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Legal Study on Supervision of Traditional Drug and Supplements During Pandemic in Jayapura City

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Abstract

Traditional medicine is one of the alternative medicine which is widely used on the society, including at the Jayapura city. The purpose of this research is to identify the supervisory of the traditional medicine and supplement on this pandemic at Jayapura city and to analyze the responsibility of the businessman of the traditional medicine and supplement. This research is normative research. The result showed that the National Agency of Drug and Food Control (BPOM) has conducted good supervision on the distribution of traditional medicine at Jayapura in order to ensure the traditional medicine is safe to consume. In terms of an error arising from the consumption of the traditional medicines and food supplements, the business actor is responsible and providing compensation.

Keywords: UN General Assembly; The United Nations; Human Rights and Humanitarian Law

1. Introduction

On the implementation of health development, it requires a new perspective that prioritize the preventive and promotive efforts without neglecting the curative and rehabilitative efforts, known as "Healthy Paradigm". In line with the healthy paradigm, the independence of society needs to be pushed to stay healthy through communication, information and education.

The health problems are a comprehensive problem at all levels of society, not just occurred on the poor and underprivileged groups but also can occurred on the privileged group level. In this case, it can be referred that health is one of a complex problems and comprehensive at all levels on society. Of course, we seen that underprivileged group become the most vulnerable group which cannot obtain health access, because the low level of education and social-economic level of society, especially related with the self-care to keep healthy.

Traditional medicine is an important component on the health services. Besides on relieving the symptoms of a disease, traditional medicine can also prevent a disease and event curing the disease. But on the other hand, traditional medicine can cause an unwanted effect if the it used incorrectly. Therefore, providing a true, objective, and complete information will be supporting on giving a good service to the society so it can increase the benefit and security of the traditional medicine usage.

On this context, society as the traditional medicine user, placed as consumer which protected by the Law No. 8 of 1999 concerning of Consumer Protection (UU PK). The existence of the Consumer Protection Law is expected to giving a positive influence for the businessman and the consumer, which can be seen on the purposes of the consumer as stated on the Article 3 of Consumer Protection Law, which stated "to improve the awareness, ability and independence of the consumers to protect themselves, to enhance the integrities and values of the consumers by avoiding negative excess of using the goods and/or services. to improve the ability of the consumers to select, determine and claim their rights as consumers, to create a consumers protection system containing legal security and information transparency and access to information, to develop entrepreneur's awareness on the importance of consumers protection. Thus, creating an honest and responsible behavior in conducting their business, to improve the quality of the goods and/or services which will guarantee the business will continue producing goods and/or services, conforming to health, comfort, Security and safety to the consumers.²

Seen the purpose of consumer protection as stated on the Article 3 of Consumer Protection Law, the businessman is expected to have awareness about the importance of consumer protection and responsibility on doing business including giving a traditional medicine service to the society. Therefore, on a business it's have a big responsibility on giving a traditional medicine service to the consumer. According to the supervision result, sampling and laboratory testing, the National Agency of Drug and Food Control (Badan POM) have made an instruction to withdraw the traditional medicine and supplement from market which contain medicinal chemical Sibutramine Hydrochloride, Sildenafil Citrate, Tadalafil, Dexamethasone, Phenylbutazone, Mefenamic Acid, Methampirone and Paracetamol as many as 60 items.

Therefore, the focus of this research is how the supervisory of the traditional medicine and supplement on this pandemic at Jayapura? and how the businessman responsibility on the traditional medicine and supplement?

2. Research Method

This research is normative research that examine the problems related to the supervision of the traditional medicine and food supplement containing traditional medicinal chemical. This research is done at National Agency of Drug and Food Control of Papua Province, because the institution is authorized to supervise the existence of traditional medicine and supplement on this pandemic at Jayapura City. The was collected through observation, interview, and literature review. The collected data then analyzed qualitatively.³

3. Result and Discussion

3. 1 General Description of National Agency of Drug and Food Control (BPOM)

- a. According to President Decree No. 166 of 2000 concerning of National Agency of Drug and Food Control, it is pointed as a government institutional non-department which responsible to the president and coordinating with the Ministry of Health and Social Welfare.
- b. The main secretary coordinates the strategic and organizational planning, employee development, financial management, legal assistance and legislation, public relation and international cooperation, as well as public access to the National Agency of Drugs and Food Control through the Consumer

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¹ Miru, A. & Yodo, S. 2004. Hukum Perlindungan Konsumen. Jakarta: PT. Raja Grafindo Persada. p.1

² Brotosusilo, A. 1999. Dampak Undang-Undanag Nomor 8 Tahun 1999 tentang Perlindungan Konsumen Bagi Pelaku Usaha dan Konsumen. Jakarta. p.45

³ Sunggono, Bambang. 2004. Metodologi Penelitian Hukum. Jakarta: Raja Grafindo Persada

Complaint Services which receives and follows up on complaints from the public in the field of medicine and food. Besides that, the administrative guidance is carried out in several centers within the National Agency of Drugs and Food Control and its technical units which spread throughout Indonesia.

c. On the National Agency of Drugs and Food Control there also a Drug and Food Investigation center whose task is to carry out an investigation into unlawful acts in the field of products such as therapeutics, narcotics, psychotropics and additive substance, traditional medicine, cosmetics, and complementary products and food, and other similar products and there also a food research center whose task is to provide a research in the field of toxicology, safety, food and therapeutic products research, and there also a drug and food information center whose task is to provide drug and food information services, information on poisoning and coordination of information technology activities of National Agency of Drugs and Food Control.

d. Those are violation on:⁴

- 1. The Law No. 36 of 2009 concerning of Health, Article 197 jo. Article 106 Paragraph (1):
 - "Anybody who is intentional produce and/or distribute pharmaceutical supply and/or medical equipment without distribution permit as referred to in Article 106 paragraph (1) shall be convicted with imprisonment at the longest 15 (fifteen) years and fine at the most Rp1.500,000,000.00 (one billion five hundred million Rupiah)."
 - Article 106 Paragraph (1): Pharmaceutical preparation and medical devices can only be distributed after obtaining a distribution permit.
- 2. The Law No. 36 of 2009 concerning of Health, Article 196 jo. Article 98 Paragraph (3):
 - Article 196: Anybody who is intentionally produce and/or distribute pharmaceutical supply and/or medical equipment which do not meet the standard and/or requirement of the safety, efficacy or usefulness, and quality as referred to in Article 98 paragraph (3) shall be convicted with imprisonment at the longest 10 (ten) years and fine at the most Rp. 1,000,000,000.00 (one billion Rupiah).
 - Article 98 Paragraph (3): Provision concerning procurement, storage, processing, promotion, circulation of pharmaceuticals and health equipment to meet quality service standards established by the pharmaceutical Government Regulation.
- 3. The Law No. 8 of 1999 concerning of Consumer Protection, Article 8 paragraph (2) jo. Article 62 Paragraph (1) stated:⁵
 - Article 8 Paragraph (2): Entrepreneurs are prohibited from trading damaged, defective or used and tainted goods without providing complete and correct information.⁶
 - Article 62 Paragraph (2): Entrepreneurs who violate the provisions as intended by Article 8, Article 9, Article 10, Article 13 Paragraph (2), Article 15, Article 17 Paragraph (1) point a, point b, point c, point e, and Section 2, and Article 18 shall face a maximum criminal penalty of 5 (five) years imprisonment or a maximum fine of Rp. 2000,000,000,- (two billion rupiah).

3.2 Supervisory of Traditional Medicine and Supplement at Jayapura City

To understanding the problems, it needed to find a solutions, in order to lead to the goals, therefore it need a conceptual framework of thought that departs from theories that are relevant to the problem. The approach which the writer used is a concept where the role of National Agency of Drug and Food Control (BPOM) on consumer protection for traditional medicine and supplement to increase male stamina in carrying out activities as social control or community control for the distribution of the

⁴ Shofie, Y. 2003. Perlindungan Konsumen dan Instrumen-Instrumen Hukumnya. Bandung: Citra Aditya Bakti

⁵ Sidabalok, J. 2006. Hukum Perlindungan Konsumen di Indonesia. Bandung: PT. Citra Aditya Bakti.

⁶ Wijaya, J.G., Yani, A. 2003. Hukum Tentang Perlindungan Konsumen. Jakarta: PT. Gramedia Pustaka Utama. p. 15-16

pharmaceutical industry products, original Indonesia medicine, food, cosmetics and medical health which are inseparable system and event an integral part which influence each other.

It said that the relation between people or consumer on the social system is one unit of the social interaction which then build a structure, means that those element is interdependent part and merge with social system. Therefore, the role of National Agency of Drug and Food Control (BPOM) especially National Agency of Drug and Food Control (BPOM) of Papua Province in carrying the social control or society role is a social system which build from the interaction between developed individual according to the standard of value and mutual agreement. Therefore, the role of National Agency of Drug and Food Control (BPOM) in carrying the society control is one of social activities, whereas the perpetrator in this case seen have ability to make a choice to act, but their act is limited and possible by the environmental state and biological state or limited by the value and norms which control the social structure. In other words, the acts seen from the social reality which are the basis or the smallest one.

The supervisory of traditional medicine and supplement has been attempted by National Agency of Drug and Food Control at Jayapura by giving warning to the business actors to not selling traditional medicine and food supplement which contain Medicinal Chemical. In reality at Jayapura, traditional medicine and food supplement which containing medicinal chemical which are sold at pharmacy, local medicine shop, or stall still exist, therefore it needed more supervisory or waning from the related agency in this case are the duties and the authorities of National Agency of Drug and Food Control to supervise and giving warning to the business actors or the traditional medicine and food supplement seller which containing medicinal chemical. The supervision which held by the National Agency of Drug and Food Control of Papua Province, every month there is an inspection at the pharmacy, drug store, or stalls at Jayapura and if there are sales of pharmacies, drug store, or in stall than the National Agency of Drug and Food Control will provide a guidance, but if coaching has been carried out, and on the next month there still a sales of traditional medicine and male stamina enhancing food supplement which containing medicinal chemical, then a warning will be issued to the seller.

3.3 Analysis of the Responsibilities of Traditional Medicines and Supplement Business

The government in this cas'e as the authority whom established the standard and condition of health so the stamina booster traditional medicine and supplement is safe to consume by the society and has been regulated on the Law of Consumer Protection that the traditional medicine and supplement cannot be sell if it contains medicinal chemical.

The form of the responsibility of the business actors on the Law No. 8 of 1999 Concerning of Consumer Protection, on one article which regulated about the responsibility which are Article 19 of Consumer Protection Law stated:

- (1) Entrepreneurs are obligated to give compensation for the damage, taint and/or losses the consumers suffer as a result of using or consuming the goods and/or services produced or traded by the entrepreneurs.
- (2) Compensation as untended by Section 1 above can be in the form of refund or goods and/or services of the same type or has equal value, or in the form of health care and/or insurance coverage in accord with the prevailing law.
- (3) Compensation shall be given within the period of 7 (seven) days after the date of transaction.
- (4) Compensation as intended by Section 1 and Section 2 above shall not exclude the possibility of a criminal charge based on further evidence of the existence of a fault.

(5) The provisions as intended by Section 1 and Section 2 above shall not be valid if the entrepreneurs can prove that the consumer is at fault.

The principle of responsibilities is a very important subject in consumer protection law. In cases of consumer rights violations, it needed a caution in analyzing who should be responsible and how far the responsibilities can be assigned to the related parties.

With many cases of traditional medicine and supplement which containing medicinal chemical then the business party in his case are pharmacy, drug store or stall should responsible if from the result of selling the stamina booster traditional medicine and supplement for men containing medicinal chemical resulting a harm to the consumer or in this case the customers are harmed. It can be seen on the Article 19 Paragraph (1) of the Consumer Protection Law, that the business actors responsible on giving compensation for the damage or loss for consumer due to consuming goods and/or services which produced or sell. Therefore, if there is a damage or loss caused by men stamina booster traditional medicine and supplement containing medicinal chemical then the seller should give a compensation to the consumer and if the consumer were got a damaged caused by consuming the traditional medicine and supplement, then the seller party should be giving a compensation in form of health fund which have been used by the consumer for a treatment. This is in line with Article 19 Paragraph (2) of Consumer Protection Law which are compensation, as stated on paragraph (1) can be in form of refund or goods and/or services of the same type which are equal and in line with the laws and regulation.

Conclusion

From description above, it can be concluded that the supervisory on traditional medicine and supplement at Jayapura has been attempted by the by National Agency of Drug and Food Control and giving a warning to the business actor to not selling traditional medicine and supplement which contains a medicinal chemical. In terms of the traditional medicine and supplement business responsibilities, then the actors should give a compensation for the damage and/or loss for the consumer caused by consuming the goods and/or services which produced or sell.

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