

Enforcement law against abuse medicinal chemicals reviewed from law no. 8 of 1999 concerning consumer protection

Yandi Saputera

Law Study Program Faculty of Humanities, Sari Mulia University

ABSTRACT: The use of traditional medicine in Indonesia is very widespread as a method of treating and preventing diseases, ranging from mild to degenerative diseases. However abuse material chemistry drug (BKO) in stock herbal medicine to increase therapeutic effectiveness becomes a serious problem that endangers consumer health. This study aims to analyze the problem of BKO abuse in herbal medicine, the legal regulations governing it, and law enforcement efforts in Indonesia. The research method uses literature studies from various trusted sources.

The results show that regulations such as the Minister of Health Regulation and BPOM supervision have provided a clear legal framework, but law enforcement is often limited to downstream actors. Commonly found BKO include paracetamol, dexamethasone, and sildenafil, whose uncontrolled use can cause serious side effects and even death.

KEYWORDS: Traditional medicine, chemical drugs (BKO), law enforcement.

INTRODUCTION

Indonesia is a country with a very abundant variety of flora and fauna. From this diversity, some of them are known to have medicinal properties. Medicines derived from plants, animals, and minerals or a mixture of these materials that have been used for treatment for generations are known as Traditional Medicines. Based on the level of proof of claims/efficacy, traditional medicines are classified into three types, namely herbal medicine, standardized herbal medicine, and phytopharmaceuticals.

Considering the use of herbal medicine as a natural alternative treatment is quite high, especially with its affordable price, irresponsible parties take advantage of this to their advantage by adding BKO to traditional medicine preparations. BKO is added to accelerate the therapeutic effect or efficacy claimed by the traditional medicine, so that the product it is said more potent. Matter This very dangerous for health body, Where BKO This Of course own effect side light until weight which, if used excessively, can be harmful to consumer health. [1]

In Indonesia, herbal medicine or traditional medicine has a special position because it is a cultural heritage in the health sector. Article 1 number 1 of the Regulation of the Minister of Health of the Republic of Indonesia Number 07 of 2012 states that Traditional Medicine is a material or concoction of materials in the form of plant, material animal, material mineral, stock galenic or mixture and these ingredients, which have been used for generations for medicinal purposes, And can applied in accordance with norm Which applicable in society. This means that the quality and safety of traditional medicines must be carried out from the beginning of the process of making traditional medicines, starting from the selection and use, the entire production process until the products circulating in society have quality. Which Good, so that every inhabitant country can life worthy And For ensure welfare.

Viewed from the consumer's point of view, if they find herbal medicine containing chemical medicinal ingredients, it is something that is very detrimental, and the regulation of this matter is contrary to Article 4 of Law Number 8 of 1999 concerning Consumer Protection, which states that consumer rights are to obtain comfort, security and safety in consuming goods and/or services and to obtain the right to clear, correct and honest information regarding the condition of the consumer. And guarantee goods And or service Which available. However on the reality is that traditional herbal medicines are circulating on the market contain hazardous chemicals which have a negative impact on consumer health.

Also in Article 68 of Presidential Decree Number 13 of 2001 concerning the Food and Drug Supervisory Agency has a function as a permit giver and supervision of drug distribution and supervision of the pharmaceutical industry. But in reality, traditional herbal medicines containing dangerous chemicals are circulating in the community .

Meanwhile, regarding the marketing of herbal products made from chemical drugs can be prosecuted under Article 197 of Law Number 36 of 2009 concerning Health. [2]

Concrete steps have been implemented jointly by both the government and entrepreneurs in prevention, as well as among government agencies in the enforcement process which has been intensively implemented by the PPNS BPOM. with party court country through decision court Which always in harmony with support positive. Matter This proven with existence The trial was held

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on February 11, 2020, which demanded a criminal sentence in the form of a prison sentence of 2 months and 15 days and a fine of 2.5 million rupiah for the defendant. case making And to circulate Traditional medicine without permission And without permission distribution and Traditional Medicine Which checked and contains Chemical Drugs , Threat criminal the set up in Article 196 in conjunction with Article 98 paragraph (2) and paragraph (3) of the Law on Health .[3]

RESEARCH METHODS

This research is a normative legal research that focuses its study by viewing law as a complete system that includes a set of principles, norms, and legal rules, both written and unwritten. The approach used in this research is: [4]

Legislative approach is carried out by examining all statutory regulations.-invitations related to the Protection of Indonesian Female Workers Abroad.

2. Conceptual Approach , Carried Out by Examining Theory - Theory, Principles - Principles, and certain definitions used as a basis related to Enforcement Law Against Abuse Chemical Drugs Reviewed from Law No. 8 of 1999 Concerning Consumer Protection.

The legal material collection technique used in this research is through a literature study that examines relevant laws and regulations, books.-books or reading materials and scientific works of legal experts. The analysis used is qualitative analysis which provides a descriptive picture of the problems discussed.

DISCUSSION

Traditional medicine is used globally. Especially in Indonesia as a treatment and prevention measure against a disease. The use of traditional medicine can overcome various diseases, from mild diseases to degenerative diseases. Traditional medicine is commonly used for reduce fever, pain/soreness rheumatic, enter wind, hot in, painful menstruation, and indigestion BKO Which general found in stock drug traditional, specifically herbal medicines, namely paracetamol, sodium diclofenac, antalgine, prednisone, phenylbutazone, sibutramine hydrochloride, glibenclamide, piroxicam, theophylline, dexamethasone, and sildenafil citrate .[5]

The rights of traditional medicine distributors include having and presenting traditional medicines at the point of sale through the distribution channel of traditional medicines. The distribution channel of traditional medicines starts from the traditional medicine industry, which distributes them to agents then to retailers who then distribute them to consumers. The form of traditional medicine sales can be in the form of pharmaceutical distribution facilities, either in the form of pharmaceutical wholesalers and pharmaceutical preparation installations. OT distributors also have the right to act as distributors of pharmaceutical preparations that include traditional medicines. PP 51 of 2009 concerning Pharmaceutical Work states the difference between pharmacies and drug stores. In relation to business actors, both manufacturers and distributors of traditional medicines, as legal subjects, both have legal responsibilities arising along with the legal relationship between the two parties based on a contract or agreement. The parties in this case do not have to be a legal entity but can also be individuals. Rights as business actors as previously mentioned that is between other is is right For accept payment which is in accordance with the agreement regarding the conditions and exchange value of goods and/or services traded, receives legal protection from consumer actions with bad intentions, carries out proper self-defense in the legal settlement of consumer disputes, rehabilitation of good name if it is legally proven that the consumer's loss was not caused by the goods and/or services traded, as well as the rights regulated in other statutory provisions. [6]

Rights and obligations will result in a responsibility. Article 19 to Article 28 of the Consumer Protection Law regulates the responsibility of business actors to consumers if consumers suffer losses due to business actors.

As for the distributor's obligations Traditional medicine is an obligation to provide compensation, responsibility for advertising and all consequences caused by advertising, as well as not quite enough answer as importer if import No done by official agent as a foreign representative. The obligation is as stated in the Consumer Protection Act . Business actors who sell products to other business actors are obliged to fulfill consumer compensation if the product obtained from business actor 2 (not making product changes) is detrimental to consumers. [7]

Law enforcement requires strong supervision and control of the community so that there are no illegal drugs intensively and periodically so that it has a deterrent effect. In fact, this is actually rare, as a result there are still illegal drugs carried out by certain sellers. The cause Because for enforcer law only capable dismantle from side downstream or the distributors or small fry, have not been able to reach upstream or those who produce the illegal drugs" There is a need for more effective law enforcement efforts and more intensive education for the public regarding the dangers of the distribution and use of hard drugs without a distribution permit.

Previous research also shows that the application of criminal sanctions against perpetrator distributor drug hard own challenge alone. Mr. Heriyanto, M., Hidayatullah, W., & Mulyadi. (2020) explained that "The results of the research on the provisions criminal Which only arrange stage production And circulation illegal, but does not touch the buyers, storers, owners, and/or illegal users, causing enforcement law not enough certainty And fair. A multidisciplinary approach is needed to address this

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problem effectively." By emphasizing the importance of a multidisciplinary approach in handling these cases so that the sanctions given can provide maximum deterrent effect. [8]

The Food and Drug Monitoring Agency (BPOM) is a government agency in Indonesia Which responsible answer on supervision drug, food, and other health products. Based on the Regulation of the Minister of Health of the Republic of Indonesia Number 007 Year 2012 , step Which must done For memp e roleh permission distribution of traditional medicines is to collect all the documents required for registration, including information on drug composition, safety reports, and production specifications. The second step is that BPOM will assess the submitted documents to ensure that the traditional medicine meets the safety and efficacy requirements set by applicable regulations. Third, BPOM can examine preclinical evidence that supports the safety and efficacy of the traditional medicine, including toxicity tests and pharmacological studies. Fourth, provide the results of clinical studies that support the efficacy and safety of this traditional medicine. Fifth, ensure that traditional medicines are produced in accordance with the production standards set by BPOM. Sixth, submit an application for a traditional medicine distribution permit to BPOM by attaching all the required documents and pay cost application Which Possible required. Seventh, BPOM may conduct inspections at production sites to ensure compliance with applicable production standards. Furthermore, after the distribution permit is granted, it is necessary to continue to comply with regulations and there may be further supervision regarding the safety and efficacy of traditional medicines.

Law is a regulation or custom that is considered officially binding, which is confirmed by the ruler or government. Law is also defined as statutes, regulations, and so on to regulate the social life of society. In addition, law is defined as a benchmark (rule, provision) regarding certain events (nature and so on) [8]

Herbal medicine distribution law refers to a series of rules and regulations that govern the production, distribution, marketing, and use of herbal medicines. The main purpose of herbal medicine distribution law is to ensure the safety, efficacy, and quality of herbal medicine products sold and consumed by the public. In many countries, these regulations are established to protect consumers from unsafe or ineffective herbal medicine products, as well as to avoid potential health risks that may arise from the uncontrolled use of herbal medicines.

A distribution permit on the packaging of traditional medicines is the main requirement for sellers to market traditional medicine products to the public, which proves that the product meets the standards for making traditional medicines. Which Good and safe used by consumer. Regulation Supervision Drugs and Food Number 31 of 2022 concerning Aspects of Making Good Traditional Medicines abbreviated as CPOTB with the aim of 'ensuring that products meet the quality requirements that have been set according to their use. Safety in the distribution of herbal medicines is very important to maintain the health and safety of consumers, because herbal medicines use natural ingredients, but are not always tested.

Public knowledge of laws and regulations regarding herbal medicines can vary. Some society may have a different understanding good about regulation This, temporary Which other Possible not enough understand. Public which own background behind education Which more tall And good health awareness levels tend to be more familiar with regulations related to herbal medicines. Sources of information such as news, social media, and health programs in television or radio can influence public knowledge about drug regulations herbal. If media give coverage Which Good about regulation this, society can more aware about importance permission distribution and condition others [9] Prednisone is glucocorticoids anti-inflammatory synthetic which originate from cortisone.

Prednisone is a slow-release corticosteroid that acts as a immunosuppressive or agent anti-inflammatory For treat diverse diseases, including gastrointestinal, allergic, edematous, dermatologic, hematologic, rheumatic, immunosuppressive/endocrine, and respiratory. Prednisone reduces inflammation by restoring increased capillary permeability and inhibiting polymorphonuclear leukocyte migration. So it can maintain the immune system by reducing the volume and activity of the immune system. The main side effects of prednisone are hyperglycemia, insomnia, increased appetite, hypertension, osteoporosis, edema, adrenal suppression, cataracts, and delayed wound healing. Prednisone is a synthetic anti-inflammatory glucocorticoid derived from cortisone. Prednisone is a slow-release corticosteroid that has a role as an immunosuppressive or anti-inflammatory agent to treat a variety of diseases, including gastrointestinal, allergic, edematous, dermatologic, hematologic, rheumatic, immunosuppressive/endocrine, and respiratory. Prednisone reduces inflammation by restoring capillary permeability Which increase And withhold migration leukocytes polymorphonuclear. So it can maintain the immune system by reducing the volume and activity of the immune system. The main side effects of prednisone are hyperglycemia, insomnia, increased appetite, hypertension, osteoporosis, edema, adrenal suppression, cataracts, and delayed wound healing.

Uncontrolled use of herbal medicines containing chemical substances can cause... effect side Which Serious, start from Dizzy, Sick head, painful chest pain, diarrhea, nausea, chest pain, visual disturbances, kidney damage, liver damage, even death. Therefore, an analysis method or identification method is needed to every Chemical Drug Ingredients use ensure drug traditional safe For consumed. Chemical Drugs can be analyzed qualitatively or quantitatively. Qualitative analysis aims to determine the presence of BKO contained in the sample, while analysis in a way quantitative aiming For to know level BKO in sample. [10]

Analysis BKO Already Lots done use method thin layer chromatography with appropriate developer. However, this method

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is relatively long so it becomes less effective. Therefore, a new method was created using indicator strips or strip test tools. Indicator strips are commonly used as tools to test blood sugar levels, uric acid, cholesterol and pregnancy tests. The composition of the indicator strip is a membrane that contains specific reagents in it.

The indicator strip has three components to be used, including a membrane, reagent which mobilized, And comparator. Membrane is a polymer as a matrix. Commonly used membranes are polysulfone, polyethersulfone, polyvinylidene fluoride, polyacrylonitrile, cellulose acetate, cellulose, other polyamides.

In 2014, Saka created a prototype indicator strip used to analyze the compounds paracetamol, mefenamic acid and aspirin. From the prototype that was created, it has been proven that each strip is specific only to compound his. Then prototype strip indicator the tested on herbal medicine samples and the results showed the presence of paracetamol compounds in the sample named J1 and mefenamic acid in the sample named J2.

On year 2015, Saputra researching jamu sore rheumatic packaging And brew circulating in the market using the thin layer chromatography method. From the test results it was said that the herbal medicine for aches and pains, the brewed herbal medicine positively contained dexamethasone and paracetamol, while the packaged herbal medicine for aches and pains, positively contained paracetamol. [11]

Indicator strip Indicator strip is a strip test tool which is a specific reagent for detecting a compound. Indicator strips can not only be used to detect standard compounds such as rhodamine B, metampiron, formalin and others, but can also be used to detect circulation antigen cathodic (Circulating cathodic Antigen/CCA) as a diagnosis for Schistosomiasis. [12]

In 2008, the application of the use of CCA indicator strips and real-time PCR was compared with microscopy to detect Schistosomiasis Haematobium in the Ghana region. After being studied, the use of microscopy had sensitivity and specificity. low when tested using indicator strips and PCR the sensitivity and specificity are quite high, when using PCR the sensitivity obtained is 89% and the specificity is 100% and using CCA strips the sensitivity is 41% and the specificity is 91%. Thus, looking at the specificity and sensitivity values using PCR is better. However, even so, detection of Schistosomiasis Haematobium can still be done using indicator strips, and indicator strips This Still Can developed so that specificity And its sensitivity become taller. [13]

Initially, to detect schistosomiasis, immunology methods were used, namely using the ELISA (Enzyme-Linked Immunosorbent Assays) method, however, this method takes a long time and requires special equipment, the procedure is quite complicated. Therefore, an indicator strip was made. The indicator strip used is made from nitrocellulose which has been cut to a certain size. Then the complex is inserted immune antigen And antibody monoclonal anti-CCA into the strip nitrocellulose base indicator. [14]

The dangers of chemical substances contained in traditional medicines cannot be seen in a way fast or on moment consume it direct but in long term, such as the continuous use of paracetamol (painkillers and fever reducers) and in large doses can cause liver damage, phenylbutazone (painkillers/analgesics) can cause stomach bleeding because it inhibits prostaglandins, dexamethasone (a class of corticosteroid drugs) if used not according to recommendations can cause increased blood sugar levels, bone loss, inhibit child growth and can cause obesity especially on the face (moon face). The use of herbal medicines containing sildenafil and or tadalafil can cause death because of their effects on blood vessels [15]

CONCLUSION

Use drug traditional, specifically in Indonesia, show that these drugs are widely used for the treatment and prevention of various diseases, from light until degenerative. However, use Which No Uncontrolled can cause serious side effects and even death, especially if it contains chemical drugs (BKO) such as sildenafil or dexamethasone. Strict regulations, such as distribution permits from BPOM, are important to ensure the safety, efficacy, and quality of traditional medicines before they are marketed. More effective law enforcement and intensive education for the public are also needed to reduce the risk of using illegal or dangerous traditional medicines.

Consumer protection for users of traditional medicines containing hazardous chemicals is regulated by Law Number 8 of 1999 concerning Consumer Protection. Business actors are responsible for providing compensation to consumers who consume products containing hazardous chemicals.

Consumer Protection Law Article 3 letter e, namely consumer protection aims to raise awareness of business actors regarding the importance of consumer protection so that an honest and responsible attitude grows in business. In this case, consumers also have consumer rights and obligations as regulated in Article 4 and Article 5 of Law Number 8 of 1999 concerning Consumer Protection. One of the consumer rights in Article 4 letter a is the right to comfort.

Article 62 paragraph (1) of the Republic of Indonesia Law Number 8 of 1999 concerning Consumer Protection, Business Actors who violate the provisions as referred to in Article 8 letter a: "Business actors are prohibited from producing and/or trading goods and/or services that do not meet or do not comply with the required standards and provisions of laws and regulations". The pharmaceutical preparations in the form of traditional medicines distributed by the suspect do not have a distribution permit, meaning that the product does not comply with the provisions of applicable laws and regulations.

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