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## LAW & SOCIAL POLICY | RESEARCH ARTICLE

# Legal Protection Against Consumers at Drugs That Do Not Have a Distribution Permit

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**Abstract:** This study aims to determine how the legal protection for drug consumers without a distribution permit at the Makassar Drug and Food Control Center and to find out what factors cause drugs without distribution permits. This study uses empirical legal research methods, namely legal research that seeks to see the law in a real sense or can be said to see, examine how the law works in society. Empirical research methods can be said that legal research is taken from the facts that exist in a society, legal entity, or government agency. The results of this study indicate a form of legal protection for drug consumers without a distribution permit at the Makassar Drug and Food Control Center by carrying out pre-market and post-market supervision, both supervisions carried out from the inspection substance group, namely inspection and action group by conducting intelligence operations and providing criminal sanctions. and administration for perpetrators. The factors that cause drugs that do not have a distribution permit are abuse factors, lack of education about the dangers of drug abuse, business actors who do not have the expertise and authority. Recommendations for research by BPOM as an authorized institution should further improve its supervision in this case. The cooperation between the local government and the community is also expected to take part and be actively involved in the implementation of the supervision of drugs and foods that do not have distribution permits.

**Keywords:** Legal Protection, Consumers, Distribution.

## 1. INTRODUCTION

Health is a very valuable factor in life, health is a gift from God that should be maintained by every human being. Article 1 paragraph (1) of the Law of the Republic of Indonesia Number 36 of 2009 concerning Health defines "Health is a healthy condition, both physically, mentally, spiritually and socially that allows everyone to live socially and economically productive". Health plays an important role in daily activities, both in terms of physical and non-physical. Also, in Islam it is recommended to maintain health because maintaining health is an obligation for humans. The state also has an important role in providing health rights to its citizens as stated in Articles 14 to 20 of Law no. 2009 on health. As part of public health services, the availability of drugs is one of the most important health components, because drugs are used to save lives, restore or maintain health. In health services, drugs are an important component because they are needed in most health efforts. Nowadays, increasing public awareness and knowledge about health also encourages people to demand health services, including drug services that are more qualified and professional. (Rani & Wirasila, 2016)

Being healthy is certainly the hope of every human being. Along with the development of the times in human life, medicines that can be consumed for health also develop. This is in line with the development of existing technology so that medicines are more effective and easier to distribute to consumers. This is certainly very helpful for the community in meeting the needs of life. The wide reach of technology makes people as consumers freely choose the medicines they need and want. All these conveniences also have a positive impact on business actors to trade their goods and/or services, including buying and selling drugs. The public as consumers have the right to know clear information

related to drugs consumed, the content of substances in a drug, the efficacy of a drug, and the authenticity of the drug. Indonesia as a legal state has provided a legal umbrella for drug consumers in the enactment of Law no. 36 of 2009 concerning Health. (Lidia, 2014). Medicines are so important in human life, with the hope that if you consume drugs your body will become healthy, but the hope to be healthy does not immediately come true, considering the rampant sales of drugs that do not have distribution permits, (Nurcahyo, 2018) business actors as producers seem to forget that there is an obligation that must be met in buying and selling. For their personal interests and to get a lot of profit, some business actors abuse this opportunity by selling illegal or counterfeit drugs and drugs that have not gone through the testing process first or are known as drugs that do not have distribution permits. (Hidayat & Basuki, 2014)

Reported from Suara.com Head of the POM Penny K. Lukito announced the findings of traditional medicines related to Covid-19 without a distribution permit or containing medicinal chemicals, as well as processed food without a distribution permit, on Wednesday, September 23, 2020. While carrying out his illegal business, said Penny, the suspect managed to achieve a turnover of billions of rupiah every year (voice.com). This is certainly very contrary to the principle of protecting the health/property of consumers. (Rossa & Efendi, 2020). It was even found that drugs that did not match the registration number registered with BPOM and did not have a BPOM distribution permit. Example: medicine *Pi Kang Shuang cream* with registration number registered with BPOM, namely DKL1842200229A1 is produced by Sano Gratia Farma but circulating drugs with the same product name produced by PT. Saras Subur Ayoe with POM QI number 024 700 071 which is not registered on the BPOM RI Website. This is certainly contrary to the existing regulations as in Article 98 paragraphs (1) and (2) of Law no. 36 of 2009 concerning health which reads:

- (1) Pharmaceutical preparations and medical devices must be safe, efficacious/useful, quality and affordable.
- (2) Everyone who does not have the expertise and authority is prohibited from producing, storing, processing, promoting, distributing drugs and materials with medicinal properties.

According to Article 106 paragraph (1) of Law no. 36 of 2009 concerning Health "pharmaceutical preparations and medical devices can only be circulated after obtaining a distribution permit." Also, in Article 2 paragraph (1) of the Minister of Health of the Republic of Indonesia Number 1010/Menkes/Per/XI/2008 concerning Drug Registration which states that "drugs that are circulated in the territory of Indonesia, previously must be registered to obtain a Circulation Permit"

Although it has been regulated in Law Number 8 of 1999 concerning Consumer Protection, concerning Prohibited Actions for Business Actors, namely: "Business actors are prohibited from producing and/or trading goods and/or services that do not meet or do not comply with the required standards and regulatory provisions legislation." (Pranata & Rudy, 2019). So, with the above case, the community as consumers feels the need to know how to form legal protection for drug consumers who do not have the distribution permit themselves. (Alfan nur zuhaid et al., 2016) The public as consumers not only have rights that are the obligations of producers but also have obligations that must be carried out to protect their own rights, which are regulated in Law Number 8 of 1999 concerning Consumer Protection. The attitude of business actors who seem not to heed the regulations that must be carried out in carrying out trade in buying and selling drugs is very detrimental to consumers (Nurhalis, 2015). The position of consumers must be given more attention, especially in the sale and purchase of drugs given the importance of drugs for human life, as well as the content and substances in drugs that can endanger health and cause other undesirable consequences, as well as the weak position of consumers to obtain legal protection for the perpetrators' tendencies effort. This is also caused by the legal instruments that protect consumers have not been able to provide a sense of security, or are inadequate to directly protect the interests of consumers. Likewise, *law enforcement* itself is felt to be less firm. Such conditions of consumers have the potential to become victims of business actors. It is also supported by the thinking orientation of some business actors who are still *profit-oriented* in the short-term context, without paying attention to consumer safety, which is the guarantee of the business continuity of the business actors in the long-term context. (Hamid, 2017).

The state has provided a legal umbrella for consumers in Law no. 8 of 1999 concerning Consumer Protection but in practice there are still many sales of drugs that are not in accordance with the

provisions of the legislation, including drugs that do not have distribution permits. This is certainly very detrimental to the community as drug consumers. As stated above, the author shares the opinion of Happy Susanto (2008) in his book *Consumer Rights If Harm*, which states that consumers are one of the parties in economic relationships and transactions whose rights are often ignored (by some business actors), consequently consumer rights need to be protected. (Susanto, 2008) The formulation of the problem in this study is how the legal protection of drug consumers without a distribution permit at the drug and food control center of Makassar and what factors? which causes the drug without a marketing authorization.

## 2. Research Method and Materials

Research method used in this research is empirical legal research that is taken from the facts that exist in a society, legal entity or government agency. This research was conducted by taking the location at the Food and Drug Administration in Makassar City. This location was chosen with the consideration that BPOM has the task of supervising drugs in the Makassar area. The types and sources of data in this study use secondary data and primary data, with field research techniques which will then be processed and analyzed using qualitative descriptive methods to describe and explain problems regarding consumer protection which are clearly closely related to research in order to provide a clear and focused understanding of research result.

## 3. Results and Discussion

Consumer legal protection is divided into two, namely preventive legal protection, namely legal protection provided by the government with the aim of preventing violations before the occurrence of violations and repressive legal protection, namely legal protection aimed at resolving disputes. Preventive legal protection provided by Balai Besar POM Makassar is by conducting supervision. Based on the results of an interview with Muhammad Faisal, as Staff for Enforcement (Monday, 29 March 2021) Legal protection provided by the Makassar City POM Center with do supervision. The supervision carried out by the Makassar City POM Center consists of two forms of supervision, namely:

1. *Pre-Market Control*, namely supervision carried out before the drug is produced and inspection of facilities in order to obtain a distribution permit for the product, before being circulated to the market or consumers.
2. *Post Market Control*, namely supervision carried out after drugs and food are marketed. By conducting regular monitoring every week.

Supervision of drugs and food before they are circulated is as a preventive measure to ensure that drugs and food in circulation meet the standards and requirements for safety, efficacy/benefit, and product quality. (Hutt, 1973) Supervision during circulation is supervision that aims 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. The form of supervision at the Makassar City POM Center has several fields, but in 2021 the name used is no longer a field but changed to Substance Group. Namely the substance of the examination and the substance of prosecution. The inspection substance group, which includes a sub-inspection, is tasked with carrying out routine supervision of three facilities, namely service facilities, distribution facilities, and production facilities. Service facilities, including pharmacies, drug stores, health centers, or hospital pharmacies, and for distribution facilities including PBF (Pharmaceutical Wholesalers). Supervision is carried out regularly every week from the beginning of the year to the end of the year. As for drug production facilities, Makassar itself does not yet have a drug factory. The enforcement sub-group carries out intelligence operations such as investigations or deepening of information and continues to act against suspected criminal acts of drug trafficking that are illegal or do not have distribution permits. Based on the results of an interview with Muhammad Faisal, the investigation process carried out by the Makassar City POM Center, if elements of a criminal act are found in the perpetrator, will be prosecuted by way of investigation. Based on the research that the author conducted at the Makassar City POM Center, there were several cases that circulated pharmaceutical preparations without a distribution permit. The following table shows the number of cases circulating pharmaceutical

preparations without a distribution permit at the Makassar City POM Center. (Aprianti & Abbas, 2021)

**Table 1: Violations: Deliberately distributing pharmaceutical preparations without a marketing authorization/Somadril Compositum Tablets/PCC Tablets (Marketing Permit Revoked) and intentionally distributing “G” List of Hard Drugs which are Certain Hard Drugs (OKT) such as Tramadol, Trihexyphenidil (THD), Gastrul.**

Year	Number of Cases	Pro Justicia	Non-Pro Justicia
2012	1	1	0
2013	1	1	0
2014	8	4	4
2015	1	1	0
2016	0	0	0
2017	2	2	0
2018	3	2	1
2019	4	4	0
2020	9	4	5
<b>Total</b>	<b>29</b>	<b>19</b>	<b>10</b>

Source: Case Data from the Makassar City Center for Drug and Food Control in 2021

Supervision carried out during the COVID-19 Pandemic namely *Cyber Patrol* or Cyber Patrol by monitoring drug sales online. This is because the situation does not allow for direct supervision. The sanctions given to drug business actors who do not have a distribution permit are criminal sanctions and administrative sanctions as stated in Article 197 of Law Number 36 of 2009 concerning Health and Article 198 of Law Number 36 of 2009 concerning Health. Article 197 of Law Number 36 of 2009 concerning Health which reads:

"Everyone who intentionally produces or distributes pharmaceutical preparations and/or medical devices that does not have a distribution permit as referred to in Article 106 paragraph (1) shall be subject to a maximum imprisonment of 15 (fifteen) years and a maximum fine of Rp. 1,500,000,000.00 (one billion five hundred million rupiah)"

Article 198 of Law Number 36 of 2009 concerning Health, which stipulates that: "Everyone who does not have the expertise and authority to practice pharmacy as referred to in Article 108 shall be punished with a maximum fine of Rp. 100,000,000.00 (one hundred million rupiah). Settlement of consumer disputes which is a form of repressive legal protection is regulated in Article 45 of Law Number 8 of 1999 concerning Consumer Protection. In general, as for dispute resolution through non-litigation channels, consumers can go through an institution in charge of resolving disputes between consumers and business actors, namely the Consumer Dispute Settlement Agency (BPSK), which reads "Consumer Dispute Settlement Agency is a body tasked with handling and resolving disputes between business actors and consumers. Regarding distribution permits, cases of drug distribution without a distribution permit in the city of Makassar itself can be said to be rare, this is seen from the data on cases of distribution of pharmaceutical preparations without a distribution permit at the Makassar City POM Central Office from 2012 to 2020, there were only 29 cases. However, in the data received from the Makassar POM Center in 2017 to 2020 there was an increase in cases, so the factors causing the drug without distribution authorization according to the author are very important things to know. Because this is the root of the problem. With this, the government can be more aware and concerned about the settlement of drug trafficking without a distribution permit or illegally. Based on the results of an interview with Muhammad Faisal as Staff for Enforcement (Monday, March 29, 2021), the factors that cause drugs without distribution authorization are:

1. Abuse Factor.

Abuse is one of the factors that can be said to have the most influence on the existence of drugs without a distribution permit, the factor of drug abuse is also the reason why the distribution

permit is revoked by BPOM, because most drugs are not used according to their designation. For example, revocation of drug distribution license due to PCC type drug abuse.

Drugs containing Carisoprodol have a muscle relaxant effect, besides that it can also cause sedative and euphoric side effects. At higher doses above the therapeutic dose, it can cause seizures and hallucinations, as well as other effects that endanger health and cause death. Therefore, in 2013, all drugs containing carisoprodol (Carnophen, somadril, New Skelan, Carsipain, Carminofein, Etacarphen, Rheumastop, Cazeril, Bimacarphen, Karnomed) which were given a distribution permit by the POM RI were revoked and are no longer allowed to circulate in the market. Indonesia.

2. Lack of education about the dangers of drug abuse.

Lack of consumer education about the dangers of drug abuse is one of the factors that cause drugs without distribution authorization. This can be seen from the high demand for drugs without distribution permits in the market, so that there are elements or business actors who produce these drugs, while those that produce are usually household factories. Therefore, understanding and awareness of consumers and business actors is very necessary because according to the author these things are interrelated with each other. (pom.go.id, 2022)

3. Business actors who do not have the expertise and authority.

Based on the results of interviews with Mr. Muhammad Faisal, those who become business actors of drugs that do not have distribution permits are usually those who do not have a pharmacy license, are not pharmacists and do not have a certificate of competence. service facilities and not drug distribution facilities.

#### 4. Conclusion

Legal protection for consumers on drugs without a distribution permit given to the public is by carrying out two forms of supervision, namely supervision before distribution and routine supervision every week to ensure the quality and efficacy of drugs after distribution, which is carried out by two groups of substances at the POM Center, namely the group the substance of the examination, namely the substance of the inspection and the group of the substance of the action. The settlement of consumer disputes can be reached through litigation and non-litigation. The cause of drugs that do not have distribution permits in the community consists of several interrelated factors, namely, abuse factors, lack of education about drug abuse, business actors who do not have the expertise and authority. The supervision carried out by BPOM as the agency authorized to represent the government in the supervision of drugs that do not have distribution permits must be further improved. This is because the role of BPOM is very necessary in order to protect the public as drug consumers. Cooperation between local government and the community or various parties is also expected to participate in the supervision of drugs and food.

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