Government Responsibility in Managing Illegal Drug Circulation During the Covid-19 Pandemic

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Abstract: - The circulation of illegal drugs continues to increase from year to year, including during the COVID-19 pandemic. The circulation of these drugs must be disciplined and guarded so that the public is not harmed in terms of health or materially because the illegal drugs in circulation do not meet product and drug distribution standards. The research aims to explore the government's role in overcoming the distribution of drugs that are banned from circulating freely during the COVID-19 pandemic. The data comes from secondary data obtained by study documents, especially legal documents, including primary and secondary legal materials. Based on a study of the 1945 Constitution and health legislation found that the government must be responsible for tackling the circulation of drugs that are illegal from circulating freely to realize comprehensive public health. To deal with the distribution of drugs that are banned from circulating freely, the government established the Drug and Food Control Agency (BPOM) which oversees the distribution of pharmaceuticals and food in Indonesia. The supervision of drug distribution starts from the drug produced or before it is marketed (pre-market) to the drug marketing process (post-market).

Key-Words: - Illegal Drugs, Government, The COVID-19 Pandemic, Drug Control, Drug Distribution, Pre-Market, Post-Market

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1 Introduction

The circulation of illegal drugs, especially during the COVID-19 pandemic, requires serious handling so that the community is not harmed economically or healthily, [1]. During the pandemic, everyone has great concern about the high number of cases of COVID-19 transmission, [2]. Therefore, everyone tries improving their health by taking vitamin supplements or taking medication according to the symptoms experienced. One thing that must be considered in this condition is that someone will easily trust and consume vitamins and drugs that are claimed to be able to treat COVID-19, [3].

Generally, illicit drug trafficking is a phenomenon in the world of illicit drugs and is now the largest black market in the world because there are more than 200 million people who are willing to use it, [4]. In Indonesia has increased every year, the number of illegal drug items and their economic value. Based on data from the Food and Drug Monitoring Agency (BPOM) of the Republic of Indonesia, in 2013 the circulation of illegal drugs was 71 items with an economic value of IDR 5.67 billion. In 2014 the number of illegal drug trafficking rose sharply to 3,656 items with a total value of IDR 31.6 billion. In 2015 items of illegal drugs increased by 15 items to 3,671 but economically it decreased quite a lot with a nominal value of IDR 20.8 billion. In 2016 the period from February to March, which means only two months, the circulation of illegal drugs experienced a high increase where 4,441 items of illegal drugs were found with an economic value of IDR 49.8 billion, [5], [6]. The circulation of illegal drugs in 2017 also increased with the economic value reaching IDR

117 billion.

The circulation and marketing of illegal drugs have increased in the era of online trade (e-commerce). This is not just through traditional drug stores in major cities, but also through online platforms and information technology. The reason for distributing illegal drugs online is that it enables direct transactions between sellers and buyers without any oversight from authorities and allows for drug delivery to reach all parts of Indonesia. 10% of illegal drug trafficking occurs online. BPOM has been monitoring websites, social media, and e-commerce marketplaces such as Shopee, Bukalapak, Lazada, blibli, and Tokopedia and found 4,063 sites or accounts selling illegal drugs between 2018 and June 2019, [7]. During the COVID-19 pandemic, BPOM took action against 5,653 website links illegally trading chloroquine and similar drugs in March-April 2020, [8]. In March-September 2020, the COVID-19 pandemic led to a 100% increase in the circulation of illegal drugs compared to the previous year, with illegal drug operations carried out in 29 provinces and an evidence value of Rp 46.7 billion. In 2019, BPOM identified 24,573 links selling illegal drugs and food, increasing to 48,058 links in the first semester of 2020, [9].

Several types of illegal drugs are often found on the market, including slimming drugs, drugs that are included in the G list category (gevaarlijk or dangerous) which includes all injection drugs, anti-bacterial drugs, anti-histamine, anti-epileptic, anti-hypertensive, tramadol, alprazolam, hexymer, trihexyphenidyl, misoprostol, diazepam, valium, clonazepam, riklona, trivam and so on as well as branded strong drugs such as Cialis, Levitra, maxman and viagra. The illegal use of drugs was shown by a survey conducted by the National Narcotics Agency in 2014 which stated that 6% of 1000 people who abuse drugs have consumed tramadol and trihexyphenidyl, [10]. These drugs are consumed or used for non-medical purposes. During the COVID-19 pandemic, the most widely circulated types of illegal drugs were dexamethasone, actinomycin, and hydroxychloroquine. The high circulation of these illegal drugs during the pandemic was because these drugs were claimed to be able to treat COVID-19.

These illegal drugs, if consumed for a long time, will have a negative impact that is not good. Fake drugs that only contain flour in heart disease drugs, for example, if consumed in the long term, will worsen the disease because they are supposed to contain certain substances that can improve heart performance, but the fake drugs do not have any effect. Strong Drugs that do not have a distribution permit or are faked will have side effects in the form of heart problems, bleeding, kidney damage, and impaired liver function.

2 Government Responsibility in Drug Circulation

Illegal drug circulation, especially during the COVID-19 pandemic, must be a serious concern for the government to create welfare for citizens under the mandate of the 1945 Constitution, which provides guidelines that obtaining health services is a human right that must be provided by the state. The state is responsible for providing healthcare facilities, [11]. Moreover, Indonesia, as a country that adheres to a democratic system, has a great responsibility to protect the basic rights of its citizens, [12].

The government, as a representation of the state, has a responsibility to provide health services as a basic right, as stated in international law. This is supported by Article 25 of the Universal Declaration of Human Rights and Article 12 of the International Convention on Economic and Socio-Cultural Rights, which was later ratified in Law No. 11 of 2005 regarding the ratification of the International Covenant on Economic, Social, and Cultural Rights.

2.1 Philosophy of Government Responsibility

The connection between drug study and health cannot be ignored, as health is a basic human right that the government must uphold and provide services for. The 1945 Constitution (UUD 1945) in Article 28 letter h guarantees the right to health services for everyone. Thus, the constitution recognizes health as a fundamental human right that must be fulfilled by the government as the representative of the people's sovereignty. The government, as the guardian of the citizens' welfare, must ensure the provision of health services and facilities to support their survival and well-being. The COVID-19 pandemic, which has seen a surge in cases, requires significant attention from the government to address this issue, [13].

The government's responsibility to provide health services or insurance to the community, as mandated by the 1945 Constitution, is outlined in Articles 4-8 of Law No. 36 of 2009 on Health. This law assigns the government the task of ensuring health for all members of society, as improving public health is viewed as a crucial aspect of increasing national development. The state recognizes the improvement of the health status of

the population as an investment in development, [14].

As a result, Law No. 36 of 2009 on Health affirms that every individual has the right to health. Health is defined as a person's ability to lead a productive life in a socio-economic environment and is characterized by physical, spiritual, mental, and social well-being, according to the World Health Organization. A person's health is not just the absence of disease or illness but encompasses their physical, mental, and emotional well-being, [15].

2.2 Government Policy in Drug Circulation

The health of a person or society, in general, must continue to be pursued and cultivated through a series of activities carried out in a comprehensive, integrated, and sustainable manner using a maintenance approach, preventive (disease prevention), curative (disease healing), and rehabilitative (recovery) approaches. An effort made to achieve curative health is done through the provision of drugs, [16]. Drugs, or "pharmakon" in Latin, are materials or substances derived from animal sources, vegetable sources, or chemical processes that are used by a person to prevent disease and its symptoms, relieve or prevent disease, cure disease, restore condition after disease, or substance used to improve health.

Everything related to health efforts, including curative efforts, to realize health is to provide good medicine. Medicine is a basic need in human life, [17]. Therefore, the government is responsible for procuring quality, safe, efficient, and affordable medicines for the people's purchasing power. To guarantee safe and quality drugs, the government must ensure that the circulating drugs comply with quality standards and drug safety standards. The government must guarantee the legality of circulating drugs and at the same time ensure the availability and equitable distribution of affordable drugs, especially drugs that fall into the category of essential drugs. The government must provide guarantees to all levels of society to be able to obtain medicines related to disease at affordable costs and meet drug safety standards even though the drugs are made by private institutions or obtained from imports. Every drug in circulation must comply with the national pharmacopeia that has been set by the government, [18]. This needs to be done to protect the public from the effects that may arise from the use of drugs that do not meet the standards of safety and efficacy of the use of drugs that will harm the wearer.

To guarantee the compliance of drugs consumed by the public with drug and safety standards, Article 106 of Law No. 36 of 2009 on Health mandates that every pharmaceutical preparation or drug must have a distribution permit before circulation. Any drug without a proper distribution permit, fake permits, drugs not meeting established standards, drugs brought in without authorization from the relevant authority, drugs with revoked permits still being circulated, drugs distributed by unauthorized individuals or entities, or in general, any circulation contravening applicable laws and regulations, is considered an illegal drug.

Based on the provisions of Article 106 of the Health Law, the government, as the policyholder, stipulates that every drug circulating within the territory of Indonesia must have a distribution permit, which can be obtained by registering the drug. Although the manufacture of drugs can be carried out by private companies, the government remains the party responsible for the availability of drugs and must guarantee the safety of drugs made by the private sector. Generally, every drug in circulation must be authorized by the government, except in special cases where the government is authorized to make policies for the procurement or use of certain drugs, [19].

3 Circulation of Drugs During the COVID-19 Pandemic

To ensure the public's safety from harmful drugs, the government entrusts the Food and Drug Supervisory Agency (BPOM) with supervising the distribution of drugs and food. BPOM's drug distribution monitoring process is depicted in Figure 1.

Fig. 1: BPOM's drug distribution monitoring process diagram, [20]

BPOM carries out two stages of drug distribution supervision as depicted in the above picture, these are pre-market supervision and post-market supervision in the community. Based on the Presidential Decree (Keppres) No. 80 of 2017, BPOM is the executor of government duties that has the responsibility of supervising drugs and food throughout the territory of the Indonesian state. In terms of drug supervision, BPOM conducts supervision both before the drug is circulated (premarket) as a form of guarantee of the safety, quality, and efficacy of the drug to prevent the public from being exposed to dangerous drugs and after the drug is circulated (post-market) as an implementation of the implementation of supervision to ensure that the drugs in circulation have met the standards of safety, efficacy, and quality of drugs and to enforce the law on drugs deemed to have violated the provisions of laws and regulations.

Based on the diagram above, there are two types of supervision carried out by BPOM, namely, pre-market and post-market:

a. Pre-Market: To guarantee the safety and quality of drugs, every drug before being circulated in the community has been carried out under quite strict supervision. Three activities are carried out under supervision before the drug is circulated (pre-market):

1. Product registration; to get approval or a distribution permit, each drug must go through a registration process and, simultaneously, an evaluation of the drug to be circulated. Under the Regulation of the Head of the Food and Drug Supervisory Agency No. 27 of 2016 concerning Criteria and Administration of Drugs, drug registration is submitted to BPOM. There are three types of drug registration categorization, namely, new registration, variation registration, and re-registration. Every drug that wants to be registered must have a name whose determination is made by the applicant by choosing a generic name or trade name. If you choose a generic name for each drug you want to register, you can use a name that is following the Modified International Nonproprietary Names set by the World Health Organization. The generic drug label must include the highest retail price and a green generic logo.
If the applicant chooses a trading name, the applicant determines the name of the drug he wants to search for by conducting an independent study that is requested to be registered regarding general drug guidelines, including that the use of drug names must be objective and must not mislead users. They must not use generic names, have no similarities between the name and the name of the drug that has been previously recorded, and may not use the name permitted with the permission of the name of the drug canceled.
To make it easier for business actors in the fields of medicine or pharmacy to register their drugs, the government through BPOM has provided a means of drug registration through an online application at https://new-aero.pom.go.id/ which can be used by business actors at any time. -time without waiting for the effective day. During the COVID-19 pandemic, drug registration was carried out faster than before the pandemic, as shown in Table 1:

Table 1.Drugs Registration Process

Type of Service/ Process/ Condition	Normal Condition	Pandemic Conditions For COVID-19 medicine
Pre-registration	40 working days	6 hours
Evaluation of Registration of New Drugs and Biological Products	100 working days, 120 working days and 300 Working Days (according to risk assessment)	20 working days
Evaluation of Generic Drug Registration	150 working days	5 working days
Quality Document	Pilot scale batch size with 6 months stability and for Bioequivalence test results can be given Comparable Dissolution Test and BioEquivalence commitment (according to risk assessment)	Pilot scale batch size with 6 months stability and for Bioequivalence test results can be given Comparable Dissolution Test and BioEquivalence commitment (according to risk assessment)
Clinical and Non-Clinical Documents	Must be complete	Can provide data on the use of these drugs during a pandemic outbreak in Indonesia or other countries (according to risk assessment).

Source: Data Processed, 2022

The accelerated pre-registration timeline for COVID-19 drugs only takes 6 hours compared to non-COVID-19 drugs, which take 40 working days. Meanwhile, the time needed to evaluate the registration of COVID-19 drugs is only 20 working days, while non-COVID-19 drugs are carried out for 100 working days. Every drug registered with BPOM will be thoroughly evaluated based on its benefits and risks. The higher the value of benefits compared to the risks of registered drugs, the faster the evaluation process. The value of the benefit that exceeds the risk will be approved in the form of conditional approval.

The regulation of drug registration also encompasses traditional medicines intended for distribution in Indonesia. Traditional medicines refer to ingredients or medicinal substances that have been passed down through generations for the treatment of certain ailments and can be plant, animal, mineral-based, or a combination of these materials. Traditional medicine registration can be completed online through www.asrot.pom.go.id/asrot, as per the Minister of Health Regulation No. 007 of 2012 for Registration of Traditional Medicines. Business actors must register these medicines to ensure their safety, efficacy, and quality. The distribution permit requirement applies to all traditional medicines, except for herbal concoctions, galenic preparations in traditional medicine, and traditional medicines used for research, testing, or exhibitions.

Traditional medicine to be registered must not contain drugs that endanger health, narcotics and psychotropic substances, medicinal chemicals, or ethyl alcohol that exceeds 1% alcohol content. Additionally, traditional medicine should not be made in the form of intravaginal, eye drops, parenteral, or suppositories. Several criteria must be met by traditional medicine to obtain a distribution permit, including, [21];

a) Made with non-harmful materials that meet drug safety standards and have quality assurance;
b) conform to the requirements of the Indonesian Herbal Pharmacopoeia or other recognized standards;
c) Registered drugs have been tested for efficacy for generations and can be proven emotionally or scientifically;
d) The manufacturing method meets the standards for good manufacturing practices (GMP);
e) Registered traditional medicines must be packaged in packages that contain non-misleading, complete, and objective information.

2. To get a distribution permit, a registered drug must comply with the criteria outlined in Minister of Health Regulation No. 1010/Menkes/Per/XI/2008 and its amendment by Regulation No. 1120/Menkes/Per/XII/2008 on drug registration. Additionally, according to the Food and Drug Supervisory Agency Regulation No. 24 of 2017, the drug must also meet certain standards, namely:
   a. has demonstrated efficacy and adequate drug

safety after undergoing a series of clinical and non-clinical trials;

b. The registered drug has good quality and meets the requirements or standards that have been set by the GMP standard (Good Manufacturing Practices of Medicine), which is equipped with justifiable evidence;
c. Registered drug products and labels contain objective, non-artificial, and non-misleading information to ensure proper and safe drug use;
d. Drugs in the psychotropic category must have advantages or advantages over drugs registered and have distribution permits in Indonesia;
e. In particular, for drugs included in national health programs, registered drugs must meet the requirements established by the government as the organizer of the national health program.

After meeting the above criteria, the drug to be registered or registered must complete the required documents;

a) Drugs originating from domestic production must have a pharmaceutical industry permit and have a valid GMP certificate following the drug to be registered unless the drug to be registered by the pharmaceutical industry is still in the process of being developed or being developed or the pharmaceutical industry is currently expanding its production facilities.
b) Drugs that come from outside or are imported, either in bulk form or in finished products, must have a justification that the drug cannot be produced in Indonesia by a party that has obtained a written permit from the pharmaceutical industry abroad that contains a period of cooperation with partner companies outside the country. Every country must have a pharmaceutical industry permit from the government where the pharmaceutical industry is located and fulfill the GMP requirements accompanied by evidence of a report on the results of the latest drug supervisory authority inspection no later than 2 years. Additionally, there must be efforts from representatives of the foreign pharmaceutical industry to transfer technology so that it can be produced in Indonesia in the form of product development, techniques or methods in the production process, or drug quality control.

Regarding the circulation of drugs that are included in the psychotropic category, during the COVID-19 pandemic, the circulation of these drugs has increased. This is due to the large number of people who have lost their jobs and the increasing economic pressure. Therefore, during the COVID-19 pandemic, supervision of the circulation of psychotropic drugs must be increased, [22]. In Law No. 5 of 1997 concerning Psychotropics, it is stated that the circulation of psychotropic drugs can only be carried out by drug manufacturers, large pharmaceutical traders and storage facilities, hospitals, pharmacies, and pharmaceutical preparation storage facilities whose delivery is carried out by pharmacies, hospitals, health centers, medical centers, and doctors to the public. patients who need it based on a doctor's prescription. Drugs that are included in the psychotropic category may not be circulated widely and openly. The circulation of drugs that are included in the psychotropic category is carried out on a limited basis. As a result, those without a legal basis for storing, carrying, or possessing such drugs face a 5-year prison sentence and an IDR 100,000,000 fine. If the action is carried out by a corporate company, the fine can be doubled and be subject to additional penalties in the form of revocation of business licenses.

3. Good Manufacturing Practices; Every drug that wants to be circulated to the public must meet the standard of good drug manufacture, which is manifested in the issuance of certificates of Good Manufacturing Practices of Medicine (GMP) or Traditional Good Manufacturing Practices for traditional medicines. GMP covers the entire process of drug production and drug quality control carried out to ensure that drugs are made consistently, meet the requirements set, and are made according to their use. Several things become general principles of GMP, such as those related to drug ingredients, drug manufacturing processes, supervision of drug quality, building facilities where drugs are made, sanitation and hygiene, personnel who make drugs, and equipment used to make drugs.

During the COVID-19 pandemic, pre-market supervision of drugs was simplified as stated in the Guidelines for Public Services in the Drug Sector in the 2020 COVID-19 Pandemic Conditions. In these guidelines, BPOM simplifies requirements and accelerates public services in the drug sector, which includes drug registration, clinical trial testing, and GMP certification, as well as certification of good drug distribution methods. During the pandemic, the

pre-registration of new drugs only took 6 hours, whereas, before the pandemic, the drug pre-registration process took 40 working days. Likewise, the evaluation of new drug registrations, which under normal conditions takes 100 working days, 120 working days, or 300 working days according to the risk assessment of the drug, is accelerated to 20 working days during a pandemic. Evaluation of generic drug registration only takes five working days, whereas it normally takes 150 working days.

b. Post-Market: Based on the responsibilities of BPOM as stated in Presidential Decree No. 80 of 2017, BPOM has the authority to issue distribution permits and issue certificates for drugs and food to be circulated to the public, conduct supervision in the form of investigations, observations, and investigations as a form of supervision of drugs and food, and has the authority to determine sanctions for parties who violate the law in the field of drugs and their distribution. To improve the supervision of the distribution of drugs and food at the same time post-market, BPOM, as the implementer of government policies, takes three approaches;
   1) Preventive approach: The supervision of drug distribution is carried out by BPOM as an extension of the government to prevent the emergence of illegal drugs through regulation. This effort, among others, is manifested in the issuance of BPOM Regulation No. 33 of 2018 concerning the Application of 2D Barcodes in Drug and Food Control. The regulation states that the circulation of drugs and food produced and circulated domestically or imported for circulation in the territory of Indonesia applies to 2D barcodes with authentication and identification methods. Additionally, to supervise the distribution of drugs and food online, BPOM has issued BPOM Regulation No. 8 of 2020 concerning the Control of Drugs and Food circulation Online. In the regulation, it is stated that every drug that is circulated must have a distribution permit and fulfill the requirements for a good way of making and distributing drugs following the provisions of the legislation. Drug circulation is carried out online by the pharmaceutical industry, pharmaceutical wholesalers, branch pharmacy wholesalers, and pharmacies must use the electronic system owned by the pharmaceutical industry and wholesalers. Branch pharmacy wholesalers can only distribute drugs online using the pharmaceutical wholesaler's electronic system.
   2) Detection approach: This approach is carried out by BPOM as the implementer of government policies in the field of drug control to conduct inspections and supervision of drugs based on a good risk-based inspection and surveillance system. The inspection and supervision system has been assessed by the World Health Organization as mature.
   3) Responsive approach: This approach is carried out through sampling tests on circulating drugs, an inspection of drug production facilities and drug distribution, and monitoring of pharmacovigilance (a science and activity concerned with the detection, assessment, understanding, and prevention of side effects or other problems associated with drug use), and supervision. BPOM also conducts special activities through a series of operations on drug distribution in the community. Operations with special targets carried out by BPOM include storm and Pangea operations. This operation is carried out by BPOM in collaboration with the International Criminal Police Organization (ICPO), which focuses on the circulation of illegal drugs, the circulation of fake stamina-enhancing and slimming drugs, and the use of hazardous materials in drugs circulating in the community.

      Based on the results of the series of actions, a law enforcement process will be carried out by the level of violation committed by giving sanctions in the form of administrative sanctions such as being prohibited from being circulated, withdrawn from circulation, revoking distribution permits, or confiscated for destruction, as stated in BPOM Regulation No. 19 of 2020 concerning Guidelines for Follow-up Monitoring of Drugs and Drug Ingredients. If there is a criminal element, then the criminal violation of drug trafficking is carried out through criminal proceedings by the applicable laws and regulations, such as in the case of business actors who distribute drugs without a permit, the prosecution is carried out in court with sanctions in the form of imprisonment for 15 years and a maximum fine of IDR 1.500.000.000.

The government continues to monitor the circulation of illegal drugs during the COVID-19 pandemic, both in the pre-market and post-market processes. Pre-market surveillance during the

COVID-19 pandemic is faster than conditions before the pandemic. When there is no pandemic, the post-market is still carried out using the same approach method.

4 Conclusion

The responsibility of the government in tackling the circulation of illegal drugs during the COVID-19 pandemic is carried out by BPOM. BPOM is a government organ whose function is to supervise the circulation of drugs both before the drug is circulated (pre-market) and after the drug is circulated in the community (post-market). Pre-market supervision, among others, is in the form of an obligation for every drug manufacturer to register, use the Good Manufacturing Practice standard for chemical-based drugs and use the Good Traditional Medicine Manufacturing Standard for traditional medicines. Meanwhile, post-market supervision is carried out by BPOM through inspection of production and distribution facilities, drug sampling and laboratory testing, monitoring of advertisements, promotions and labeling of matters related to drugs such as side effects, and legal action and sanctions for those found to have violated the law.

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