



Legal Protection Of Consumers Against the Distribution Of Chemical-Based Traditional Medicines in Indonesia

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Abstract. *The circulation of traditional chemical-based medicines in Indonesia is a serious problem because it can endanger consumer health. Although traditional medicines are supposed to contain natural ingredients, the practice of mixing harmful chemicals is still found in products on the market. This article aims to analyse the legal protection for consumers against the circulation of traditional chemical-based medicines in Indonesia. This study uses a normative juridical method with a legislative approach as well as a case study of related regulations and law enforcement. Legal protection for consumers is regulated in Law Number 8 of 1999 concerning Consumer Protection, as well as other regulations such as the Regulation of the Food and Drug Supervisory Agency (BPOM) and regulations related to traditional medicines. However, despite the existing regulations, various obstacles to implementation are still encountered, such as weak supervision, lack of consumer awareness, and illegal practices by irresponsible producers. Therefore, there is a need to strengthen regulations, supervision, and education for the public so that consumers are better protected from the dangers of traditional medicines containing harmful chemicals.*

Keywords: *Legal protection, Consumers, Traditional medicines, Chemicals, Regulations*

1. INTRODUCTION

Development in the health sector is basically aimed at increasing awareness, willingness, and the ability to live a healthy life for everyone to realise an optimal degree of health as one of the elements of welfare as mandated by the opening of the 1945 Constitution of the Republic of Indonesia. Human nature always wants to be healthy and in many different ways will try to maintain its health. This is illustrated by the saying: 'Prevention is better than cure'. However, as far as business is concerned, God determines where and how, but humans can only suffer and try to heal themselves or follow the advice of doctors. The popularity of the *back to natural* style and the concern for natural medicines has now made traditional treatments more popular, as evidenced by the number of herbal medicine industries and pharmaceutical industries that produce traditional medicines. In western countries, when traditional medicine has found its place in hospitals. The use of traditional medicines has been discussed among experts as one of the ways to support herbal medicine and traditional medicines are still very relevant and rational for supporting herbal medicine, not as the main treatment.

Traditional medicines are ingredients or ingredients that are plant ingredients, animal ingredients, mineral ingredients, cellular ingredients (galenics) or a mixture of

ingredients that are passed down through generations and used for medicine based on experience. The ingredients used can be whole plants, plant parts or plant extracts. Article 1 number 17 of Law Number 17 of 2023 concerning Traditional Medicines defines traditional medicines as natural ingredients, ingredients, or products that originate from natural resources in the form of plants, animals, microorganisms, minerals, or other materials from natural resources, or a mixture of these materials that have been used for generations, or have been proven to be effective, safe, and of high quality, used for health maintenance, health improvement, disease prevention, healing, and/or health recovery based on empirical and/or scientific evidence.

Traditional medicine is one of the efforts to treat and cure in ways other than medical science and treatment science. Traditional medicine usually uses traditional medicine or what is considered traditional in Indonesia as a 'herbal medicine' as a means of healing. The parts of traditional herbal medicine that are used are the roots, rhizomes, stems, fruits, leaves and flowers. Traditional herbal medicines contain various ingredients that are widely sold in the market in the form of capsules, powders, liquids, tablets and tablets. Traditional medicines have benefits and functions for the prevention of disease (prevention), improving health (promotion), and healing disease (cure).

Nowadays, various traditional medicinal products that are well-known in the community have emerged. Traditional medicines also include herbal medicine, which is believed to be able to cure various diseases. Traditional medicines are also considered herbal medicines, which means herbal ingredients that have been trusted since ancient times to cure various ailments because they are natural ingredients. Technologists began to explore the fastest way for factories or producers to increase their production and the natural ingredients that had always been used were replaced with medicinal ingredients that were not dangerous for consumers. In the world of trade, a product does not reach the consumer directly from the producer, but always through various intermediary channels such as wholesalers, retailers, distributors and retailers. This is where problems arise, where consumers are left wondering who is responsible for which business actor.

The use of pharmaceutical ingredients, subsequently referred to as BKO, to increase the yield of traditional medicines and beyond the knowledge of consumers, of course, violates the rights of consumers which have been accommodated in Article 4 letter a of the UUPK, granting various rights to consumers for goods and / or services consumed, one of which is: the right to convenience, security, and safety in consuming goods and/or services'.

The Food and Drug Supervisory Agency, hereinafter referred to as BPOM, collects 14, 000-20,000 samples of traditional medicines from all regions in Indonesia, based on the annual collection of samples, the National Food and Drug Agency found three formulas, one of which contained undeclared BKO. The National Agency of Drug and Food Control (BPOM) took action by confiscating, destroying, and cancelling illegal products for 6 years and for violations of the law, 31 cases were filed in court. The National Agency for Food and Drug Control (BPOM) also carries out surveillance of traditional medicines containing BKO because they have a dangerous impact on the community who consume them without treatment. In laboratory testing, the National Agency for Food and Drug Control found that the number of BKO tablets in each pack was not the same and that the number of missing tablets was very large. Traditional herbal medicines are consumed by the wider community because they are considered safer than chemical medicines, but traditional medicine producers add chemicals to increase their healing power.

Consumer Protection Law

A.Z. Nasution believes that consumer protection law is a part of consumer law which includes principles or rules that regulate and contain the meaning of protecting consumer interests, while consumer law is the law that regulates the relationships and issues between various parties to each other. It deals with goods or consumer services in domestic relations. However, some believe that consumer protection law is a branch of consumer law. [It](#) It can be seen that consumer law covers a wide scale because consumer law includes various legal aspects in which consumer rights are protected, and one aspect of consumer law is the protection aspect, for example, how to defend consumer rights against other rights.

Consumer protection law in Indonesia has a legal basis that has been determined by the government. With a clear legal basis, the protection of consumer rights can be carried out optimally. Regulations regarding consumer protection law are stipulated in Law Number 8 of 1999 concerning Consumer Protection. Based on the provisions of Article 1 number 1 of Law Number 8 of 1999 concerning Consumer Protection, it is stated that consumer protection is all efforts to ensure the existence of legal certainty to provide protection for consumers.

Purpose Of Consumer Protection Law

Basically the rights and responsibilities between business actors and consumers in law. Consumer protection is parallel and symmetrical. The objectives of consumer protection, as stipulated in the provisions of Article 3 of Law Number 8 of 1999 concerning Consumer

Protection, are:

- a. Increase consumers' awareness, ability, and willingness to protect their rights.
- b. Uplift the status and dignity of consumers by protecting them from the exploitation of goods and services.
- c. Enhance consumer empowerment in identifying, determining, and demanding their rights as consumers.
- d. Create a consumer protection system that contains legal certainty and information disclosure as well as access to information.
- e. Raising the awareness of business actors to fulfil their consumer protection obligations so that an honest and responsible business culture can grow.
- f. Improving the quality of goods and/or services that ensure the sustainability of production and/or service businesses, as well as the quality, safety, and security of consumers.

Consumer protection is one of the most fundamental (*substantial*) issues in the national development agenda of a country, including Indonesia. This issue involves regulations that are full of considerations from various social strategies (society's perspective), such as consumer protection efforts in Indonesia in recent years, including efforts to establish consumer principles such as for example, users or beneficiaries of goods and/or services who need to be protected by law. Basically, the status of every citizen is equal under the law.

All citizens have the right to legal protection without exception. Legal protection must be in line with the general purpose of the law, which is to enforce justice, so that justice and community security can be realised. In other words, the law aims to ensure the existence of legal certainty in society and the law must also be based on fairness, that is, the principles of fairness from society. Based on the above, consumer protection is something that needs to be realised in order to create a balance of power between business actors and consumers in their legal relationships. Legal protection is a right of every citizen. If legal awareness grows in society, legal protection in the state will proceed well. Legal protection for the people is a universal concept, in the sense that it is upheld and implemented by state institutions that uphold the rule of law.

Form Of Legal Protection For Consumers From The Distribution Of Traditional Medicines Containing Chemical Substances Based On Law Number 8 Of 1999 Concerning Consumer Protection

In discussing traditional medicine, basically the existence of traditional medicine is a kind of effort in traditional healing. Traditional healing in our country is one of the cultures of the nation that

involves healing and or treatment other than medical science or treatment science. The reality shows that in our society, both traditional healing and alternative medicine as well as modern medicine are still found in the midst of Indonesian society. Both systems have their advantages and disadvantages. People will obviously seek out any method of treatment, as long as they think it will work. Because of this, traditional treatments by doctors are still considered a challenge.

In accordance with Article 1 number 1 of the Traditional Medicine Regulation Number: 246/Melnkels/Pelr/V/1990 concerning the Law on Traditional Industrial Businesses and the Registration of Traditional Medicines in accordance with Regulation Number 007 of 2012 concerning the Regulation of Traditional Medicines states that: Traditional medicine is an ingredient or mixture of ingredients that consists of plant ingredients, animal ingredients, mineral ingredients, cellular or molecular ingredients, or a mixture of these ingredients, which have traditionally been used for treatment based on experience. Furthermore, in the same regulation, article 1 number 2 discusses that the Traditional Medicine Industry is an industry that produces traditional medicine with a total asset of more than IDR 600,000,000 (six hundred million rupiah), not including the price of land and buildings.

Traditional medicines have recently received attention in the world of science. Some people believe that traditional medicines also have effects that are no less effective than medicines made from chemical ingredients, and are also safe. Despite the same biological properties as drugs made from natural ingredients, not all traditional medicines can be dispensed. Traditional medicines are divided into three categories, namely herbal medicine, standardised herbal medicine, and phytopharmaceuticals. Phytopharmaceuticals are made from plants and have gone through laboratory tests. Of the three types, only phytopharmaceuticals can be marketed and their use is aligned with model drugs.

Some doctors are still reluctant to prescribe pharmaceuticals, because many people think that traditional medicines are of low quality compared to modern medicines. The use of traditional medicines is currently being recognised by more and more people. Traditional medicines are basically used as a supporting therapy, not as the main treatment. Traditional medicines or herbal medicines were also not created based on market demand, but rather by creating a market that did not exist. This shows that Indonesian traditional medicine (Obat Asli Indonesia) has the same cultural background as Western medicine (Obat Asli Barat) or pharmaceutical medicine (Obat Farmasi), so it is very unwise if for industrial reasons Indonesian traditional medicine is forced to be pharmaceuticalised using pharmaceutical science tools, because the nature of traditional medicines is different from pharmaceutical drugs.

Based on the above discussion, traditional medicines are made and their legalisation is regulated as discussed in Law Number 17 of 20223 concerning Traditional Medicines as one of the alternative healing methods. Furthermore, based on the above regulation, regulations were issued specifically for

traditional medicines in Health Regulation Number 246 of 1990 concerning Industrial Business Licences for Traditional Medicines and Registration of Traditional Medicines in conjunction with Health Regulation Regulation Number 007 of 2012 concerning the Registration of Traditional Medicines. The regulation was issued as a demand for regulations regarding the legality of traditional medicines in Indonesia.

Regulations concerning the industrial business of traditional medicines and the registration of traditional medicines sold for the legality of traditional medicines are also required, among other things, for:

- a) The community's immunity to things that can disrupt and endanger safety needs to be prevented by the existence of traditional medicines that do not meet safety, usage and quality requirements, including regulations, permits and registrations;
- b) Issuing a regulation that is beneficial for the development of traditional medicine business needs to be done by simplifying the licensing of industrial businesses and the registration of traditional medicines, without compromising the intent stated in letter a;

In the regulation, the definition states that traditional medicine is ingredients or ingredients that are plant ingredients, animal ingredients, mineral ingredients, cellular or galelnilk ingredients or mixtures and ingredients, which have traditionally been used for treatment based on experience. Furthermore, in terms of sales, there are also various categories of traditional medicine production, including:

- 1 Traditional Medicine Industry: is an industry that produces traditional medicine with a total expanded area of IDR 600,000,000 (six hundred million rupiah), not including the price of land and buildings
- 2 Traditional Medicinal Industry: is a traditional medicinal industry with a total asset value not less than IDR 600,000,000 (six hundred million rupiah), not including the price of land and buildings) Home Industry (*Homel Industry*):
 - a. Jamu Racikan (Traditional Herbal Medicine) Business: is a business that produces, mixes, and/or processes traditional medicines in the form of extracts, powders, syrups, pills, capsules or tablets on a small scale, sold in one place without branding and/or trademark.
 - b. Herbal Medicine Business: is the business of selling, mixing, processing and marketing traditional medicines in the form of drinks, pills, capsules or tablets, without branding and or trade marks and sold for direct use.

Traditional Medicine Licence: a traditional medicine licence is produced by a traditional medicine industry for the purpose of the company concerned using the company's brand and trade name.

In the production of traditional medicinal products, in the Ministry of Health Regulation Number 007 of 2012 concerning the Registration of Traditional Medicines, it is stated that:

- a. A ministerial permit is required to establish a traditional medicine business;
- b. A ministerial permit is not required to establish a herbal medicine business or a herbal medicine peddler business

Based on the regulation, it is clear that the legality of traditional medicines in Indonesia is part of an effort to provide alternative treatments and solutions with existing regulations, namely Health Service Regulation Number 007 of 2012 concerning the Regulation of Traditional Medicines. In the aforementioned Regulation, it is stipulated, among other things, that:

- 1) To authorise and implement the Requirements for Traditional Medicines as listed in the annex to the Decision on the requirements that must be met.
- 2) The Traditional Medicine Industry and/or the Small Traditional Medicine Industry are prohibited from marketing products that do not meet the requirements of the circulation.
- 3) The requirements for Traditional Medicines referred to in the first paragraph may be reviewed and determined by the Director General of Drug and Food Supervision.

The legal decision is effective from the date specified. For Small-Scale Traditional Medicine Industries, the legal decision takes effect 1 (one) year from the date specified. For Small-Scale Traditional Medicine Industries with a total asset value of less than Rp. 50,000,000 (fifty million rupiah) excluding land and buildings, the legal decision shall take effect as of 2 (two) years from the date specified. The regulation will be amended as necessary if any inconsistencies are found.

Based on the results of the investigation, it is confirmed that the existence of traditional medicines is legal and valid, but must be carried out in accordance with the regulations and conditions as stated in the decision of the investigation. Furthermore, the Traditional Medicine Industry and/or the Traditional Medicine Small Industry have the legal right to market their products that do not meet the requirements of distribution. This is natural considering that traditional medicines have always been related to healing for personal ailments. The trend towards *back to natural* and natural remedies, as well as the growing popularity of traditional medicines, has led to an increase in their use. This is proven by the number of herbal medicine industries and pharmaceutical industries that produce traditional medicines. In Western countries, when traditional medicine has found a place in hospitals.

The use of traditional medicines has been discussed among doctors as one of the ways to support herbal medicine and traditional medicines are still very relevant and rational for supporting herbal medicine, not as the main treatment. However, according to manufacturers, the government continues to produce traditional medicines based on the requirements and regulations that apply as for the legality of distributed traditional medicines. However, when problems arise regarding legal protection for consumers of traditional medicines containing chemical ingredients based on Law Number 8 of 1999 concerning Consumer Protection.

Legal Protection For Victims According To Applicable Laws

Regarding the enactment of Law Number 8 of 1999 concerning consumer protection, it is clear that aggrieved consumers can take legal action by reporting the businessperson in question to the police if they feel they have been harmed, and the case will then be processed through prosecution and a court decision. This must be done with careful consideration and planning, especially with strong and valid evidence from consumers or victims of consumer fraud, considering that the case can be a mistake, if our report is not valid, it is precisely the consumers concerned who will be accused of damaging the brand's name and there will be demands for accountability and lawsuits for compensation for the matters discussed.

In addition to the legal remedies mentioned above, consumers can file a lawsuit in a civil court where they can demand compensation for the impact caused by traditional medicines produced by the traditional medicine industry. In accordance with Article 4 letter h of Law Number 8 of 1999 concerning consumer protection, it is stated that: consumers have the right to obtain compensation, compensation, and or replacement if the goods and or services experienced do not comply with the promises or are not as advertised. Based on the above discussion, legal protection provided to consumers of traditional medicines can be done through legal remedies that consumers can pursue through legal channels, either criminal charges or civil lawsuits. With legal protection for consumers, it is hoped that traditional medicine producers will continue to maintain the quality of their products so that they can continue to serve consumers.

However, the legal rules that apply, especially regarding consumer protection, do not prevent business opportunities (for entrepreneurs) to conduct research or business in various fields, especially the production of traditional medicines. With the existence of legal regulations that protect consumers, they should not become a means of intimidation for entrepreneurs to carry out their business activities. Laws and related regulations must function

as an effort to improve the quality of services provided to consumers. In the case of traditional medicine products, producers must maintain the quality of their products carefully.

In the implementation of consumer protection law, it is necessary to consider the implementation of the rights and interests of each party so as to achieve a fair and equitable promise. The principle of responsibility is a very important issue in consumer protection law. In cases of consumer rights violations, care must be taken in analysing who should be held responsible and to what extent responsibility can be assigned to the parties involved. In certain formal legal sources, regulations and standard agreements in the field of property law, there are limitations on the responsibilities imposed on violators of consumer rights, especially in the case of traditional medicine consumers.

The problem of legal protection for traditional medicine producers and consumers in terms of information is a civil right. What is the problem? When the problem arises, there is widespread falsification of illegal traditional medicine products that are illegal and can be sold by irresponsible people who are only looking to make a profit. Misrepresentation of communication between others is done in various ways, including: re-producing with incorrect drug doses, re-packaging with drug doses that are not in accordance with the safety of marketable products, or changing the expiry date (expiry date) of traditional medicines.

The issue that has become a challenge in the implementation of consumer protection laws in Indonesia is also related to the legality of traditional medicines in Indonesia. The number of counterfeit traditional medicines has become a terrifying spectre in society, where consumers of traditional medicines hope to be cured at an affordable price, but suffer serious or even fatal consequences when they take fake medicines. Also, traditional medicine products will be very vulnerable to counterfeit production. In the case of counterfeit traditional medicines, there is a need for consumer vigilance and supervision by the relevant authorities. Supervision by producers or business actors has a very important role when it comes to product fraud in a legal manner with responsibility for the quality, safety, results, and benefits of all products that are produced and distributed in the community. For this reason, textile products must have internal control mechanisms that can guarantee the quality of the textile products produced until the products are distributed to the community. Distributors or business actors in the distribution sector are also expected not to distribute drugs or other means that are not entitled. Supervision by the community as consumers must also be able to identify the dangers of products that can affect their health, safety, and finances. The community or consumers need to be aware of their rights and responsibilities regarding product quality and safety.

If the public is aware of the correct use of medicinal products, in the case of unsafe traditional medicines, it is expected that the public will: not to buy and use drugs that are distributed from the black market, and to report to the authorities, in the event that the National Agency of Drug and Food Control (Badan POM) through the Consumer Complaint Service Unit (ULPK) finds violations in the field of pharmaceuticals. Realising that the level of public knowledge and awareness still needs to be improved in many ways, the POM Agency has implemented a community empowerment programme through the sharing of communication, education and information.

In order to protect the community from the use of medicinal products that do not meet the requirements, the Indonesian Food and Drug Authority (BPOM) continuously supervises the distribution of medicines and takes action against violations in the field of medicine with a progressive approach. In recent years, the National Agency of Drug and Food Control (Badan POM) through the POM Office has carried out joint operational and administrative actions to carry out national joint operations involving the participation of police authorities. The provisions of the Law on Criminal Procedure state that: A person who deliberately and unlawfully carries out fraudulent work in the procurement, production, distribution and service of pharmaceutical services, shall be punished with a prison sentence of at least 5 (five) years and/or a fine of at least Rp. 100,000,000 (one hundred million rupiah). What is more interesting is the court decision that was issued regarding the health insurance not causing any legal consequences for the perpetrator.

Thus, the duties of the state, in this case the Ministry of Health, the National Agency for Drug and Food Control, and the Police, have been to provide protection under state administrative law, namely by seeking to fulfil the rights and obligations between the government and citizens, between state bodies/officials and members of bodies, and between superiors and subordinates in accordance with the rule of law.

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