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Consumer Protection Against Traditional and Dangerous Medicines in Indonesia

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Abstract

Indonesia is a country that has abundant biological wealth. It encourages the rate of production of traditional medicines which is then followed by a high level of community culture towards the consumption of traditional medicines. Traditional medicine is an alternative medicine in addition to generic drugs sold in pharmacies. Many traditional medicines that circulate in the community. It turns out that not a few are included in the category of dangerous drugs. The formulation of the problem in this research is how to protect consumers when problems arise due to dangerous traditional medicines. This research uses normative juridical research methods, while the results show the Food and Drug Supervisory Agency *(Badan Pengawas Obat dan Makanan /BPOM)* is a agency that has the authority to give permits and has the right to withdraw traditional medicines. The role of BPOM is also to provide recommendations on policies, especially in the regulation of traditional medicines. It turns out that there are rules regarding traditional medicines still overlap between the Government and BPOM in terms of supervision and protection of the community so that there are still many violations. The rules regarding traditional medicine are not yet comprehensive. The task of BPOM supervises production and distribution. The sanctions for violations for traditional medicine producers are in Articles 60 to 63 of the UUPK, namely administrative sanctions, criminal sanctions, and additional criminal sanctions. Meanwhile, dispute resolution can be through litigation, non-litigation, or the Consumer Dispute Settlement Agency.

Keywords: Consumer protection, Traditional Drugs, Dangerous Drugs.

Introduction

Traditional medicine has existed for a long time and is consumed by people in Indonesia. These traditional medicines contain benefits for human health, besides that

they can also increase the body's metabolism and even become drugs in the process of healing diseases (Sudewi et al., 2020). According to Sukandar, the evidence of traditional medicine is the nation's ancestral heritage comes from the existence of old manuscripts that is described that there are people concocting medicines with plant ingredients. The old manuscripts are in several areas in Indonesia including *Husodo* palm leaf in Java; *Lontarak pabbura* in South Sulawesi; *Usada* in Bali; *Fiber Primbon* document in Jambi and there are reliefs at Borobudur temple. They indicate that traditional medicine is a product has been around for a long time in Indonesia (Hariri, 2019). History has proven that herbal medicine has become part of the culture of the Indonesian people, so that herbal medicine has become the hallmark for the Indonesian nation. (Dhiva & Gunarto, 2020).

The definition of traditional medicine is a concoction in the form of plant materials that consists of mineral materials, mixtures of these materials. Traditional medicine can also be interpreted as a concoction of ingredients in the form of plant materials, animal materials, mineral materials which have been used for generations for treatment (Regulation of the Minister of Health of the Republic of Indonesia Number 07 of 2012 which is in article 1 number (1) (Sonhaji, 2020).

In Law Number 36 of 2009 concerning Health has been regulated about traditional medicine although not comprehensively. The government raises the position of traditional medicine in line with factory-made modern medicine, which later on traditional medicine can be one of the treatment efforts in formal health. Traditional medicine that does not have a curative claim is obliged to preserve it because it is part of culture (Maufiroh & Lukmana, 2020).

Traditional medicines or herbs circulating in the market contain harmful chemicals which have a negative impact on the health of consumers. Since the development of the times and technology, the impact on the circulation of herbal or traditional medicines is a concern for the health of consumers, in 2019, the POM Agency revealed a value of 6.2 billion rupiah of traditional medicines and health supplements that are illegal and/or contain medicinal chemicals (Cahyono et al., 2019). Traditional medicines and health supplements containing BKO have health risks, such as loss of vision and hearing, stroke, heart attack, liver damage, and even death (Perempuan, n.d.). Whereas in the previous year, 2015 BPOM revealed Rp 75.7 billion and raw materials traditional medicine for Rp. 63.35 billion traditional medicine which is illegal and harmful to health traditional medicines (Yusuf & Rohmah, 2020).

From the potential for losses due to the large number of dangerous circulating in the market that is necessary to protect consumers both materially and formally, because of the development of science and technology as a stimulus for the productivity and efficiency of traditional medicine business actors, so that the protection of the interests of consumers must be considered and be a serious concern (Zuhairi, 2016). Legal research methodology is a way to determine what is allowed

and not by humans and society based on applicable laws. This type of research is normative legal research. The data in normative legal research that are secondary data, namely books, books, laws and regulations, court decisions, legal theories and opinions of legal scholars (Wiratraman & Putro, 2019).

The approach is the legislation approach to legal products (Yunansah & Herlambang, 2017). The statutory approach is chosen as the approach to review the product of legislation or regulations related to the object of the research. This approach focuses on the question whether there is conformity and consistency in the legislation (Barakati, 2015).

Result and Discussion

Consumer Protection Against Traditional and Dangerous Medicines

The definition of legal protection in Indonesian dictionary is defined as all efforts made to provide legal certainty to citizens. For Hadjon, as quoted by Kadek Ayu, argues that legal protection means that legal subjects have protection related to their rights as creatures. The protection aims to avoid arbitrary actions. Thus, the consumer legal protection meant the fulfilment of the rights owned by consumers caused by those rights not being fulfilled (Sudewi et al., 2020).

The opinion of Sidabalok related to consumer protection that was the law regulates the rights and obligations of consumers and producers. They arise in their efforts to ensure the realization of legal protection for the interests of consumers. Meanwhile, according to Shidarta, Consumer Protection is a legal rule that can regulate the relationship and one of the problems between various parties related to consumer goods or services in a social life.

AZ opinion. Nasution related to consumer protection that is the overall rule of law protects consumers in their relationships and problems with business actors. Consumer protection contains principles or rules that regulate and protect consumers.(Zuhairi, 2016) While the principles in guaranteeing consumer protection as enshrined in Article 2 of Law Number 8 of 1999 concerning Consumer Protection are: first for benefit principle, second for fairness principle, third for balance principle, fourth for consumer safety and security principle, and fifth for legal certainty principle. meanwhile, the objectives of the consumer protection aspect contained in Article 3 of Law Number 8 of 1999 concerning Protection in order to be achieved include; the first for increasing consumer awareness; the second for raising the dignity of consumers; the third for improving consumer empowerment; the fourth for creating a consumer protection system.

Regarding consumer rights, it can be found in Article 4; first for the right to comfort, security, and safety; second for the right to choose goods; third for the right to correct information; fourth for the right to have their opinions and complaints heard; fifth for the right to get advocacy; sixth for the right to get guidance and education, seventh for the right to be served properly; eighth for the right to obtain

compensation, compensation.(Soekorini, 2015) The ways that can be done in the aspect of consumer protection are: first for creating a definite consumer protection system; second for protecting the interests of consumers; third for improving quality; fourth for coordination with other institutions to maximize the realization of consumer protection.

Supervision of Traditional and Dangerous Medicinal Products

The establishment of the Food Drug Supervisory Agency (*Badan Pengawas Obat Makanan/BPOM*) is caused by development of science and technology (*Ilmu Pengetahuan dan Teknologi/IPTEK*) resulting in changes to food products, beverages, health drugs. Therefore, BPOM is formed to be able to detect, supervise products to protect consumers for their safety and security (Soekorini, 2015). The Role of BPOM in Protecting Pollution and Sanctions for Violations for Producers and Their Solutions. BPOM is a Non-Ministerial Government Institution (*Lembaga Pemerintahan Non Kementrian /LPNK*) in accordance with the functions and authorities of BPOM as stated in Presidential Regulation Number 80 of 2017 concerning BPOM.

The functions of BPOM are first for preparation of program plans; second for laboratory inspection; third for quality testing and assessment; fourth for local inspection; fifth for inspection of production facilities; sixth for investigation and investigation; seventh for implementation of product certification (Tambuwun et al., 2020). While the authority possessed by the Food and Drug Supervisory Agency are first for issuing product distribution licenses and certificates; second for conducting intelligence and investigations; and third for giving administrative sanctions.

Meanwhile, the method of making traditional medicines is as regulated in PBPOM Number 34 of 2018 concerning Guidelines for Good Manufacturing Practices (*Cara Pembuatan Obat Yang Baik/CPOB*. CPOB is a way of making drugs to ensure the quality of the drugs produced in accordance with quality standards. The purpose protects the public from events that can harm health.

As for traditional medicines that can be circulated or distributed, they must obtain a distribution permit. Based on Article 6 of the Regulation of the Minister of Health of the Republic of Indonesia Number 07 of 2012 concerning Registration of Traditional Medicines, the criteria are as follows: First for using the safety requirements; Second for following the instructions from CPOTB; Third for using the requirements of the Indonesian Herbal Pharmacopoeia; Fourth for using the special product; Fifth for using the objective complete information.(Cahyono et al., 2019)

Meanwhile, the provisions regarding the establishment of traditional medicine businesses require a permit from the Minister of Health. In addition to this, a traditional drug business license can also be granted if the drug does not contain more than 1% ethyl alcohol. It does not contain medicinal chemicals that are not narcotics or psychotropics (Bolendea, 2019).

The forms of supervision carried out by BPOM include the following: 1. Regulation 2. Standardization. 3. Registration. 4. Inspection. 5. Sampling. 6. Public warning 7. Customer service.(Cahyono et al., 2019) From the form of supervision above, it is hoped that the circulation of traditional medicines in Indonesia can be prevented from an early age so that losses to consumers can be minimized.

Efforts to Settle Consumer Protection Disputes The

definition of a consumer as set out in article 1 point 2 of the Law on Consumer Protection is a user of goods available in the community, both for their own interests. There are the elements of the definition of Consumers as follows (Hariri, 2019): first for every person; second for users; third for goods and/or services; fourth for the available ones in society; fifth for self-interest, family, other people, other living beings; sixth for goods and/or services are not for trade.

Dangerous traditional medicines can be classified according to the stage of production, namely the presence of product defects, design defects, and the absence of honest information. The injured product can harm consumers.(Tambuwun et al., 2020) Based on Article 19 paragraph 1 of the Consumer Protection Law that business actors are responsible and obliged to provide compensation for goods that can cause losses.

The principle of absolute liability or the principle of strict liability is based on consumers who are victims. It relates to the reverse burden of proof. Regarding accountability, there are two principles that can be used, namely: First for product responsibility that producers are responsible for the circulation of products had a negative impact on consumers and Second for professional responsibility, namely legal responsibility, to determine whether an action violates professional responsibility, it is necessary to have a clear measure (Hariri, 2020).

In the provisions for the application of administrative sanctions, business actors are subject to compensation of a maximum of Rp. 200,000,000.00. Criminal Sanctions Criminal sanctions are a causal punishment, because it is the case and the result is the punishment, the person affected can be sentenced to prison or other punishment from the authorities (Mochklas & Hariri, 2019).

The criminal sanctions that are threatened against business actors of dangerous traditional medicines can be seen in the following table;

No.	Law 8 of 1999 concerning Consumer Protection	Norms

1	Article 60 (1)	The consumer dispute settlement agency is authorized to impose administrative sanctions on business actors who violate Article 19 paragraphs (2) and (3), Article 20, Article 25, and Article 26.
	Article 60 (2)	Administrative sanction in the form of stipulation of compensation for a maximum of Rp. 200,000,000.00 (two hundred million rupiah).
	Article 60 (3)	The procedure for determining administrative sanctions as referred to in paragraph (1) shall be further regulated in laws and regulations.
2	Article 61	Criminal prosecution can be carried out against business actors and/or their management.
	Article 62	(1) Business actors who violate the provisions as referred to in Article 8, Article 9, Article 10, Article 13 paragraph (2), Article 15, Article 17 paragraph (1) letter a, letter b, letter c, letter e, paragraph (2), and Article 18 shall be sentenced to a maximum imprisonment of 5 (five) years or a maximum fine of Rp. 2,000,000,000.00 (two billion rupiah).
	Article 62 (2)	Business actors who violate the provisions as referred to in Article 11, Article 12, Article 13 paragraph (1), Article 14, Article 16, and Article 17 paragraph (1) letter d and letter f shall be sentenced to a maximum imprisonment of 2 (two) years or a maximum fine of Rp. 500,000,000.00 (five hundred million rupiah).
	Article 62 (3) Any	violation that results in serious injury, serious illness, permanent disability or death shall apply the applicable criminal provisions.

	Article 63	For criminal sanctions as referred to in Article 62, additional penalties may be imposed, in the form of: a. confiscation of certain goods; b. announcement of judge's decision; c. payment of compensation; d. orders to stop certain activities that cause consumer losses; e. obligation to withdraw goods from circulation; or f. revocation of business license.

Regarding sanctions for violations made or violated by business actors/producers, we can see in Articles 60 to 63 of the Consumer Protection Law. In this case it means that this dispute is settled in a civil manner. However, it cannot also rule out the possibility of a legal relationship that occurs between business actors and consumers, it can also constitute a criminal law relationship. As can be seen in Article 19 paragraph (4) jo. Article 22 UUPK. This can happen if business actors are deemed to have harmed consumers and can be threatened with criminal law.

To minimize the occurrence of losses experienced by consumers raises awareness of business actors about the importance of consumer protection. Therefore, an honest attitude guaranteed quality of goods and does not contain harmful chemicals.

Business actors may be released from their responsibilities, namely: (1) if the goods are not intended to be circulated; (2) if the damaged goods arise in the future; (3) if the damaged goods due to compliance with the provisions regarding the qualification of goods; (4) the consumer negligence; (5) the expiration of the prosecution is 4 (four) years.

The dispute resolution of cases of dangerous traditional medicines can be pursued in two ways that are litigation and non-litigation. For litigation, it is to bring the case to a general court. How to sue traditional medicine business actors to court. Consumers with their legal representatives make a letter of claim, but before that the attorney must have a power of attorney from the consumer. It is in the form of a power of attorney which clearly and in detail states what the power of attorney is for.(Kristyanti, 2008) However, settlement by litigation is the *ultimum remidium*, which is the last option. Since the litigation path is also related to the relatively large costs and time spent and often do not find a win-win solution.

While the non-litigation route is dispute resolution outside the court. In this case, the Consumer Dispute Settlement Agency (*Badan Penyelesaian Sengketa Konsumen/BPSK*) is an institution that functions as a settlement of consumer disputes and traditional medicine business actors with a burden on health by means of mediation or consolidation or arbitration. BPSK can be authorized to resolve disputes

between business actors and consumers outside the court. In addition to BPSK, the law also regulates the National Consumer Protection Agency (*Badan Perlindungan Konsumen Nasional/BPKN*), and the Non-Governmental Consumer Protection Agency (*Lembaga Perlindungan Konsumen Swadaya Masyarakat/LPKSM*).

Conclusion

Consumers who are harmed by harmful traditional medicines can receive legal protection. It is contained in Article 19 paragraph 1 of Law Number 8 of 1999 concerning Consumer Protection. The sanctions for business actors who produce dangerous traditional medicines can be subject to administrative sanctions in article 60 as well as criminal sanctions as written in article 61 to article 62 as well as additional penalties regulated in article 63 of the Law on Consumer Protection. To minimize the occurrence of consumer losses carried out by irresponsible drug businesses is to maximize the role and function of the Food and Drug Supervisory Agency (*Badan Pengawas Obat dan Makanan /POM*). The task of BPOM is to supervise production and distribution. Meanwhile, dispute resolution can be through litigation, non-litigation, or the Consumer Dispute Settlement Agency.

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