Legal Substance in the Supervision of Traditional Medicines Containing Medicinal Chemicals as an Effort to Protect Consumers in Indonesia

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Abstract

Traditional medicine is a product made from natural ingredients with very diverse types and properties, so to ensure the quality of traditional medicine, an exemplary manufacturing method is needed. The Food and Drug Supervisory Agency (as BPOM for short) still finds a number of traditional medicinal products where medicinal chemicals are mixed (abbreviated as BKO). Thus, the widespread circulation of traditional medicines without permission to distribute has become urgent today to protect consumers of conventional medicines. This study analyzes how the legal substance and form of supervision of traditional medicines containing medicinal chemicals is a form of consumer protection in Indonesia. This is legal research that uses qualitative methods with analytical descriptive data analysis techniques. This article concludes that the substance of the legislation that regulates supervision and sanctions related to the circulation of traditional medicines containing medicinal chemicals or which do not meet the requirements is sufficient. However, there need to be more explicit implementation rules regarding technical implementation, including rules for dividing tasks and authority between related parties. The supervision of traditional medicines containing medicinal chemicals has not been adequate. This is caused by various obstacles, one of which is the low level of public knowledge about traditional medicines containing medicinal chemicals or those that do not meet the requirements and the low active role of the community in the implementation of supervision.

Keywords: Law, traditional medicine, supervision, society, and medicinal chemicals

1. Introduction

The use of traditional medicine in Indonesia is part of the nation's culture and has been used by the community for centuries in the treatment and maintenance of public health. The WHO recommends using traditional medicines, including herbs, to maintain public health, and prevent and treat diseases, especially chronic diseases, degenerative diseases, and cancer. WHO also supports efforts to improve the safety and efficacy of traditional medicines (Saputra, 2017).

In the National Health System, it is stated that the development and improvement of traditional medicines in Indonesia are aimed at obtaining traditional medicines that are of high quality, safe, have tangible properties that are scientifically tested, and are widely used, both for self-medication by the community and used in formal health services. Making traditional medicine a superior commodity that provides multiple benefits for the community, namely improving the community's quality of health and economic growth, providing job opportunities, and reducing poverty and various other benefits need to be improved (Wirastuti, Dahlia, & Najib, 2016).

Indonesian traditional medicine is the nation's cultural heritage, so it needs to be explored, researched, and developed to be used more widely by the community. Regarding this, the government has made regulations contained in Law Number 36 of 2009 concerning Health Article 100 paragraph (1) that Sources of traditional medicines that have been proven to be efficacious and safe to use in the prevention, treatment, care, or permanent health maintenance preserved. The government has also guaranteed the development and maintenance of raw materials for traditional medicines, as contained in paragraph (2) (Haerandi, 2020).

In the last decade there has been a global trend of going back to nature with the emergence of various modern drugs and new types of modern drugs in the market. Factors encouraging people to use natural medicines include high cost and many side effects of modern/synthetic medicines. Also, promotional materials through mass media play a role in increasing the use of natural medicines (Sudevi, Budiyarth, & Ujiti, 2020). Hence, naturopathy is becoming increasingly popular. Their use is increasing in developing countries such as Indonesia and developed countries such as Germany and the United States.

The increasing public interest in traditional medicine has spurred the pharmaceutical industry in Indonesia to participate in producing traditional medicines. In 2015 the number of pharmaceutical industries

producing traditional medicines registered with the POM was 210 companies and increased to 227 in 2020. The number of industries producing traditional medicines until the end of 2020 in Indonesia was 129 herbal medicine industries, with 22 companies producing herbal medicines standardized (OHT) (Warsiki, Irianti, & Christina, 2021).

To provide a conducive business climate for producers of traditional medicines, it is necessary to regulate the industry and business of traditional medicines by considering the safety, efficacy/benefits, and quality of the traditional medicines made. The implementation of licensing for the traditional medicine industry, which was previously regulated in the Regulation of the Minister of Health Number 246/Menkes/Per/V/1990 concerning Traditional Medicine Industry Business Permits and Registration of Traditional Medicines, is considered to be incompatible with the development of science and technology as well as legal requirements (Yudiatmaja et al. 2021).

For this reason, the government reorganized the traditional medicine industry by issuing the Minister of Health Regulation Number 006 of 2012 concerning the Traditional Medicine Industry and Business. Following the applicable laws and regulations, traditional medicines are prohibited from using isolated or synthetic chemicals with medicinal properties, narcotics or psychotropics, and protected animals or plants. In order to protect the public from the circulation of traditional medicines that do not meet the requirements for safety, efficacy/benefit, and quality, on February 13, 2012, the Minister of Health signed the Regulation of the Minister of Health Number 007 of 2012 concerning Registration of Traditional Medicines (Puspitasari et al. 2018). This is following the mandate of Law Number 36 of 2009 concerning Health Article 105 paragraph (2) that pharmaceutical preparations in traditional medicines, cosmetics, and medical devices must meet the specified standards or requirements.

Traditional medicine is a product made from natural ingredients whose very diverse types and properties. To ensure the quality of traditional medicine, an exemplary manufacturing method is needed with more attention to the production process and handling of raw materials (Vandebroek et al. 2014). Good Manufacturing Practices of Traditional Medicines (abbreviated as CPOTB) covers all aspects related to the manufacture of traditional medicines, which aim to ensure that the products produced always meet the quality requirements that have been determined according to their intended use. Product quality depends on starting materials, production processes, quality control, buildings, equipment, and handling personnel (Haerandi, 2020). The application of CPOTB is an essential eligibility requirement for implementing an internationally recognized quality assurance system. For this reason, a quality system should be built, strengthened, and implemented so that the established policies and the desired goals can be achieved. Thus, the application of CPOTB is an added value for Indonesian traditional medicinal products so that they can compete with similar products from other countries, both in the domestic and international markets.

Given the importance of implementing CPOTB, the government continuously facilitates the traditional medicine industry, both large and small, to implement CPOTB through programmed steps and stages. With the development of types of natural medicinal products, not only in the form of Traditional Medicines (Jamu) but also in Standardized Herbal Medicines and Phytopharmaceuticals, this Guide to Good Traditional Medicine Manufacturing Practices can also be applied to industries that produce Standardized Herbal Medicines and Phytopharmaceuticals (Sari, 2015).

The widespread circulation of traditional medicines without distribution permits is the urgency of protecting consumers of traditional medicines today. Moreover, it is also necessary to pay attention to the certainty and guarantee that after registration by BPOM, things will not happen that will harm consumers, which producers can do without the knowledge of BPOM. In this case, of course, consumers must get legal protection if things happen that harm consumers. The position between consumers and producers is equal so that consumers of traditional medicinal products also have rights that need to be known by producers. The interests of these consumers are protected and regulated in Law no. 8 of 1999 concerning Consumer Protection (abbreviated UUPK).

Cases of violations of traditional drugs that are often encountered today are: registered containing medicinal chemicals, registered but not meeting pharmaceutical requirements, not registered, advertisements not meeting the requirements: and overclaim. The phenomenon of traditional medicines and herbs which are attached/containing strong medicinal chemicals has been found around 93 brands of herbal medicines and traditional medicines mixed with strong medicinal chemicals by the Food and Drug Supervisory Agency (BPOM), such as traditional medicines produced by manufacturers medicines from China as well as several regions in Indonesia, including Banyumas, Jakarta, Makassar, Cilacap, Malang, Solo and Central Java which have been proven to be mixed with solid medicinal chemicals (BKO) of the type phenylbutazone, metampirone, dexamethasone, CTM, allopurinol, sildenafil citrate, paracetamol, and sibutramine hydrochloride. The use of those mentioned above complex medicinal chemicals (BKO) as a mixture in

traditional medicine without a prescription and supervision from a doctor can endanger the health and can even cause death (Roihanah, 2020).
Based on the results of BPOM supervision in 2021, as many as 64 products (0.65 percent) of the total 9,915 traditional medicinal products that have been sampled and tested are known to contain BKO. The most widely added BKOs were Sildenafil Citrate and its derivatives (claims of Traditional Medicine for male stamina), Paracetamol (claims of Traditional Medicine for aches and pains), Tadalafil (claims of Traditional Medicine for male stamina), Dexamethasone (claims of Traditional Medicine for aches and pains), and Sibutramine hydrochloride (claims of Traditional Medicine for aches and pains) Traditional medicine slimming). BPOM always carries out comprehensive supervision of Traditional Medicines, including the possibility of mixing them with Medicinal Chemicals (BKO).
The Risk Analysis of the findings of the supervision of Traditional Medicines-BKO by BPOM within ten years showed the following trends: 1) At first, the findings of Traditional Medicines-BKO showed a trend toward rheumatic drugs and painkillers, for example containing Phenylbutason and Metampiron; 2) Since 2017 the findings of Traditional Medicines-BKO have shown a changing trend towards slimming and stamina drugs, including those containing Sibutramine, Sildenafil, and Tadalafil; 3) Most of the surveillance findings are illegal products or are not registered with BPOM, but include a fictitious registration number on the label (Roihanah, 2020). Based on the risk analysis of the supervision of Traditional Medicines-BKO, the supervision of traditional medicines circulating in the first half of 2021 still found traditional medicines containing medicinal chemicals (BKO), which were prohibited from being mixed into traditional medicines. Until now, BPOM still finds several traditional medicinal products mixed with medicinal chemicals (BKO). BKO in traditional medicine is the selling point for producers. This may be due to the lack of knowledge of producers about the dangers of consuming medicinal chemicals uncontrolled, both in dosage and how to use them, or even simply to increase sales because consumers like traditional medicinal products that react quickly to the body. Consumers who are not aware of the dangers of the traditional medicines they consume, let alone pay attention to the contraindications for the use of some chemicals for sufferers of specific diseases or the interactions of drug ingredients that occur when users of traditional medicines are taking other medicines, are of course very dangerous. In this regard, it is necessary to study the legal substance in the supervision of Traditional Medicines containing Medicinal Chemicals as a form of consumer protection in Indonesia.

2. Method

This type of research is legal research that uses qualitative methods. In this study, the researcher tried to use a qualitative approach to reveal events or reveal hidden values by analyzing secondary data presented descriptively. Thus, this study uses a descriptive-analytic approach (Sedarmayanti & Hidayat, 2002). Sources of data used in this study are secondary data consisting of 1) Legal Theory and legal science textbooks relevant to the research problem; 2) Opinions or interpretations of various parties, both obtained directly through textbooks and journals; 3) Data obtained from relevant agencies in the form of documents related to research; 4) The results of previous studies that are relevant to the research problem. The data obtained were analyzed qualitatively and then presented in an analytical descriptive manner, describing and explaining the research problem (Soekanto & Mamudji, 1995).

3. Result and Discussions

3.1 Legal Substance in the Protection of Consumers from the Abuse of Traditional Drugs Containing Medicinal Chemicals

Law Number 8 of 1999 concerning Consumer Protection and Law Number 36 of 2009 concerning Health clearly explain drug products that have been mixed with other substances, namely Article 386 paragraph 1 and paragraph 2. Article 386 paragraph 1 states that: Whoever sells, offers, or delivers goods of food or drink or medicine, while knowing that the goods are counterfeit or the counterfeit is hidden, is sentenced to a maximum imprisonment of four years. Paragraph 2 states that goods of food, drink, or medicine are considered counterfeit if their price or use is reduced because they have been mixed with other substances. According to the researchers, the issue of public legal protection of products, especially drugs that could endanger public health, has long been a matter of concern for the government. The role of the government in its efforts to protect public health from drug abuse is becoming increasingly visible through the enactment of section (1) of section 104 of the Act No. 36 of 2009 that pharmaceutical preparations and safety of medical equipment have been directed to protect the public from the risks posed by pharmaceutical

preparation and use that do not meet the requirements of quality or safety or efficacy/convenience. Article (2) says: The use of medicines and conventional medicines must be done logically. The use of traditional medicine must meet predetermined standards or requirements, as stated in Article 105: Pharmaceutical preparations in traditional medicine and cosmetics and medical devices must meet certain standards or requirements.

The government's role related to supervision has also been regulated in Law Number 36 of 2009 concerning Health in Chapter XVIII concerning Guidance and Supervision. Coaching is carried out through a) communication, information, education, and community empowerment; b) utilization of health workers; and c) financing. In terms of supervision, Article 182 paragraph (1) states that: The Minister supervises the community and every organizer of activities related to resources in the health sector and health efforts. In carrying out supervision, the Minister may delegate to non-ministerial government institutions, heads of provincial and district/city offices whose main tasks and functions are in the health sector as regulated in Article 182 paragraph (3) and paragraph (4) states that the Minister In carrying out the supervision, the community is involved (Sutedi, 2008).

Following the principles of development, which state that development is carried out jointly by the community and the government and therefore becomes a shared responsibility. Government efforts to protect the public from harmful products can be carried out by regulating, supervising, and controlling products' production, distribution, and circulation so that consumers are not harmed, both their health and finances (Miru & Yodo, 2004).

Supervision of traditional medicines circulating in the market has an essential meaning in achieving optimal health status. The role of consumer protection against various health risks from traditional medicinal products containing medicinal chemicals or those that do not meet these provisions is in line with Law no. 8 of 1999 concerning Consumer Protection. Supervision carried out in consumer protection efforts is carried out by the government, the community, and non-governmental consumer protection institutions, as mandated by Law Number 8 of 1999 concerning Consumer Protection Article 30 paragraph (1) that supervision of the implementation of consumer protection and the application of provisions the laws and regulations are administered by the government, the community, and non-governmental consumer protection institutions (Zuhaid, Turisno, & Suharto, 2016).

The formulations included in the Consumer Protection Act (UUPK) reflect consumer protection as one of the national legal subsystems, including the following: The Consumer Protection Act is intended to be a solid legal basis for public and private consumer protection organizations to empower consumers through consumer coaching and education.

In the future, there is still the possibility of forming a new law that has provisions to protect consumers. Thus, this law on consumer protection is an umbrella that integrates and strengthens law enforcement agencies in consumer protection. A provision of the Consumer Protection Act (UUPK), namely Article 64 (interim provision of Chapter XIV) is as follows: It is not expressly regulated or in conflict with the provisions of this Act.

This provision ensures that the Consumer Protection Act (UUPK) is a special provision of the existing statutory provisions (Lex Specialis) that lex specialis derogate leggy generali follows. This means that provisions outside the Consumer Protection Act (UUPK) will remain valid unless they are explicitly regulated in the Consumer Protection Act (UUPK) or are in conflict with the Consumer Protection Act (UUPK).

In this context, it is consistent with what was said by Suedi (2008), that special laws override common laws if manufacturers are the same. This means that memorable events must be considered by a law that refers to the event. However, such special events can also be treated by a law that refers to a broader or more general event, which may also include special events.

Judging from its content, this Consumer Protection Act outlines protections for consumers, which again can be regulated in separate laws. This Consumer Protection Act contains the following: 1) general provisions; (2) principles and objectives; 3) rights and obligations; 4) prohibited activities for business actors; 5. Provisions for inclusion of standard clauses; 6) responsibility of business actors; 7) guidance and supervision; 8) National Consumer Protection Agency (BPKN); 9) Private Consumer Protection Agency (LPKSM); 10) dispute resolution; 11) Consumer Disputes Redressal Agency (BPSK); 12) investigation; 13) prohibition; 14) Interim provisions and 15 closing terms.

According to the researchers, Section 30 of the Consumer Protection Act, which regulates the supervision of the implementation of consumer protection in substance, did not provide adequate measures for consumer protection. The implementation of supervision in the article focuses on the role of communities and private consumer protection organizations (as in short LPKSM), who do not have adequate skills, adequate time, adequate costs, and do not have the facilities and infrastructure to supervise. Meanwhile, the government

only acted after receiving reports from the public about deviations from applicable laws and regulations and endangering consumers (Miru & Yudo, 2004).

According to the researcher, the article governing the implementation of consumer protection oversight should not put the government in a passive position that only acts after reports or complaints from the public. However, the government, the community and the LPKSM have to be jointly supervised. If necessary, the government must be the forerunner and regulator in implementing supervision because the government must have adequate efficiency and expenditure and have supervision facilities and infrastructure.

The criminal provisions against businessmen who cause harm to the public are very clearly and firmly stated in the Act No. 8 of 19 on Consumer Protection, Chapter XIII on Prohibition, The First Part on Criminal Prohibition, Article 61: Criminal business or its management may be prosecuted criminally. In Law 8 of 19 on consumer protection, sanctions against business actors are divided into two types of sanctions: a) criminal sanctions and b) administrative sanctions. Criminal sanctions are regulated in Articles 62 and Article 63.

Article 62 states: (1) Businessmen who violate the provisions mentioned in Article 8, Article 9, Article 10, Article 13 Paragraph (2), Article 15, Paragraph 17 Paragraph (1) Letter A, Letter B, Letter C, Letter E, Paragraph (2) and Article 18, shall have 5 (five) years or a maximum of 2,0,0,000 (two billion taka); (2) If any business person contravenes the provisions mentioned in article 11, article 12, paragraph 13 paragraph (1), paragraph 14, paragraph 16 and article 17 paragraph (1), paragraph d and f, he shall be punished with imprisonment for a term which may extend to two (two) years. or a maximum of Rs. 500,000,000.00 (Rs. 500 million); 3) Criminal provisions applicable to violations resulting from serious injury, serious illness, permanent disability or death are applied (Rohana, 2020).

Article 63 provides for additional punishment. Following the criminal code, punishment can be divided into leading offenses and additional offenses. A person sentenced for a criminal act can receive both primary and additional punishments, and only the original punishment, but not just additional punishments. Article 63 of Article 8 of The Act No. 19 states: Additional penalties may be imposed for the criminal order referred to in Article 62, a) confiscation of certain goods; (b) declare the decision of the Judge; (c) payment of compensation; d) an order to stop certain activities that harm the consumer; e) obligation to withdraw goods from circulation; or f) cancellation of business licenses (Rusley, 2012).

UUPK has provided adequate measures in case of sanctions as it includes articles on sanctions, administrative sanctions, fines, and criminal sanctions. However, according to the researcher, several provisions are incorrect, such as Article 60 of Article (2), which regulates administrative sanctions in the form of determining compensation. Indemnity sanctions are not administrative sanctions because they are not administrative, such as the temporary cancellation of business licenses for business actors who violate the administration. A number of methods can be adopted to analyze the legal protection of the public in relation to the protection of traditional medicinal products, including: first, to view the public as consumers, secondly, to view the public as a legal object among legal state-protected government officials.

According to Law 8 of 19 relating to Section 4 of the Consumer Protection, there are generally rights and obligations protected by law by assuming the consumer public to be consumers. Suppose in a legal state protected by government officials, the consumer public is seen as a legal object in society. In that case, the government can represent consumers in judging business actors on behalf of consumers. This is stated in Article 46, Article 1. In Law No. 8 of Act No. 19 relating to consumer protection, following the strictures relating to prohibition in Chapter 13, there are basically criminal prohibitions of all consumer protection rules in the Consumer Protection Act (UUPK) (Article (1) and Article (2) and Article (2) (Fatemabati, 2019).

Criminal law as a means of social defense aims to protect the interests of the community: 1) to maintain order in society; 2) Protection of community members from crimes, harm or unjust dangers committed by others; 3) Correction (re-socialization) of law breakers; 4) Maintaining/maintaining the integrity of the basic visions of social justice, human dignity, and personal justice (Mullianto & Sulchan, 2021).

Criminal sanctions in the Consumer Protection Act (UUPK) are considered to be consistent with the requirements for protecting and protecting interests enacted in consumer rights (Article 4). The existence of civil sanctions (Article 19 paragraph (1); Article 18(3) of the Consumer Protection Act (UUPK) and state administrative sanctions (Article 8 article (4) are expected to have a deterrent effect on the UUP. If initially, criminal law was used when other legal tools could not protect consumers, so on the contrary, the Consumer Protection Act (UUPK) has started a new paradigm that criminal law is used in conjunction with other legal tools (Nugroho, Nurochmat, & Hardjanto, 2016).

Regarding the problem of traditional medicines containing medicinal chemicals or medicinal chemicals that do not meet the safety standards/requirements, it also mentions the imprisonment and penalty mentioned in Section 196A of the 2009 Act No. 36A on Health that anyone intentionally produces or distributes pharmaceutical preparations or medical equipment that does not meet the safety standards or requirements, efficacy or facilities and quality standards, A maximum of 10 (ten) years of imprisonment and a maximum of 1, the fine will be Rs 000,0,000.00 (one billion rupees).

In addition to imprisonment and fines for their conduct, criminal acts committed by corporations can be imposed in the form of fines with a weight of 3 (three) times the criminal penalty, which is regulated in Article 201 paragraph (1). Furthermore, Article (2) states that in addition to penalties, corporations may be subject to additional penalties in the form of cancellation of business licenses or cancellation of the status of a legal entity.

According to the researcher, the difference between the application of criminal sanctions given to merchants producing or distributing goods that do not meet the standards or requirements of Law No. 8 on Consumer Protection (UUPK) can be seen in the length of long incarceration related to health with Law No. 36 of 2009.The number of fines and additional fines. While the Consumer Protection Act provides for a maximum of five (five) years in jail, a maximum fine of Rs 2,0,000,000 (Rs 200 crore) has been imposed.

Section 63 of the Consumer Protection Act provides for confiscation of certain products for additional penalties; pronouncement of the judge's verdict; payment of compensation; orders to stop certain activities that harm consumers; obligation to withdraw goods from circulation; Or canceling the business license. Implementation of consumer protection regulations relating to the provision of punishment for any violation of applicable provisions is also essential. This punishment is sometimes necessary if the violation is such that it does not happen again or that the other party does not repeat it. This punishment or sanction granted by the government (executive) is in the form of administrative sanctions that can be enforced periodically, ranging from warnings and fines to the cancellation of business licenses.

3.2 Control System for Traditional Medicines Containing Medicinal Chemicals as an Effort to Protect Consumers

Suti (2008) explains that preventive supervision is done through pre-audit before work begins, for example, overseeing the preparation of work plans, budget plans, human resource utilization plans, and other sources. Furthermore, repressive supervision is carried out through post audits, including inspections of on-site implementation (inspections), requests for reports, etc. The implementation of supervisory activities often may not provide adequate results. This occurs due to a number of factors, the most prominent of which are: lack of awareness and understanding of the supervision of both supervisors, party supervision, and the community, lack of integration of the supervisory system, lack of coordination of supervision, lack of human resources, lack of costs and means of supervision, and unclear follow-up of supervision.

In general, supervision conducted by BPOM includes three methods, namely surveys, research, and laboratory tests, which deal with aspects of pre-market and post-market supervision. Pre-market supervision is the supervision of traditional medicinal products before they are promoted, which includes standardization, guidance, auditing of appropriate traditional drug production methods, and evaluation and testing of safety quality before traditional medicines become conventional. Pre-market supervision can be considered preventive supervision. Post-market supervision is carried out after conventional medicinal products are disseminated within the community, which includes inspections of production and distribution facilities, monitoring of samples and laboratory tests, evaluations and advertisements or dissemination of conventional traditional medicines, side effect monitoring, and dissemination of information through public education and public alertness (Fatmawati, 2019).

Things included in the supervision of the pre-market are inspection of facilities, administrative inspection, and laboratory testing. So under supervision, there must still be a pre-market. Laboratory testing at pre-market is usually carried out at the initiative of the entrepreneur because it is an obligation and a requirement to obtain a distribution permit, and laboratory testing on post-market supervision is the task and authority of BPOM/BBPOM to see whether the owner of the facility is consistent or remains obedient to the rules or not. About the purpose of the pre-market, usually business actors at the time of pre-market, in this case, when applying for a distribution permit, they obey because there is something they want, so the product is made good (according to the requirements) at the time of pre-market. However, they throw a tantrum after running, so there is a term post-market. After being circulated to the public, the product is monitored whether it is following the initial time (pre-market) or not. If something does not match or does not meet the security requirements, a public warning will be issued (Wisnu, Sudewi, & Lolo, 2017).

Furthermore, the implementation of supervisory activities consisting of surveys, research, and laboratory testing, also includes providing questionnaires to the public. Usually, the frequency of inspection activities in 1 year is routinely carried out every month. For every month, 2 or 3 examinations are usually carried out, depending on the case, or there is no stipulation on how many times to be carried out, but what is certain is that medicine, food, and cosmetic examinations are carried out in a month. So for 12 months, supervision is carried out continuously.

In order to increase supervision of traditional medicines containing medicinal chemicals, an Action Plan for Controlling the Domestic Market is usually carried out. The controlling action was carried out because there were still many traditional medicines that contained medicinal chemicals. This control operation is intensified to control traditional medicines containing medicinal chemicals listed in public warnings, especially those registered and whose distribution permit has been canceled.

One of the problems found in the regions is that there are still sellers/business actors who claim they have never been given counseling, so they refuse when their merchandise is about to be confiscated. To overcome this, supervisory officers provide counseling and guidance and verbal warnings that if they have been given counseling, they can no longer refuse if violations are found. From this, it can be seen that there is still a lack of socialization among the public about traditional medicinal products that are prohibited from being circulated. This indeed cannot be separated from the active role of the relevant agencies, in this case, the Health Service and the Industry and Trade Office in each Regency/City area which is expected to participate in supervising all products that endanger public health, including traditional medicinal products containing medicinal chemicals.

According to Sutedi (2008), legal communication and legal socialization are supplements of leadership elements in a legal system. In other words, legal communication and legal socialization are essential factors for the effectiveness of the law. Socialization is a method/mechanism in the process of social control, so it can be said that this socialization needs to be done to support the function of law as social control.

So that the law can control the pattern of human behavior, then the human should be aware in advance of how important the rule of law is. This awareness can be grown through socialization so that he will know what rules must be obeyed and what sanctions will be encountered if these rules are not obeyed. According to the researcher, the socialization process is essential to foster legal awareness in a person so that he will know, understand, and understand which, in the end, is expected to carry out the applicable legal rules sincerely.

In addition to the active role of relevant agencies, what is no less important is the participation of the community in providing reports or complaints to BBPOM or related agencies if they find traditional medicinal products that do not meet the requirements or experience complaints due to consuming traditional medicinal products. In line with this, there is a need for guidance to the community, which is directed at increasing community/consumer resources to have a strong awareness of their rights and be willing to consume healthily and rationally.

Supervision of business actors implies ensuring the fulfillment or implementation of the rights and obligations of the parties. Therefore, supervision is an essential element in the implementation of consumer protection. In a sense, business actors as producers must constantly be monitored to act following applicable regulations so that business actors fulfill their obligations. This supervision needs to remember that the tendency to neglect obligations is seen as belonging to everyone. Sometimes opportunities make people not fulfill their obligations. Therefore, this supervision is an action to eliminate or narrow the possibility of violating the applicable provisions. This is called preventive surveillance.

At Balai BPOM, there is a Consumer Complaints Service Unit (ULPK) which is a place for consumers or the public to complain or report, or a place to obtain information services regarding the quality, safety, and legal aspects of food products, drugs, medical devices, household health supplies narcotics and psychotropic substances, hazardous substances and cosmetics. Supervision carried out by the community can be carried out through research, testing, or surveys of goods circulating in the market.

The community's supervision includes loading information about the risks of using goods if required, labeling, and advertising. For example, the public can survey the writing/inclusion of the expiration date of certain products in circulation. The information obtained is then forwarded to the government authorities. This is a form of community participation in supervision concerning consumer protection.

Furthermore, if there are reports from the public, there will be an investigation. Drug and food crime investigations are under the authority of the Drug and Food Investigation Center under the coordination of BPOM. The procedure for investigating traditional drugs is included in the BPOM Decree Number: HK.00.05.72.4473 concerning Procedures for Investigation of Crimes in the Drug and Food Sector. There is no need to wait until a case occurs to investigate a traditional medicinal product. However, it is sufficient

that if there are indications of illegal circulation, then an investigation can be carried out by the competent authorities (Nugroho, Nurrochmat, & Hardjanto 2016).
In factual conditions, the problem of drug and food product distribution can be divided into four categories, namely: 1) Legal producers, distributors/retailers produce legal/registered products; 2) Legal/registered products distributed/distributed by unauthorized distributors/retailers; 3) Illegal/unregistered products are distributed by legal/registered distributors/retailers; 4) Illegal/unregistered/fake products are produced by illegal producers and distributed by illegal distributors/retailers.
After supervision and observation, if it is deemed sufficient evidence of a violation of a criminal act, the findings are processed pro-justice by following the Technical Guidelines for Criminal Investigations for civil servants of BPOM. Meanwhile, if there is insufficient evidence, then supervision and observation will be carried out, and a comprehensive audit to obtain evidence and fulfill the elements of a criminal act following applicable regulations.
Pro-justicia steps, according to the Technical Instructions for Criminal Investigations for civil servant officials of BPOM, are: a) Conducting Investigations at the Place of Case (TKP) and set forth in the Official Report (BA); b) Carry out a search and set forth in the Minutes (BA); c) Implement the confiscation of evidence and set forth in the News (BA); d) Request approval/determination from the local District Court on the confiscation action; e) Request approval/determination from the local District Court on the confiscation action; f) Implement Provision of Evidence for Laboratory Testing and set forth in the Official Report (BA), if necessary; g) Carrying out the title of cases of criminal offenses, if necessary; h) Prepare a Notice of Investigation Commencement (SPDP) to the Public Prosecutor through the National Police Investigator; i) Summoning the Witnesses/Expert Witnesses; j) Carry out examination of the Witnesses/Expert Witnesses and set out in the Minutes (BA); k) Summoning the Suspects; l) Carry out examination of the Suspects and set out in the Minutes (BA); m) Carry out other actions in accordance with the provisions of the Criminal Procedure Code; n) Completing the Administration of Investigation into Case Files; o) Submit Case Files to the Public Prosecutor through the National Police Investigator to examine its completeness; p) Carry out functional coordination with the National Police Investigators and Public Prosecutors to complete the Case Files, according to the instructions of the Public Prosecutor (P-18), (P-19) until the Case Files are declared complete (P-21); q) Hand over responsibility for the suspect and evidence to the public prosecutor; and r) Attending Case Sessions at the Local District Court, as Officer Witness or Expert Witness.

4. Conclusion

The substance of the laws and regulations governing the supervision and sanctions related to the circulation of traditional medicines containing medicinal chemicals or which do not meet the requirements is sufficient. However, the implementing regulations still refer to the old laws and regulations, namely Law Number 23 of 1992 concerning Health. Furthermore, the implementation of supervision of traditional medicines containing medicinal chemicals by the BPOM has been running following applicable regulations as part of the duties and authorities of BPOM. However, various obstacles were found in its implementation. The BPOM supervision pattern consists of producer and government supervision systems. The producer supervision system includes good manufacturing practices, pre-market and post-market. The government supervision system includes regulation, standardization, registration, inspection, sampling, public warning, and consumer complaint services.

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