribution of food and medicines are submitted through BPOM, inseparable from syrup medicines which have resulted in the rise of GGAPA cases.

It is known that due to this case, BPOM took steps by issuing instructions to medicine manufacturers to stop selling all types of syrup medicines that contain dangerous ingredients (Gaol, 2023). However, this still does not eliminate the fact that these medicines have received permits regarding the legalization of their distribution by BPOM. Apart from that, starting from the initiation conveyed by the victim's family attorney, namely Rezza Adityananda Pramono at the Police Criminal Investigation Unit on December 8 2022, which stated that in this case the legal basis of Article 338 of the Criminal Code (KUHP) was used in the report submitted to Bareskrim Polri (Noviansyah, 2022).

So based on the problems described above, this research aims to determine criminal responsibility by BPOM as the party that supervises all distribution of medicines and food regarding the distribution of syrup medicines which cause acute kidney failure in children and indications of the application of the murder article in the Criminal Code as BPOM's responsibility.

B. Method

This type of research is normative legal research which focuses on legal discoveries in concreto in order to test whether a particular normative postulate can or cannot be used to resolve certain legal problems in concreto. So the emphasis is on finding the law in concreto for resolving certain cases. In this case, testing whether BPOM can be held responsible for cases relating to distribution permits for syrup medicine in cases of acute kidney failure and whether it is appropriate to apply the murder article in the Criminal Code to BPOM.

Based on the approach used, namely the statute approach, the data collection technique used in this research is literature study and looking for statutory regulations relating to the legal issue or problem to be researched, which in this case is statutory regulations relating to accountability for granting distribution permits for syrup medicines by BPOM and articles that can be applied to deaths resulting from consuming syrup medicines given distribution permits by BPOM. Apart from that, because the researcher also uses a conceptual approach, it would be more essential if the researcher carried out a search for law books that contain legal concepts.

Analysis of legal materials is how to utilize the sources of legal materials that have been collected to be used in solving problems in this research. The basis for using normative analysis is because the legal materials in this research lead to theoretical studies in the form of legal principles, legal concepts and legal rules. The legal materials that have been collected are subjected to descriptive analysis, namely describing (abstracting) a phenomenon as it is or the position of the legal and non-legal propositions encountered. The results of the four analysis techniques are then analyzed according to their content (content analysis), which is a content analysis with an effort to sort and select data from various existing library materials and in line with the research object in question. Content analysis is a research technique to produce an objective, systematic and qualitative description of the substance of the research itself.

C. Result & Discussion

1. Criminal Responsibility by BPOM for the Distribution of Syrup Medicine that Cause Acute Kidney Failure in Children

Health is one of various basic human needs. This also makes health a right that must be fulfilled by every community and is protected by law, because every country agrees to recognize that the basis for achieving prosperity is health. Quoting Article 1 point 1 of Law Number 36 of 2009 concerning Health (Health Law), it is explained that "health is a condition of physical, mental and social well-being that allows every person to be economically productive". Therefore, health is one aspect that determines human status. Because if a person's health is disturbed then it can be said that he does not conditionally have the same level. This is because if a person experiences health problems then he is automatically unable to obtain his other rights (Ardinata, 2020).

Through the Constitution of the Republic of Indonesia of 1945 (UUD 1945) in Article 28 H paragraph 1 it is explained that "every person has the right to live in physical and spiritual prosperity, to have a place to live, and to have a good and healthy living environment and the right to receive health services." Then comes the state's responsibility to provide adequate health service facilities and public service facilities as regulated in paragraph 3 of the article. Apart from that, rights regarding health are also described in the Health Law (Iriawati, 2017). So then we can draw the conclusion that the right to health is actually a right protected by law and guaranteed by the state.

However, it is not in line with the ideals and regulations that were originally outlined, the finding of Polyethylene Glycol, Ethylene Glycol and Dietlien Glycol compounds in high doses in syrup medicines that cause GGAPA is certainly a form of deprivation of the public's right to health (CNN, 2022). Quoting Komnas HAM data, 326 cases of GGAPA occurred in 27 provinces in the period of one year, from 2022 to February 5 2023 (Saubani, 2023). The large number of cases caused by the use of syrup medicine which was originally used by the community in the hope of curing the illnesses suffered by their children has certainly left deep sorrow behind. This can also be an illustration of the neglect of the obligations of Government Institutions which should act actively and effectively in preventing this case from occurring.

Basically, the government is given an obligation to be able to carry out state administration in the form of providing optimal services to the entire community through government units which have their respective authorities, where this authority includes the right to exercise discretion (Kemalasari, 2023). In the case of GGAPA, the agency that is responsible is BPOM. As a Non-Ministerial Government Institution, BPOM carries out the task of carrying out the government's function of supervising medicines and Food as stipulated in the Law. Through Article 4 of Presidential Regulation Number 80 of 2017 concerning the Food and medicine Supervisory Agency, it is explained that BPOM has the authority to carry out supervisory duties in the form of:

- a. Providing permits and certification for every product distributed in accordance with the requirements of the legislation
- b. Carry out supervision and investigation for medicines and food
- c. Imposing administrative sanctions in accordance with statutory provisions.

So based on these provisions, BPOM basically has the authority to supervise every medicine and food, which also includes granting permits for product distribution among the public, testing medicines and food, as well as the authority to impose administrative sanctions if a violation occurs in accordance with Applicable laws. In other words, BPOM should carry out safety checks on all types of medicines before granting distribution permits for the medicines.

In line with the provisions of Article 3 paragraphs (2) and (3) of Presidential Regulation Number 80 of 2017 which explains that supervision carried

out before and during the distribution of medicines and food is carried out as a form of prevention to maintain the quality of medicines and food according to standards and requirements. However, the finding that many cases of GGAPA are caused by purchasing syrup medicine which is purchased freely in shops or pharmacies is certainly a shame (Salsabilla, 2023). This is because the distribution of syrup medicines which can be purchased freely has certainly received legality related to the distribution permit granted by BPOM.

Article 106 paragraph (1) of the Health Law explains that all forms of pharmaceutical preparations and medical devices must obtain permission first before being distributed. So syrup medicines containing the compounds Polyethylene Glycol, Ethylene Glycol and Diethylene Glycol must have a distribution permit which was preceded by trials carried out by BPOM. BPOM itself has clarified this by stating that it has carried out supervision before and after the distribution of the medicine (Nursyamsi, 2022). However, the large number of cases of acute kidney failure due to consumption of syrup medicines contaminated with Polyethylene Glycol, Ethylene Glycol and Diethylene Glycol compounds is certainly evidence of BPOM's weak supervision of medicine distribution in Indonesia.

BPOM's negligence in carrying out its duties as a medicine distribution supervisor can then be said to be an act of maladministration, in which case Article 1 paragraph (3) of the Lawng-Law Number 37 of 2008 concerning the Ombudsman of the Republic of Indonesia explains that maladministration is an act against the law, exceeding authority, using authority for purposes other than those intended, including negligence or neglect of legal obligations in the administration of the state and government which causes material and/or immaterial losses. for society or individuals. Then the question arises, is it possible that BPOM's negligence in monitoring medicines and Food causes GGAPA to be held criminally liable.

Basically, every act of maladministration carried out by every public servant carries the consequences of liability, whether in the form of administrative, civil or criminal (Ahmad, 2011). In this case, it is clear that BPOM can be held responsible for its negligence in issuing a distribution permit for syrup medicines containing dangerous compounds. BPOM's actions in not being careful in carrying out supervision certainly violate AAUPB as stated in the provisions of Article 10 of Law Number 30 of 2014 concerning Government Administration. This principle shows that every action taken by government officials should be based on accuracy. In the criminal realm, BPOM's negligence clearly has the opportunity to be held criminally liable. Because BPOM's negligence in issuing medicine distribution permits which then resulted in the loss of life is considered an important factor in this case. In the theory of individualized causality which explains the causal relationship of an action with an event that can be held accountable in criminal law. Where if BPOM had not been negligent in carrying out its authority to carry out supervision, it would not have been possible for there to be victims of illness and death.

However, in order to be held criminally responsible, it basically must be preceded by an error within the perpetrator. Error here is an element that must be fulfilled because we recognize the principle that "there will be no criminal act without error". Where error is a basic element that forms criminal liability. Meanwhile, actions are an element that forms a criminal act (C. Huda, 2006). So then the existence of the principle "there can be no criminal act without error" makes proving the act or mistake that is the basis for a violation of the law to demand criminal responsibility very important.

However, the Criminal Code only recognizes humans as the subject of every criminal act, so it only concentrates on humans who commit criminal acts (M. Ali, 2011). However, to ensure that every corporate criminal act remains criminally accountable, the focus is then given to certain individuals who are responsible for the company (M. Ali, 2011). So BPOM as a government institution basically cannot receive criminal law, because BPOM is not a corporate legal entity. So then BPOM's criminal responsibility is transferred to the individual responsible for BPOM. In this case, the Chief Deputy for Control of medicines, Narcotics, Psychotropics, Precursors and Addictive Substances can be held criminally liable because through Article 39 Number 21 of 2020 concerning the Organization and Work Procedures of the medicine and Food Control Agency, it is explained that the Deputy for Control of medicines, Narcotics, Psychotropics, Precursors and Addictive Substances have the function of implementing and compiling all policies regarding the control of medicines, medicinal substances, narcotics, psychotropics, precursors and addictive substances.

So referring to the theory of individualization of causality, BPOM's negligence regarding the passing of distribution permits for syrup medicines containing contaminated ingredients Polyethylene Glycol, Ethylene Glycol and Diethylene Glycol in high doses which causes GGAPA which then causes death can be held criminally liable. BPOM's negligence in carrying out monitoring measures both before and after the distribution of medicines in the community can be said to be a fatal act that caused or had a big impact because it gave birth to many victims. The government should of course take quick and effective steps in handling it from the start, so that this case does not result in many victims. Ineffective handling of GGAPA cases is a form of government neglect of human rights violations, especially the right to health.

2. Use of the Murder Article as a Form of Criminal Responsibility for BPOM

The foundation of the Indonesian constitution states that Indonesia is a rule of law country where in its implementation Indonesia requires every citizen to obey and uphold existing laws. This is based on a legal concept created to regulate people's daily behavior which can be enforced due to sanctions. An action can be categorized as an unlawful act if someone carries out their obligations intentionally or negligently which then results in harm to other people (Efritadewi, 2020). Article 10 letter a of the Criminal Code (KUHP) discusses the provision of sanctions for law violators

where someone who violates the law can be subject to sanctions in the form of the death penalty, imprisonment, imprisonment, fines and/or imprisonment.

In the case of the distribution of syrup medicines, the distribution of syrup medicines contaminated with Polyethylene Glycol, Ethylene Glycol and Diethylene Glycol exceeded protocol recommendations which caused the consumer to die due to atypical progressive acute renal failure (GGAPA). Therefore, in this case, BPOM's performance as the body for controlling, supervising and distributing medicines in Indonesia is being questioned. This is of course very worrying for the Indonesian people, especially parents who have children because these dangerous chemicals are often found in fever and cough syrups which are often consumed or prescribed for children. Not only are they sold freely in pharmacies so they are easy to obtain, syrup medicines that are contaminated with the contents of Polyethylene Glycol, Ethylene Glycol and Diethylene Glycol are also circulating in health facilities and are even given by doctors as medicines that must be consumed by their patients (BBC News, 2022).

Due to their negligence, the parents of children who were victims of atypical progressive acute kidney failure due to consuming contaminated syrup medicine assume that BPOM was also involved in the distribution of the syrup medicine (BBC News, 2023). The parents of the other victims also continued that the manufacturer and distributor of the contaminated syrup medicine, apart from having violated the Health Law and the Consumer Protection Law, must also be punished under Article 338 of the Criminal Code which is used for the crime of murder because it caused the syrup user to lose his life (Noviansyah, 2022). However, to impose a crime, it is necessary to prove the action whether the elements of the crime committed have been fulfilled or not, considering the principle of presumption of innocence, so that accountability can be asked of the perpetrator of the crime. Article 338 of the Criminal Code states "Whoever intentionally takes the life of another person, is threatened with murder with a maximum imprisonment of 15 (fifteen) years." It needs to be instilled that the definition of murder in the Criminal Code is a condition where an attack is carried out on another person where this attack leads to that person's life (Chazawi, 2007). Murder itself has the basic word kill, which means taking a life intentionally (KBBI, 2016). Furthermore, it can be seen that the act of murder in this article was carried out intentionally and by a person who could be responsible for his actions which took the life or killed the victim (Wiratama et al., 2023). In other words, Article 338 of the Criminal Code is composed of the following elements: 1) the existence of a perpetrator who can be an individual or legal entity; 2) the action was carried out with full awareness or on purpose; 3) plunder; 4) life; 5) other people (Chazawi, 2010).

If we solve BPOM's negligent actions by giving permission for contaminated syrup medicine so that the medicine circulates freely in pharmacies and even health facilities throughout Indonesia based on the elements in Article 338 of the Criminal Code, BPOM has fulfilled the first element, namely as the perpetrator where BPOM

itself is a legal subject in the form of a legal entity. In its actions, the negligence caused by BPOM in the circulation of contaminated syrup medicine has resulted in the deaths of many victims, so this fulfills the third, fourth and fifth elements, namely that their actions rob or eliminate the lives of other people. The final element is the element where the action is carried out intentionally. Deliberately or intentionally here means that the criminal act was carried out at the initiation of the perpetrator. In this case, BPOM as the control, supervision and distribution agency did not initiate or intend to take the lives of victims of contaminated syrup medicine. Due to the failure to fulfill all the elements in Article 338 of the Criminal Code, BPOM cannot impose a criminal sentence on the basis of murder as requested by the victim's parents to BPOM using Article 338 of the Criminal Code.

If the elements are not fulfilled intentionally in Article 338 of the Criminal Code, the actions taken by BPOM for this negligence actually complement the criminal elements contained in Article 205 of the Criminal Code paragraphs (1) and (2) which in essence punish those who make mistakes in carrying out their obligations. causes goods that are dangerous to the life or health of other people to be sold, distributed or distributed without knowing the nature of the danger and in paragraph (2) it is written that the penalty will be increased if the action causes someone to die.

In Article 205 paragraph (1) of the Criminal Code, there are elements:

1. The perpetrator written with "whoever";
2. The action was carried out because of a mistake, which in this case is negligence or neglect;
3. The presence of items that can endanger people's lives or health;
4. Sold, offered, delivered, or distributed;
5. The dangerous nature of the item is hidden.

In Article 205 paragraph (2) of the Criminal Code there is an element that adds to the element contained in Article 205 paragraph (1), namely the death resulting from the action. BPOM as a legal entity with the authority to control and supervise the distribution of medicines in Indonesia has been negligent in carrying out its obligations as admitted by the Head of BPOM that BPOM's supervision standards do not make monitoring contamination of finished medicines a provision of its supervision (Aida and Kurniawan, 2022). Due to its negligence, BPOM caused contaminated syrup medicine to circulate on the market, such as in pharmacies and even other health facilities, so that it was very easily obtained by people who did not know that it contained dangerous chemicals that could cause consumers to experience other diseases or even cause death.

Jumanah in *Capita Selecta Indonesian Criminal Law* states that for a criminal act to be accountable it is required to fulfill 4 (four) elements, namely the commission of a criminal act regulated by law, the existence of a mistake (schuld) which is then divided into an intentional mistake (opzettelijk) and errors due to negligence or negligence (culpa), the presence of perpetrators who are legal subjects

who commit criminal acts, and the absence of excuses for the commission of such criminal acts (Jumanah, 2022).

Of these four elements, BPOM was proven to have made a mistake due to negligence and carried out actions prohibited by law, namely Article 205 paragraphs (1) and (2) of the Criminal Code where due to negligence in carrying out its obligations it resulted in the death of another person. BPOM as a legal entity is also clearly the perpetrator of the criminal act of negligence which resulted in the death of another person because it gave a distribution permit for contaminated medicines. However, it is impossible for the judge to convict all BPOM workers for the case of distributing contaminated medicines. Because the root of this case of circulation of contaminated medicines is negligence in medicine control.

In this case, the Chief Deputy for Control of Medicines, Narcotics, Psychotropics, Precursors and Addictive Substances is the main perpetrator of the circulation of contaminated medicines as written in Article 39 of BPOM Regulation Number 21 of 2022 concerning the Organization and Work Procedures of BPOM, Deputy for medicine Control, Narcotics, Psychotropics, Precursors and Addictive Substances has the function of implementing and compiling all policies regarding the control of medicines and the materials contained therein, narcotics, psychotropics, precursors and addictive substances. Because of his negligence in not making a policy to monitor contamination of finished medicines and this was done consciously, there is no excuse that can be given to BPOM, especially for the Deputy Chair for Control of medicines, Narcotics, Psychotropics, Precursors and Addictive Substances. So, based on this description, he can be held responsible because he has fulfilled all the elements of a criminal act for which he can be held responsible by the imposition of Article 205 of the Criminal Code, namely the imposition of a maximum imprisonment of 1 (one) year and 4 (four) months or a maximum imprisonment of 1 (one) year.

D. Conclusion

In line with the theory of individualization of causality, BPOM's negligence in carrying out supervision and granting distribution permits for syrup medicines contaminated with dangerous ingredients that cause GGAPA can be considered an act that violates the principles of accuracy and caution that BPOM should apply in carrying out its duties. BPOM's negligence which led to the circulation of syrup medicine which then resulted in the loss of life can then be held criminally liable. The criminal responsibility that can be imposed on BPOM is in line with the fulfillment of the four elements that must first be met in order to be held criminally responsible, namely the fulfillment of the principle of legality, the existence of an element of error, the existence of a legal subject, and the absence of an element of forgiveness. However, the fact that the victim died due to BPOM's negligence in carrying out its duties does not mean that it can be sentenced to Article 338 of the Criminal Code regarding murder, because to be sentenced to Article 338 of the Criminal Code must be preceded by the fulfillment of the five elements in Article 338. In this case, BPOM did not fulfill the second element, namely "intentionally" . So BPOM's punishment using Article 338 of the Criminal Code

cannot be used. Failure to fulfill this element on purpose then strengthens the use of Article 205 of the Criminal Code which explains that criminal liability can be sought for those who are negligent and endanger or cause the death of other people. This responsibility can then be directed to the Deputy Chairperson for the Control of medicines, Narcotics, Psychotropics, Precursors and Addictive Substances, who specifically has responsibility for the function of BPOM in implementing and compiling all policies regarding the control of medicines, medicinal substances, narcotics, psychotropics, precursors and addictive substance.

Bibliography

- Ahmad, B. (2011). Pertanggung Jawab Pidana Pejabat Atas Tindakan Mal Administrasi Dalam Penerbitan Izin di Bidang Lingkungan, *Perspektif*, 16(4), 254.
- Aida, N. R. dan R. F. Kurniawan. (2022). 5 Poin Penjelasan BPOM Soal Obat Sirup dan Kaitan Kasus Gagal Ginjal Akut. <https://www.kompas.com/tren/read/2022/10/24/113000865/5-poin-penjelasan-bpom-soal-obat-sirup-dan-kaitan-kasus-gagal-ginjal-akut-?page=all>. Diakses pada tanggal 11 Maret 2024.
- Ali, M. (2011). *Dasar-dasar Hukum Pidana*. Ed.1, Cet.1, Sinar Grafika. Jakarta. Hal. 111.
- Ali, M. (2017). *Dasar-Dasar Hukum Pidana*. Sinar Grafika. Jakarta. Hlm. 155.
- Ardinata, M. (2020). Tanggung Jawab Negara Terhadap Jaminan Kesehatan Dalam Perspektif Hak Asasi Manusia. *Jurnal Ham*, 11(2), 320.
- BBC News. (2022). Kasus Gangguan Ginjal Akut, Bagaimana Pengawasan Kualitas Obat Di Industri Farmasi Indonesia? <https://www.bbc.com/indonesia/articles/cw87nggv18yo>. Diakses pada tanggal 9 Maret 2024.
- BBC News. (2023). BPOM Diduga Terlibat Kasus Gagal Ginjal Akut, Keluarga Korban: 'Kami Harap Mereka Membusuk Di Penjara.' <https://www.bbc.com/indonesia/articles/cq519q5qx84o>. Diakses pada tanggal 10 Maret 2024.
- BBC News. (2023). Gagal Ginjal Akut: Skandal Obat Sirop Belum Berakhir, Kemenkes Laporkan Dua Kasus Gagal Ginjal Anak Terbaru. <https://www.bbc.com/indonesia/articles/cx9v2z98ze8o>. Diakses pada tanggal 10 Maret 2024.
- Catherine, R. N. dan B. Santosa. (2023). Tersangka Kasus Gagal Ginjal Akut Bertambah 2. Total Ada 4 Orang dan 5 Korporasi. <https://nasional.kompas.com/read/2023/01/30/12574821/tersangka-kasus-gagal-ginjal-akut-bertambah-2-total-ada-4-orang-dan-5>. Diakses pada tanggal 10 Maret 2024.
- Chazawi, A. (2007). *Kejahatan Terhadap Tubuh dan Nyawa*. Raja Grafindo Persada. Jakarta.
- Chazawi, A. (2010). *Kejahatan Terhadap Tubuh dan Nyawa*. Raja Grafindo Persada. Jakarta.
- CNN Indonesia. (2022). Etilen Glikol Berbentuk Kristal Di Ginjal, Alasan Gangguan Akut. <https://www.cnnindonesia.com/gaya-hidup/20221022110900-255-863954/etilen-glikol-berbentuk-kristal-di-ginjal-alasanpicu-gangguan-akut>. Diakses pada tanggal 8 Maret 2024.

- Efritadewi, A. (2020). *Modul Hukum Pidana. Cet. 1*, UMRAH Press. Kepulauan Riau.
- Gaol, L. H. L. (2023). Pertanggungjawaban Pidana Terhadap BPOM Sebagai Pengawas dalam Kasus Gagal Ginjal Akut Pada Anak Akibat Toksikasi dalam Obat Sirup. (*Skripsi, Universitas Jambi*).
- Huda, C. (2006). *Dari Tindak Pidana Tanpa Kesalahan Menuju Kepada Tiada Pertanggungjawab Pidana Tanpa Kesalahan. Cet. 2*, Kencana. Jakarta, 2006.
- Israwati, F. S. (2015) Tanggung Jawab Negara Dalam Pemenuhan Hak Atas Kesehatan Berdasarkan Undang-Undang Dasar Negara Republik Indonesia Tahun 1945. *Jurnal Ilmu Hukum Legal Opinion*, 3(2), 2.
- Jumanah. (2022). *Kapita Selekta Hukum Pidana Indonesia: Pertanggungjawaban Pidana. Ed. 1, Cet. 1*, Kencana. Jakarta.
- KBBI Daring. (2016). Bunuh. <https://kbbi.kemdikbud.go.id/entri/bunuh>. Diakses pada tanggal 10 Maret 2024.
- Kemalasar, N. P. Y. (2023). Pertanggungjawaban BPOM Terhadap Peredaran Obat Sirup Yang Menyebabkan Kematian Kematian Pada Anak Akibat Gagal Ginjal Akut. *Jurnal Aktual Justice*, 8(1), 40.
- Kusuma, D. P. R. W. (2022). Pertanggungjawaban Pidana atas Kegagalan Pengawasan Obat: Studi Kasus Gagal Ginjal Akut Pada Anak di Indonesia Tahun 2022. *Lex Renaissance*, 4(7), 691-709.
- Lutfiah, A., dkk. (2023) Frekuensi Kasus Gagal Ginjal Akut Pada Anak Yang Disebabkan Obat-Obatan Sirup Yang Mengandung Etilen Glikol Pada Tahun 2022. *Jurnal Cahaya Mandalika (JCM)*, 4(3), 126.
- Republik Indonesia, Kitab Undang-Undang Hukum Pidana, Undang-Undang Nomor 1 Tahun 1946
- Republik Indonesia, Undang-Undang Kesehatan, Undang-Undang Nomor 36 Tahun 2009, Tambahan Lembaran Negara Republik Indonesia Nomor 5063
- Republik Indonesia, Undang-Undang Perlindungan Konsumen, Undang-Undang Nomor 8 Tahun 1999, Tambahan Lembaran Negara Republik Indonesia Nomor 3821
- Republik Indonesia, Undang-Undang Administrasi Pemerintah, Undang-Undang Nomor 30 Tahun 2014
- Republik Indonesia, Undang-Undang Ombudsman Republik Indonesia, Undang-Undang Nomor 37 Tahun 2008, Tambahan Lembaran Negara Republik Indonesia Nomor 5601
- Republik Indonesia, Peraturan Presiden tentang Badan Pengawas Obat dan Makanan, Peraturan Presiden Nomor 80 Tahun 2017, Tambahan Lembaran Negara Republik Indonesia Nomor 180

Republik Indonesia, Peraturan Badan Pengawas Obat dan Makanan tentang Organisasi dan Tata Kerja Badan Pengawas Obat dan Makanan, Peraturan Badan Pengawas Obat dan Makanan Nomor 21 Tahun 2020, Tambahan Berita Negara Republik Indonesia Nomor 1002

Salsabilla, R. (2023). *Kasus Gagal Ginjal Akut Anak Muncul Lagi, Obat Sirup Ditarik?* <https://www.cnbcindonesia.com/lifestyle/20230206101349-33-411237/kasus-gagal-ginjal-akut-anak-muncul-lagi-obat-sirup-ditarik>. Diakses pada tanggal 8 Maret 2024.

Saubani, A. (2023). *Komnas HAM: Kasus Gagal Ginjal Pada Anak Tergolong Pelanggaran HAM*. <https://news.republika.co.id/berita/rrch5q409/komnas-ham-kasus-gagal-ginjal-pada-anak-tergolong-pelanggaran-ham>. Diakses pada tanggal 8 Maret 2024.

Sekretariat Kabinet Republik Indonesia (2022). *Kasus Gagal Ginjal Akut Pada Anak Meningkat, Kemenkes Minta Orang Tua Waspada*. <https://setkab.go.id/kasus-gagal-ginjal-akut-pada-anak-meningkat-kemenkes-minta-orang-tua-waspada>. Diakses pada tanggal 10 Maret 2024.

Undang-Undang Dasar Negara Republik Indonesia Tahun 1945

Wiratama, G. H., dkk. (2023). Telaah Pasal 338-340 KUHP Tentang Pembunuhan Berencana (Analisis Pembunuhan Berencana Mahasiswa Universitas Surabaya Yang Di Masukkan Koper Lalu Dibuang Oleh Guru Les Musik). *Jurnal Multimedia DEHASEN*, 2(3), 666-667.