Contents lists available at IOCS

Science Midwifery

journal homepage: www.midwifery.iocspublisher.org

Analysis of pharmaceutical crime as a bioterrorist threat in the framework of universal war in Indonesia

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ARTICLE INFO

Article history:

Received May 14, 2024
Revised May 21, 2024
Accepted Jun 18, 2024

Keywords:

Bioterorisme
Konterveit
Modified
Pharmacy
Total Warfare

ABSTRACT

Currently, the development of the flow of exchange of goods in the global world is very fast, especially in the process of goods entering and exiting a country from another country, which requires a high level of supervision to be able to record and select existing goods. This causes problems related to the circulation of counterfeit drugs or have been modified or counterfeited using trademarks that are well-known in the community and have hazardous impacts on health. Bioterrorism is a real threat that must be anticipated and acted upon carefully. The method implemented in this research uses qualitative methodology using a phenomenological approach. Data collection techniques are carried out using literature studies and case studies that occur in the world community today. One of the bodies that supervises and takes action in the food and drug trade is the Food and Drug Supervisory Agency which has the authority to carry out the withdrawal of marketing permits for companies. On this occasion, researchers would like to take a deeper look at cases of counterfeiting and modification of medicines containing dangerous ingredients in their application from the perspective of asymmetric warfare using the threat of bioterrorism in the field of national defense and the actions that need to be taken to deal with the threat of bioterrorism, especially in Indonesia.

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INTRODUCTION

In accordance with the National Defense Law No. 3 of 2002, national defense is essentially all universal defense efforts. In the life of a state, the defense aspect is a very essential factor in ensuring the survival of a nation and state. Threats to a country's defense are constantly changing in accordance with the dynamics of the development of the global, regional and national strategic environment (Dipua et al., 2021; Steingartner et al., 2021; Özlü, 2022). Kementrian Pertahanan RI. (2017) Currently, the form of threats is growing to be more complex and multidimensional why is this because this threat is a non-military threat, which is one form of modern warfare. This form of modern warfare is a form of threat that does not require a lot of funding and costs for its implementation, but the form of threat posed can damage the joints of the life of the nation and

state. This is due to the threats posed that can cause business and damage to a country from within because it is destroyed from within the nation itself.

In the era of globalization, many aspects have influenced changes in the concept of war at this time (Johnstone & McLeish, 2022; Babic, 2020; Veugelers, 2021). This is due to the development of technology, communication and transportation. The current war has changed the concept from conventional war to unconventional war (Kementrian Pertahanan RI., 2017). This war is a war that utilizes the use of technology and modern technology that is increasingly developing over time. With all the conveniences obtained by humans from the rapid development of technology, humans can develop their mindset to use weapons of mass destruction, one of which is biological weapons (Hummel & Burpo, 2020; Scharf, 2020). In its use, biological weapons have many advantages compared to using other weapons such as high production capabilities, ease of storage, proliferation potential, difficulty in tracking individuals or groups that use them, and a very broad impact on both humans and the livestock and agricultural sectors (Rachma et al., 2021).

In the era of globalization that has reached industry 4.0, which is a digital generation that makes it easier for everyone to search, use, receive, process, and also disseminate certain information with the ease of the public to access this information in various communication media (Harahap et al., 2023; Tsaramirsis et al., 2022). Perhaps in this era, attacks on the state using conventional acts of terrorism such as bombings, shootings, or terror threats are common actions carried out by anti-government groups. But behind it all, this act of terror has developed to a more deadly level, namely bioterrorism. Bioterrorism that requires biological agents such as bacteria, viruses, parasites, fungi and other biological microorganisms that can be genetically developed to achieve more fatal damage. This is very possible to be developed in biomedical laboratories by genetic engineers and experts who are qualified in this field. Thus, there are various views that terror caused by bioterrorism can only be carried out "officially" or it can be said that the government is involved in and can only be carried out by superpowers. The emergence of this view is due to the need for exclusive access to the materials needed to be able to carry out a certain microbial engineering to be turned into a dangerous weapon. However, in this era of globalization, chemical and biological materials can be easily found and obtained through special trade channels that can be accessed online such as on the dark web (Fernández et al., 2020; Ghosal & Nayak, 2022; Goswami et al., 2022).

Regarding the use of biological and chemical weapons, this will be very dangerous if used in a crowded and densely populated settlement (Crowley & Dando, 2024; Chen, 2021; Mitchell, 2020). Because it can cause very many victims and can potentially spread quickly to other residential areas. Bioterrorism is an international threat that must be anticipated by every country, especially Indonesia. Because the characteristics of biological and chemical terror attacks are different from atomic or radiation bomb attacks which usually cause an explosion, fire, and damage (Putriana et al., 2020), bioterrorism does not have these impacts or signs so the time needed to detect it takes a long time. In Indonesia, there is currently an issue regarding children's syrup containing contaminants. In response to this, the Food and Drug Administration (FDA) stated that the tainted children's syrup contained ethyl glycol (EG) and diethylene glycol (DG). Dinas Kesehatan Provinsi Kalimatan Barat, & Barat (2022) Not only in Indonesia but in San Diego, United States, 70 million drugs in the form of pills that have been modified and contain lithenol were found to be circulating and consumed by the younger generation which resulted in death. Because the form of the drug is a tranquilizer that makes humans who consume drugs get a very dangerous impact, namely death.

Bioterrorism is the intentional release or dissemination of biological agents such as bacteria, viruses, parasites, fungi, or other microorganisms, which can cause illness or death in humans, animals, or plants (Rathjen & Shahbodaghi, 2021). These biological agents are often genetically engineered to be more virulent, resistant to current treatments, or spread more easily. Unlike conventional terrorism, which typically involves acts of violence such as bombings,

shootings, or kidnappings, bioterrorism leverages biological substances to inflict harm. The primary difference lies in the stealth and potential for widespread, uncontrollable spread, making detection and response more challenging. While conventional terrorism produces immediate, visible damage, bioterrorism can cause delayed but severe health impacts that can be difficult to trace and contain.

In the context of non-military and asymmetric threats, bioterrorism is categorized as a form of modern warfare that exploits biological agents to create widespread fear, disrupt societies, and destabilize nations (Oliveira et al., 2020). Unlike traditional military threats that involve state actors and armed forces, asymmetric threats are characterized by the use of unconventional methods by non-state actors, such as terrorist groups. Bioterrorism fits into this category because it uses the advantage of surprise and the accessibility of biological materials to inflict harm without the need for large-scale military resources. This form of threat is particularly insidious because it can undermine public trust in government and health systems, create economic instability, and cause long-term health crises.

In Indonesia, a number of specific regulations and policies have been implemented to address the threat of bioterrorism and pharmaceutical crime. One of them is Regulation No. 9 of 2019 on Good Distribution Practices (GDP) issued by the Food and Drug Monitoring Agency (BPOM). This regulation sets guidelines for the proper distribution of medicines to ensure their safety, effectiveness, and quality as well as to prevent the circulation of counterfeit or inappropriate drugs that could endanger public health. In addition, Presidential Regulation No. 80/2017 on BPOM outlines BPOM's roles, responsibilities, and authorities in overseeing and regulating pharmaceutical products, including import, production, distribution, and marketing. This strengthens BPOM's ability to oversee and enforce compliance in the pharmaceutical industry. Law No. 36 of 2009 on Health provides a comprehensive legal framework for public health management in Indonesia, including measures to prevent and respond to health emergencies, infectious diseases, and bioterrorism threats.

Hummel & Burpo (2020) and Scharf (2020) highlight the potential for biological weapons to be used due to their high production capabilities, ease of storage, and difficulty in tracing their origin. These factors make bioterrorism a viable and attractive option for terrorists looking to inflict maximum damage with minimal detection. Putriana et al. (2020) discuss the differences between bioterrorism and other forms of attacks, such as atomic or radiation bombings, which have immediate, visible impacts. In contrast, bioterrorism can be silent and insidious, making it more difficult to detect and manage.

Seeing from these events, that the drugs in both cases are modified drugs and come from outside and can be purchased easily online (Raijada et al., 2021; Dockendorf et al., 2021). In this case, the Food and Drug Supervisory Agency has the authority to supervise and ensure the safety, efficacy, and quality of drugs circulating in the community in accordance with the Food and Drug Supervisory Agency regulation No. 9 of 2019 concerning Technical Guidelines for Good Drug distribution methods and Presidential Regulation No. 80 of 2017 concerning the Food and Drug Supervisory Agency. With this phenomenon, researchers are interested in discussing "The Danger of Pharmaceutical Crime as a Potential Bioterrorism in the Framework of Asymmetric Warfare Threats in Indonesia".

RESEARCH METHOD

Research on the Dangers of Pharmaceutical Crime as the Potential of Bioterrorism in the Framework of Total Warfare Threats in Indonesia uses Qualitative research. Qualitative research method is an approach or search to explore and understand a symptom (Creswell & Poth, 2016). Qualitative research methods are research methods based on the philosophy of postpositivism, used to research on natural object conditions (Sugiyono, 2009).

This research uses a phenomenological approach. The research is explained by analyzing existing qualitative data with actual facts and then applying the results of data analysis and these facts using existing theories so as to obtain conclusions, understanding and determine the answers to the research questions posed (Moleong, 1991). Data collection techniques with literature study techniques and case studies that occur in the community. This research uses theories and concepts in discussing the problems in the problem formulation. The theories used are the theory of defense science concepts, strategy theory, synergy theory, threat theory, and bioterrorism theory.

To comprehensively understand pharmaceutical crime in Indonesia, the data to be collected includes pharmaceutical crime incident reports, pharmaceutical supply chain market data, health impacts of counterfeit and modified drugs, regulatory information and law enforcement actions, public awareness and behavior surveys, counterfeit drug detection technology usage data, inter-agency coordination, and economic impacts of pharmaceutical crime. Specific data sources that will be used include government databases such as BPOM, Ministry of Health, and law enforcement agencies, healthcare facility records, market research firms, academic and research institutions, pharmaceutical company internal reports, technology company data, public surveys, and reports from international organizations such as WHO and Interpol. By collecting data from these various sources, the research can provide a comprehensive and detailed understanding of pharmaceutical crime in Indonesia.

To ensure the validity and reliability of the data in this study, several steps will be taken. Triangulation will be used by utilizing multiple data sources and methods to verify the information collected, including data from government databases, healthcare facilities, market research firms, academic studies, and international reports. Preferred data sources are those with reputation and authority, such as BPOM, Ministry of Health, WHO, and Interpol, to ensure data accuracy and reliability. Data consistency will be checked by comparing information from different sources and investigating any discrepancies found. Involvement of experts for peer review will be conducted to ensure the accuracy and rigor of the analysis. In the data analysis, the theories used will be applied thoroughly. Defense Science Theory will be used to analyze the pharmaceutical crime data in the context of national security, assessing how these crimes threaten public safety and how they can be mitigated. Strategy Theory will be used to develop a strategic approach to preventing and responding to pharmaceutical crime, creating a comprehensive plan that integrates multiple stakeholders and resources. The Synergy Theory will examine collaborative efforts between different agencies and organizations in combating pharmaceutical crime, assess the effectiveness of inter-agency coordination, and identify areas for improvement. Threat Theory will be used to assess the nature and magnitude of the threat posed by pharmaceutical crime, identifying specific vulnerabilities within the pharmaceutical supply chain and public health system. Bioterrorism Theory will be applied to understand how pharmaceutical crime can be used as a bioterrorism tool, examining the potential for this crime to cause widespread harm, and the preventative measures required. By integrating these theories in the data analysis, this research can provide a comprehensive understanding of the complex issues related to pharmaceutical crime and its implications for public health and national security in Indonesia.

RESULTS AND DISCUSSIONS

The Food and Drug Supervisory Agency, based on Presidential Regulation No. 80 of 2017, has the authority to (1) issue product distribution permits and certificates in accordance with safety, efficacy/benefit and quality standards and requirements, as well as drug and food testing in accordance with statutory provisions; (2) conduct intelligence and investigations in the field of drug and food supervision in accordance with statutory provisions; (3) impose administrative sanctions in accordance with statutory provisions.

The Food and Drug Supervisory Agency has the main task of carrying out government duties in the field of drug and food control in accordance with statutory regulations as explained in

article 2 of Presidential Regulation No.80 of 2018. Then the POM Agency itself has a function as stipulated in article 3 of Presidential Regulation No. 80 of 2017. In carrying out the task of drug and food control, the POM Agency carries out functions: a) Drafting national policies in the field of food and drug control, b) Implementation of national policies in the field of drug and food supervision, c) Preparation and stipulation of norms, standards, procedures, and criteria in the field of pre-circulation supervision and supervision during circulation, d) Implementation of supervision before circulation and supervision during circulation, e) Coordinating the implementation of drug and food supervision with central and regional government agencies, f) Providing technical guidance and supervision in the field of drug and food supervision, g) Implementation of actions against violations of laws and regulations in the field of drug and food supervision, h) Coordinating the implementation of tasks, coaching, and providing administrative support to all organizational elements within BPOM, i) Management of state property / assets is the responsibility of BPOM, j) Supervision of the implementation of tasks within BPOM, k) Implementation of support of a substantive nature to all organizational elements within BPOM.

Supervision before circulation as referred to in paragraph (1) is supervision of drugs and food before circulation as a preventive measure to ensure that drugs and food in circulation meet the established standards and requirements for safety, efficacy/benefit, and product quality. Supervision during circulation as referred to in paragraph (1) is the supervision of drugs and food during circulation to ensure that drugs and food in circulation meet the standards and requirements for safety, efficacy/benefits, and product quality as well as law enforcement actions.

Drugs and food have a very big influence on the Indonesian people in fulfilling their needs as individuals who consume food and drugs as health has become a basic need for the community. With a high level of public awareness of health, it is necessary to have an institution that guarantees and protects the Indonesian people as consumers of drugs and food products circulating in the community. In carrying out its duties and functions, BPOM must synergize with elements and state institutions such as the Ministry of Defense, TNI / POLRI and other institutions in the country of Indonesia. In this case the Ministry of Defense has the authority in the implementation of national defense. Because in this case the Ministry of Defense has strategies that are prepared to achieve the strategic goals and objectives that have been set.

The Ministry of Defense strategy is compiled in the State Defense Strategy book as a basic guideline to instill understanding and awareness for every citizen, work guidelines for defense officials, and the TNI regarding defense strategies. In this case BPOM has an indispensable role in providing protection for customers / consumers of drugs and medicines and other products in circulation based on rules, regulations, standardization, evaluation of products before circulation, laboratory testing, inspection of product facilities distributor of investigation and law enforcement as well as supervision, communication, information and education through related agencies.

Currently in Indonesia, the threat of terrorism using biological and chemical weapons is still very rare. However, this cannot dismiss that the threat of bioterrorism is an actual threat that must be prepared to be faced whenever the threat will appear in the life of the nation and state. There are several examples of bioterrorism cases that occurred in Indonesia, namely the arrest of suspected terrorists in Cirebon by Densus 88 who had prepared a bomb containing poison with the power to kill 100 people containing methanol, urea, 310 grams of saga seeds which is the main ingredient of Abrin poison (CNN, 2019). Not only that, the potential for biological threats and terrorism can also arise by modifying drugs that are widely circulated in the community. And this can have a dangerous impact on society in a country which can even be fatal to health and can cause death. In a recent case that occurred in November 2022, two pharmaceutical companies have been named as suspects in the distribution of syrup containing dangerous ingredients that can cause acute kidney failure in Indonesia. Cases of acute kidney failure that occurred in Indonesia caused hundreds of children to die. The Food and Drug Administration stated that there were a number of syrupy drugs that contained dangerous ingredients that triggered acute kidney failure.

The total number of patients in acute renal failure reached 324 people on November 16, 2022, of which 111 people recovered and 199 people died and 14 others were in the treatment stage (CNN, 2022). In this case, BPOM announced that the two pharmaceutical companies allegedly did not meet the standards for the production of syrup with ethylene glycol (EG) and diethylene glycol (DG) contaminants that exceeded the threshold. Chairman of the Food and Drug Administration of the Republic of Indonesia Dr. Ir. Penny. K. Lukito, MCP explained when she was invited in a Podcast on Youtube media with Deddy Corbuzier, that this case could have been included in the threat of Bioterrorism which entered through medicinal products, food, and cosmetics containing contaminants and toxic compounds. With the ease for people to get these products at affordable prices and sold online. related to this EG and DG material is a solvent which is a pollutant that can be toxic which has a standard use of 0.1 percent in raw materials after tracing the pharmaceutical company which uses up to 90 percent which makes the syrup toxic. In this case it is a pharmaceutical crime in which there is an illegal facility that mixes and obtains a supply of solvents with the content of these dangerous solvents that are falsified intentionally. This EG and DG material is an imported material that should have a pharmaceutical title grade that goes through various stages of purification if it is to be used. And in this case, this solvent is not included in the supervision of the POM because this material can be used in other industries. And this makes a "gap" in the quality assurance system and security against the entry of these raw materials which are currently not under the supervision of BPOM and the negligence of the pharmaceutical industry.

BPOM itself has a communication network with all drug authorities with other countries if imported products have problems. However, to stop the purchase of drugs online BPOM itself cannot carry out the action but the Ministry of Communication and Information to be able to take down the owner of the drug sales platform online. In carrying out its duties, BPOM has a deputy field of investigation that will conduct investigations in collaboration with the Criminal Investigation Unit (Bareskrim). In terms of drug and food supervision, it must have a high legal umbrella because it is related to coordination with local governments to be able to participate in supervision and BPOM has the authority to conduct prosecutions and recommendations in revoking pharmacy licenses to the relevant local government as the party that gives the license. In relation to this, BPOM itself has actually issued Technical Guidelines for Correct Drug Distribution Methods (CDOP) which are very important standards in an effort to maintain the quality and integrity of drug distribution in every distribution chain starting from the pharmaceutical industry to pharmaceutical service facilities which include pharmacies, hospitals, clinics, community health centers and drug stores. BPOM itself conducts inspections of the industry within a specified period of time to maintain the standardization and quality of the drug products issued. And if there is a violation found, BPOM has the authority to revoke the product distribution license.

In order to deal with the potential for bioterrorism through pharmaceutical crime, there needs to be good cooperation between all parties including the government, customs and excise, legal institutions, authorities (TNI / Polri), and those responsible for supplying drugs, ensuring drug quality and safety and preventing exposure to counterfeit drugs to patients. In today's digital era, people can buy goods, especially medicines, online. And this is one of the factors for the occurrence of crime in the pharmaceutical sector. Therefore, BPOM needs to collaborate with Kominfo and the Ministry of Trade. The Ministry of Trade has the function of conducting trade standardization and quality control of goods, supervision of goods in circulation and/or services in the market, and supervision of trade activities (Wikipedia, 2020). And the ministry related to online shops is the Ministry of Communication and Information (Kominfo), which functions to manage public information and communication, conduct research and develop human resources in the field of communication and information. (Kominfo, 2013). This collaboration includes systematic collaboration in its implementation to create a special internet site or website that

contains an online shop business licensing format that contains significant data and is legitimate to prevent illegal products.

CONCLUSION

In this study, it was found that pharmaceutical crimes, such as counterfeiting and modification of medicines, are serious threats that have the potential to act as bioterrorism within the framework of universal warfare in Indonesia. The circulation of counterfeit and modified medicines that are easily obtained both in person and online poses a fatal health risk to the public. Cases in various countries, including Indonesia, show that modified medicines can cause death, especially if they contain dangerous ingredients.

The Food and Drug Administration (BPOM) has an important role in monitoring and ensuring the safety of medicines circulating in the community. However, there is a need for greater awareness and education of the public, related agencies, and government institutions about the dangers of pharmaceutical crime and its impact. The government also needs to provide strong legal support to BPOM to crack down on pharmaceutical crime. The proposed recommendations include the need for stricter regulations in overseeing the circulation of pharmaceutical raw materials, imposing severe sanctions on perpetrators of pharmaceutical crime, and synergy between various related agencies such as BPOM, the Ministry of Communication and Information, the Ministry of Trade, the Ministry of Health, the Ministry of Defense, the TNI, and the Police. Good collaboration between these institutions can increase the effectiveness in preventing the threat of bioterrorism through pharmaceutical crime. Thus, a deep understanding of the dangers of pharmaceutical crime as a potential bioterrorism needs to be a common concern to maintain the security and health of the Indonesian people in facing the increasingly complex challenges of universal warfare.

The practical implications of this research for Indonesian stakeholders are significant and multifaceted. Key points of action include implementing stricter regulations to oversee the production, distribution, and sale of pharmaceutical raw materials and enforcing harsher penalties for pharmaceutical crimes to ensure accountability. BPOM (Badan Pengawas Obat dan Makanan) must enhance its surveillance and monitoring systems to ensure the safety of medicines, supported by strengthened legal authority. Public awareness campaigns are essential to educate the community about the dangers of counterfeit medicines, alongside training for related agencies and government institutions on the importance of stringent enforcement. Collaboration between BPOM and other agencies, such as the Ministry of Communication and Information, Ministry of Trade, Ministry of Health, Ministry of Defense, TNI, and the Police, is crucial for a unified response. Joint operations and information sharing will help track and prevent counterfeit medicines. Recognizing and preparing for the potential use of pharmaceutical crime as bioterrorism is vital, including implementing security measures to prevent the intentional spread of harmful pharmaceuticals. Developing comprehensive policies and investing in research and development for better detection methods are also necessary. By addressing these areas, Indonesian stakeholders can mitigate the risks posed by pharmaceutical crimes, protect public health, and enhance national security against potential bioterrorism threats.

This study has several limitations, such as limited data coverage, focus on specific types of pharmaceutical crime, generalization of findings, lack of perspectives from various stakeholders, and less in-depth exploration of inter-agency coordination. For future research, it is recommended to collect more comprehensive data from different regions, expand coverage to different types of pharmaceutical crime, conduct in-depth case studies on bioterrorism, involve more stakeholders, explore successful models of inter-agency collaboration, develop technological solutions to detect and prevent pharmaceutical crime, analyze the effectiveness of current policies, study the public health impact in more detail, evaluate public education and awareness programs, and conduct longitudinal studies to track changes in pharmaceutical crime over time. By addressing these

limitations and implementing the suggestions, future research can expand the understanding of pharmaceutical crime and improve strategies to reduce its impact on public health and safety in Indonesia.

ACKNOWLEDGEMENTS

In this study, the researcher would like to thank various parties who have supported and assisted in completing the analysis of pharmaceutical crime as a bioterrorist threat within the framework of universal warfare in Indonesia. First of all, thank you to the Food and Drug Administration (BPOM) for the information and guidance provided in this research. Thanks also to all respondents and informants who have participated in this research, providing valuable insights. The researcher would also like to thank the supervisors and peers who have provided valuable input and suggestions in the development of this research. Support from family and friends has also been a motivation in completing this research. Thank you to all those who have participated in this research process, hopefully the results of this analysis can make a positive contribution to efforts to prevent the threat of bioterrorism through pharmaceutical crime in Indonesia.

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