



**THE ROLE OF THE FOOD AND DRUG SUPERVISORY AGENCY (BPOM) IN
COMMITTING THE DISTRIBUTION OF COUNTERFEIT DRUGS IN CONSUMER
LEGAL PROTECTION**

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ABSTRACT

The circulation of counterfeit drugs is a serious problem that threatens public health in Indonesia, particularly in Central Java. These dangerous counterfeit drugs not only harm consumers economically but can also cause fatal health effects, including poisoning, drug resistance, and even death. The Food and Drug Monitoring Agency (BPOM), as the government agency responsible for drug and food supervision, plays a crucial role in addressing this problem. BPOM's duties include supervision, law enforcement, and public education about the dangers and risks of using substandard drugs. This study aims to determine the role of BPOM in addressing the circulation of counterfeit drugs within the legal framework of consumer protection in Central Java. This research is a non-experimental study using qualitative descriptive methods, triangulation (combined) data collection, and inductive or qualitative analysis. The data collection techniques used were interviews, observation, and documentation, which were then processed and analyzed. Data were collected through in-depth interviews with the informants, as well as through observations and documentation of counterfeit drug cases provided by the Semarang City Food and Drug Monitoring Agency (BPOM). The study found that the Food and Drug Monitoring Agency (BPOM)'s role in addressing counterfeit drug distribution and protecting consumers in Central Java remains ineffective, with numerous counterfeit drug discoveries occurring. Factors such as limited inspection resources, low public awareness of the dangers of counterfeit drugs, and the complexity of distribution networks are key challenges, indicating that current oversight and law enforcement efforts are inadequate.

Keywords: consumer; counterfeit drugs; distribution; legal

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INTRODUCTION

To date, many Indonesians still lack awareness of the importance of a healthy lifestyle, which defines health as an optimal and comprehensive state of physical, mental, and social well-being. However, in Indonesian society, and in Central Java in particular, a person's health is not only seen in terms of physical and mental well-being, but also in relation to productivity in daily life. Human efforts to maintain health include simple methods such as consuming nutritious foods, regular exercise to accelerate calorie burning and increase oxygen flow to body cells, and adequate sleep. These are fundamental requirements for maintaining a healthy lifestyle. In addition to implementing the simple methods mentioned above, one way to help maintain body health is now becoming increasingly popular through the development and utilization of technology in the field of pharmaceutical health. Aphrodisiacs have become a common choice among the public as a healthy lifestyle choice. This is also supported by the rapid development of pharmaceutical technology, including aphrodisiacs. While numerous issues and findings in the community about counterfeit aphrodisiacs have not diminished interest in them, as evidenced by the current increase in demand and sales. The problem is that many people don't understand or even recognize the difference between genuine aphrodisiacs and counterfeit ones. Moreover, counterfeit aphrodisiacs are extremely dangerous to the health of those who consume them. The circulation of counterfeit aphrodisiacs in Indonesia remains extremely high. In fact, as of 2013 alone, 45% of aphrodisiacs

circulating in Indonesia were counterfeit. This percentage is expected to increase by 2024. Research conducted by the Faculty of Medicine, University of Indonesia, in collaboration with Cipto Mangunkusumo Hospital (RSCM), concluded that aphrodisiacs are the most frequently counterfeited type of medication. This phenomenon serves as an important warning to the public to immediately find ways to avoid the dangers of counterfeit aphrodisiacs (Augustinus, 2023).

In fact, the types of counterfeit drugs circulating in Indonesia are not limited to aphrodisiacs. In general, the number of counterfeit drugs circulating in Indonesia in 2023 was recorded at 430,000, seized by the BPOM and the police. Among the confiscated counterfeit drugs were Ponstan, Incidal-OD, Super Tetra, Amoxcillin, Paracetamol, and Insto. Ironically, although these counterfeit drugs are produced through cottage industries, each production house can produce 1,178 pills per day. This discovery further strengthens the government's concerns, through the BPOM, about the potential dangers of aphrodisiac circulation in the community.(Augustinus, 2023).

Specifically, in Central Java Province, the circulation of counterfeit drugs cannot be underestimated. The Indonesian Food and Drug Authority (BPOM) routinely pays serious attention to this case every year. This is evident in the Central Java BPOM's annual report. In 2021, out of 663 drug samples, 85 were classified as non-compliant. In 2022, out of 733 samples, 85 were non-compliant. In 2023, out of 669 samples, 12 were found to be non-compliant. Indeed, these reports show a significant decrease in the number of non-compliant drugs found. However, it is believed that many counterfeit drugs are still circulating and even being consumed by the public, with the quantity and type of counterfeit drugs still undetected.(BPOM, 2023). The government, through the BPOM, has very strict laws and regulations regarding the problem of counterfeit drugs. This is regulated in Article 98 paragraph (2) of Law Number 36 of 2009, which explains that "Any person who does not have the expertise and authority is prohibited from procuring, storing, processing, promoting, and distributing drugs or materials that have medicinal properties."

This rule is also emphasized in Article 14 paragraph (1) of Government Regulation number 51 of 2009 concerning Pharmaceutical Work, which requires every drug distribution or distribution facility to have a pharmacist as the person in charge. Meanwhile, in terms of legal protection against the circulation of counterfeit drugs, it is stated in Law number 36 Article 196, stating that anyone who intentionally produces or distributes counterfeit drugs that do not meet the standards or requirements for safety, efficacy or benefits, and quality in Article 98 paragraph (2) and paragraph (3) will be subject to legal action. The stages of the legal action process include administrative sanctions in the form of a written warning letter to the company or individual who commits the violation, if the warning letter is not heeded, BPOM will stop production and confiscate the product, destroy the product, up to criminal charges in accordance with applicable laws. Therefore, BPOM always works together with the Police to verify and monitor so that these violations can be prevented and not repeated.(BPK RI, 2009).

A 2023 raid by the Food and Drug Monitoring Agency (BPOM) revealed drugs using counterfeit permit numbers, and some packaging was not yet registered with the BPOM. The following products were found by the BPOM: Viagra, Cialis Tadalafil 80mg, Big Penis, Black Ant King, Cees Plegg, Max Man, Darling, Tian Xia di yi bang, and Qiang Jin Wei Ge Wang Blue Pill. The counterfeit drugs discovered by the BPOM are often consumed by the public to increase stamina or strength. Because many drugs offer solutions to public complaints, this has created a new problem: the existence of counterfeit drugs unregistered with the BPOM has attracted consumer interest and sold well among the public. To make the drugs appear authentic and not suspicious on the market, manufacturers create these drugs by including fake distribution permit numbers on the drug packaging. This certainly makes consumers believe that the drugs they consume are safe because the BPOM permit number is on the drug packaging. However, when checked, the registration number, product name, and data from the distribution permit number listed on the drug packaging

could not be found. To overcome problems like this, the Food and Drug Monitoring Agency conducted market inspections at several drug distribution facilities in Central Java, such as pharmacies, hospitals, pharmaceutical wholesalers (PBF), licensed drug stores (TOB), community health centers and clinics.(BPOM, 2023).

Indonesia has a non-ministerial government agency, namely BPOM, based on Presidential Regulation concerning the Food and Drug Supervisory Agency No. 80 of 2017 article 2 has the task of carrying out government duties in the field of drug and food supervision in accordance with the provisions of laws and regulations. BPOM in carrying out certain operational technical tasks and/or certain supporting technical tasks in the field of drug and food supervision by forming a Technical Implementation Unit within the BPOM environment consisting of the Center for Drug and Food Supervision (BBPOM), the Center for Drug and Food Supervision (Balai POM) and the Center for Drug and Food Supervision (Loka POM). Drug and food commodities are one of the strategic commodities in trade because they are directly related to basic human needs. Conditions like this, on the one hand provide benefits to consumers because the need for the desired product can be met. However, on the other hand, this condition also has a negative impact on consumers, where consumers become objects of business activities of business actors who seek profit only, either through promotions, sales methods, product quality, or the content of drugs and food that will be consumed by consumers. The rapid growth of pharmaceutical and food companies in Indonesia has led to the widespread circulation of hazardous substances in the market. These products are frequently consumed daily without the public realizing they may contain hazardous substances. These hazardous substances are still freely sold in pharmacies, drug stores, markets, and supermarkets, causing public concern. This concern stems from the misuse of the efficacy and purity of drugs by irresponsible parties, particularly drug manufacturers who seek only financial gain without regard for the interests and health of consumers. Many drug manufacturers intentionally mix their drugs with hazardous substances, which can endanger health and even cause death (Prabowo, 2021). This research is significant because it provides a valuable reference for the public and consumers to better understand the health risks associated with counterfeit medicines and enhances their understanding of the existing regulations governing consumer legal protection. The purpose of this study is to examine the role of the National Agency of Drug and Food Control (BPOM) in addressing the circulation of counterfeit medicines and protecting consumers' legal rights in Central Java.

METHOD

This research is a non-experimental, descriptive qualitative study using triangulation (combined) data collection and inductive or qualitative analysis. By using qualitative research methods in this study, it is hoped that detailed information will be obtained regarding the research conducted by the researcher, namely the role of the Food and Drug Monitoring Agency in Central Java in reducing the circulation of counterfeit drugs.. Four informants participated in this study: the Head of the Inspection and Examination Subdivision, the Head of the Enforcement Subdivision, the Head of the Information and Communication Subdivision, and a consumer of counterfeit drugs in Semarang City. Data were collected through in-depth interviews with the informants, as well as through observations and documentation of counterfeit drug cases provided by the Semarang City Food and Drug Monitoring Agency (BPOM).

RESULT

This study examines the role of the Food and Drug Monitoring Agency (BPOM) in addressing the circulation of counterfeit drugs and providing legal protection for consumers in Central Java. Counterfeit drugs are pharmaceutical products produced illegally and do not meet established quality standards. Counterfeit drugs are produced to gain unlawful profits by imitating the identity of genuine pharmaceutical products with distribution permits. This illegal activity is carried out by falsifying labels, packaging, or the active ingredients contained therein. In 2024, the Food and Drug

Monitoring Agency (BPOM) in Central Java Province discovered a total of 25 counterfeit drug trademarks. Data on counterfeit drugs can be seen in Table 1.

Table 1.
Data on Counterfeit Drugs in East Java

No.	Product name	Unit	Amount
1	Viagra	Box	11
2	5 minutseffective	Box	18
3	Tian Xia di yi bang	Box	10
4	Darling	Pcs	72
5	Max Man	Pcs	6
6	Black Ant King	Pcs	24
7	Hajar Hell Egypt	Pcs	6
8	Big Penis	Box	30
9	Cialis Tadalafil 80 mg	So	11
10	Cialis Tadalafil 100 mg	So	6
11	Pil Biru Qiang Jin Wei Ge Wang	Strip	40
12	Magic Penis	Fruit	6
13	Great Penis	Fruit	10
14	Cees Pleng	Strip	3

Based on interviews with the BPOM, the institution's primary duties in Central Java Province include monitoring the distribution of drugs and food, inspections, and law enforcement against violations. BPOM also registers and evaluates products to ensure that all drugs and food meet safety and quality standards. Public education about the dangers of counterfeit drugs and how to recognize safe products is a crucial part of their duties. In handling counterfeit drug cases, BPOM collaborates with authorities to take firm action. Collaboration with other institutions, such as the Health Office and the Department of Industry and Trade, is carried out to increase the effectiveness of supervision. Data from the Semarang BBPOM in 2023 showed the presence of 14 brands of counterfeit drugs, with the most frequently found Qiang Wei Ge Wang Blue Pill.

Counterfeit drugs have the potential to harm consumers and undermine public trust in legitimate medical products. Therefore, consumer legal protection is crucial. The Indonesian Food and Drug Authority (BPOM) has taken proactive steps, including education and investigations into reports of counterfeit drugs, to raise public awareness of these risks. Consumers need to understand their rights and the steps they can take when facing issues related to non-conforming products. Education and active involvement from the government and the public are essential to creating a safer environment from the threat of counterfeit drugs. In 2024, the Food and Drug Monitoring Agency (BPOM) in Central Java Province discovered a total of 25 counterfeit drug trademarks. Data on counterfeit drugs in Central Java can be seen in table 2.

Table 2.
Data on Counterfeit Drugs in Central Java

No	Product's Name	Unit	Amount
1	Cromium Picolinate	Tablet	360
2	Guarana 1600 mg	Capsul	100
3	Krim H Herpes	Pot	8
4	Krim Racikan	Pot	20
5	Krim Racikan Apotek Permata	Pot	1
6	Krim Racikan Apotek Taruna Sehat	Pot	1
7	Krim racikan JK jamur kulit	Sachet	5
8	Obat Alergi	Wrap	44
9	Obat Asam Urat	Wrap	48
10	Obat Batuk Pilek	Wrap	10
11	Obat Diare	Wrap	4
12	Obat gigi	Wrap	15
13	Obat Maag	Wrap	15

No	Product's Name	Unit	Amount
14	Obat Racikan Pegel-pegel	Wrap	32
15	Obat Spesialis Dengkul	Sachet	10
16	Permanganas Kalicus 2 5 gr	Pot	21
17	Racikan obat gatal	Sachet	8
18	Racikan obat sakit gigi	Sachet	10
19	Racikan sakit gigi	Wrap	3
20	Raspberry Ketones	Capsul	60
21	Stelan pegel linu encok	Wrap	16
22	Sulfanilamide Forte Sterile Powder	Sachet	91
23	Super Kecetit Asam Urat	Sachet	16
24	Super Strength Digest	Capsul	30
25	CEMAKC 1	Dus	6

DISCUSSION

Based on data from the Semarang Food and Drug Monitoring Agency (BBPOM) in 2023, there were 14 brands of counterfeit drugs circulating in Central Java Province, with the Qian Jin Wei Ge Wang Blue Pill brand being the most common. Research conducted by Muhammad Rifky in 2024 showed that high market demand, a lack of public awareness, and weak legal protection contributed to the rise in counterfeit erectile dysfunction drugs. The use of counterfeit drugs can have serious health impacts, including allergic reactions and even death. For counterfeit Qian Jin Wei Ge Wang Blue Pills, the potential risk is poisoning and worsening erectile dysfunction, as the product may not contain the appropriate active ingredients. This can also lead to public distrust of legitimate medical products and harm the healthcare industry as a whole.(Rifki, 2024).

Legal protection for consumers against counterfeit drugs in Indonesia is regulated by Law No. 8 of 1999 concerning Consumer Protection and Law No. 17 of 2023 concerning Health. The Indonesian Food and Drug Monitoring Agency (BPOM) can confiscate products and revoke the operating licenses of stores or industries. To protect consumers, BBPOM also regularly conducts outreach on the distribution and dangers of counterfeit drugs. Specifically for the Qiang Jin Wei Ge Wang Blue Pill, BBPOM will respond to public reports by conducting an investigation. Following the legal process, the counterfeit drugs will be destroyed, and the business owner will be subject to sanctions in the form of fines or imprisonment in accordance with applicable laws.

Table 2, the largest number of counterfeit drugs is under the brand name Cromium Picollinate. Cromium Picollinate supplements are quite popular among the public, especially among diabetes sufferers. According to data from the International Diabetes Federation (IDF), Indonesia ranks 5th in the world for the number of diabetes sufferers. According to a 2023 research journal by Jerry Shalmont, Grace I, Dermawan, and Dora Dominica, the most common reasons for counterfeiting supplements are increased consumer demand, the rise of online shopping, which makes monitoring more difficult, and a lack of public awareness about the differences between genuine and counterfeit supplements. Consequently, many businesses are exploiting this situation to increase the production of counterfeit supplements for profit. The impact and dangers of consuming counterfeit supplements are no less dangerous than those of counterfeit medications. They can trigger allergic reactions, organ failure, and even poisoning, which can lead to death if not treated promptly by a medical professional. Specifically, consumers who regularly and long-term consume counterfeit Chromium Picollinate can experience delayed healing, digestive disorders, allergic reactions, organ damage, and even poisoning (Law, 2024).

Legal protection for consumers against counterfeit drugs in Indonesia is regulated by Law No. 8 of 1999 concerning Consumer Protection and Law No. 17 of 2023 concerning Health. The Indonesian Food and Drug Monitoring Agency (BPOM) encourages the public to report counterfeit drugs and will collaborate with authorities to conduct investigations. If proven illegal, the BBPOM can

confiscate the product and close the operating license of the store or industry. To protect consumers, the BPOM also regularly conducts outreach on the distribution and dangers of counterfeit drugs. Specifically for Qiang Jin Wei Ge Wang Pills, the BPOM will respond to public reports by conducting an investigation. After the legal process, the counterfeit drugs will be destroyed, and the business owner will be subject to sanctions in the form of fines or imprisonment in accordance with applicable laws.

Based on interviews with the BPOM, this institution plays a crucial role as a drug and food supervisor in Central Java Province, ensuring the safety and quality of products in circulation. Given the rampant cases of counterfeit supplements, particularly those investigated by Shalmont et al. (2023) that The Indonesian Food and Drug Authority (BPOM) is committed to increasing oversight and educating the public about the risks of using unsafe products. Research shows that consuming counterfeit supplements can cause allergic reactions, organ failure, and even death. Therefore, BPOM is actively promoting information on how to distinguish between genuine and counterfeit products to protect public health from the negative impacts of substandard products.

The credibility test results indicate that the research data is reliable. The researchers established good relationships with informants through in-depth observation. Using the triangulation method, the researchers compared information from interviews, observations, and official documents to ensure data accuracy. Checking with informants demonstrated that the research results were consistent with reality. This research is not only credible but also helps understand the role of the Indonesian Food and Drug Authority (BPOM) in protecting consumers from counterfeit drugs. Data credibility is important for policymaking, helping BPOM plan strategies and improve drug oversight. The results of this study can also be used to educate the public about the dangers of counterfeit drugs, encouraging active participation in self-protection.

The study's findings demonstrate the importance of consistent and reliable data for consumer protection in Central Java. Through audits and re-interviews, researchers uncovered accurate information on the prevalence of counterfeit drugs, with 14 brands in 2023 and 25 brands in 2024. These findings support the need to strengthen BPOM's actions to protect consumers. This study provides the basis for policy recommendations to ensure consumers receive safe products. Related research demonstrates that effective oversight by BPOM is crucial in preventing the circulation of counterfeit drugs, with public awareness and access to accurate information being key challenges.

The confirmability test results demonstrated high validity and reliability. The data verification process ensured that information from interviews with informants was consistent with official BPOM documents. This study emphasizes the BPOM's crucial role in protecting public health and raising awareness about the dangers of counterfeit drugs. Collaboration between BPOM and consumers, along with support from relevant parties, is necessary to create a safe consumer ecosystem. The study also recommends increasing BPOM's capacity in training and utilizing technology for more efficient and effective oversight.

The Central Java Food and Drug Monitoring Agency (BPOM) plays a crucial role in addressing the circulation of counterfeit drugs as part of consumer legal protection. An interview with the Head of the Inspection Substance, Enforcement, and Information and Communications Division revealed that BPOM actively conducts routine inspections of drug production and distribution facilities. This inspection process aims to ensure that products in circulation meet established safety and quality standards. Between 2023 and 2024, counterfeit drug detection increased significantly, with BPOM successfully identifying a number of dangerous products, including Qiang Jin Wei Ge Wang Blue Pills and Cromium Picolinate, which were proven to not meet regulatory requirements and potentially endanger public health. In response to counterfeit drug detection, BPOM has taken several strategic steps. First, after identifying counterfeit drugs, BPOM immediately confiscated the

products involved to prevent their distribution in the market. Furthermore, BPOM conducted investigations to identify parties involved in the production and distribution of counterfeit drugs. Furthermore, BPOM also educated the public about the dangers of counterfeit drugs through information campaigns and outreach. These programs aim to increase public awareness about how to recognize safe drugs and distinguish between genuine and fake drugs.

The BPOM's collaboration with relevant agencies, such as the Civil Servant Investigators (PPNS) and the Police, is crucial in strengthening law enforcement against perpetrators involved in the distribution of counterfeit drugs. Through this collaboration, BPOM can carry out more effective law enforcement actions, including investigations and arrests of perpetrators, as well as legal proceedings against them. With this synergy between BPOM, PPNS, and the Police, it is hoped that prevention and enforcement efforts against the distribution of counterfeit drugs will be more optimal and have a significant impact on consumer protection.

Regarding sanctions, the BPOM has the authority to impose administrative sanctions on counterfeit drug businesses, including revocation of distribution permits, fines, and other legal actions in accordance with applicable regulations. In addition to administrative sanctions, the BPOM can also refer more serious cases of legal violations to the police for further legal action. This includes handling criminal cases, where perpetrators can be subject to criminal sanctions in accordance with applicable laws. With strict sanctions and collaborative law enforcement, the BPOM is committed to maintaining the integrity of the health system and consumer protection in Central Java. This is stated in Presidential Regulation No. 80 of 2017 concerning the Food and Drug Monitoring Agency (BPK RI, 2017).

In carrying out its duties, the BPOM utilizes various regulations as the basis for its actions against the distribution of counterfeit drugs. One of the main regulations is Law Number 36 of 2009 concerning Health, which provides the legal basis for BPOM to supervise and enforce provisions related to drugs and food. Furthermore, Regulation of the Head of BPOM Number 20 of 2016 concerning Drug and Food Supervision also serves as a reference in carrying out its supervisory and enforcement duties. In an effort to provide more comprehensive supervision, BPOM also conducts laboratory testing to ensure the quality and safety of drugs in circulation. Distribution supervision is carried out to ensure that drugs not only originate from legal sources but are also distributed appropriately. By strictly enforcing the law against violations, BPOM plays a vanguard role in protecting consumers from the risks posed by the distribution of counterfeit drugs in Central Java, particularly against products that have been identified as dangerous, such as Qiang Jin Wei Ge Wang Blue Pills and Cromium Picolinate.

In addition to regulations related to drugs, the BPOM also adheres to Law Number 8 of 1999 concerning Consumer Protection. This regulation emphasizes consumers' rights to obtain safe, high-quality products and clear information about the products they consume. Through this law, the BPOM has the authority to protect consumers from potentially dangerous products, including counterfeit drugs. With these measures, the BPOM plays a vanguard role in protecting consumers from the risks posed by the circulation of counterfeit drugs in Central Java, particularly against products that have been identified as dangerous such as the Qiang Jin Wei Ge Wang Blue Pill and Cromium Picolinate. This is already stated in Presidential Regulation No. 80 of 2017 concerning the Food and Drug Monitoring Agency (BPOM, 2023).

CONCLUSION

Based on the research results, it can be concluded that the role of the Food and Drug Monitoring Agency (BPOM) in resolving the circulation of counterfeit drugs in consumer legal protection in Central Java is still not running well, because there are still many findings of the circulation of counterfeit drugs in Central Java. This is caused by several factors including limited resources in

conducting inspections, lack of public awareness about the dangers of counterfeit drugs, and challenges in taking action against complex distribution networks, this indicates that existing supervision and law enforcement efforts are not yet effective enough to overcome the circulation of counterfeit drugs and protect consumers optimally.

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