

## Supervision and Registration of Traditional Medicine Brand

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### ABSTRACT

**Background:** Traditional medicine (herbal medicine, standardized herbal medicine, phytopharmaca (clinical-based herbal medicine), imported traditional medicine) is an ingredient or herb ingredients in the form of plant ingredients, animal ingredients, mineral ingredients, galenic preparations, or a mixture of such ingredients that have been used for treatment for generations, and can be applied by the norms prevailing in the society.

**Aim:** To find out and analyze related to the supervision and registration of traditional medicine brands in Indonesia.

**Methodology:** This research uses a qualitative method with a normative juridical approach. Data collection techniques are carried out through library studies.

**Conclusion:** Supervision of traditional medicine brands' registration must be carried out to the maximum by the National Agency of Drug and Food Control (NADFC). This avoids the problems that will arise in the event of the obscurity of the surveillance process. Good and proper supervision must be based on the rule of law because Indonesia recognizes the Law's existence.

**Keywords:** Supervision, Brand Registration, Traditional Medicine.

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### INTRODUCTION

In the 21st century, due to change in environmental condition and toxins, pollution, unhealthy lifestyle and excess intake of allopathic medicines increases the risk of diseases like diabetes, hypertension, renal diseases and obesity has increases<sup>1</sup>. Herbal medicinal products are getting importance globally because of their health benefits. There demand is going to increase because of increased interest of consumers in natural products as they are considered safer and more cost effective than synthetic drugs in many cases<sup>2</sup>. The relationship between plants and human cultures is not limited to the use of plants for food, clothing, religious ceremonies, ornamental and shelter but also includes their use for health care. It was officially recognized that 2500 plant species have medicinal value while over 6000 plants are estimated to be explored in traditional, folk and herbal medicine<sup>3</sup>.

Traditional medicine is an ingredient or herb ingredients in the form of plant ingredients, animal ingredients, mineral ingredients, galenic preparations, or a mixture of such ingredients that have been used for treatment for generations, and can be applied by the norms prevailing in the society<sup>4</sup>. Traditional medicine is one of the traditional health potions that are identical to the people of Indonesia. Amidst the many types of supplements and vitamins in circulation, traditional medicines such as herb and herbal medicine are still demanded by the public<sup>5</sup>. Traditional medicine becomes one of the choices of modern society to maintain the condition of the body. Based on data e-commerce health and beauty products Gogobli, herbal medicine market share is still competing with over-the-top drugs on the market. The market share of traditional medicine in 2017 in Indonesia reached 15 billion rupiahs, while over-the-top drugs amounted to 29.52 billion rupiahs. The percentage of herb and herbal medicine sales reaches about 30-40% of all sales of drugs, cosmetics, the number of herbs products, and herbal medicine online stores also range from 30-40%.

Types of Traditional Medicine can be distinguished above: Herb as a traditional medicine derived from plant, animal, and mineral materials and/or galenic preparations or a mixture of these ingredients that have not been standardized and used in treatment efforts based on experience. The dosage form is tangible as powder of brewing, copped for brewing, and so on. Herb is a traditional medicine that is traditionally provided, for example, powders, oil, and liquids containing all the plant ingredients that make up the herb and used traditionally. Standardized Herbal Medicine, is a preparation of natural ingredients that have been proven safe, and efficacy scientifically and preclinical tests and raw materials have been standardized. Phytopharmaca medicine is a preparation of natural ingredients that have been proven safe, and efficacy scientifically with preclinical tests and clinical trials, raw materials, and finished products have been standardized<sup>6</sup>.

Along with the development of the times, thanks to the support of increasing technological advances and knowledge of traditional medicine preparations in the manufacture and traditional medicine preparations also became varied as in the form of capsules, tablets, powders, and liquids. The increasing development of transportation equipment and technology makes the producers are now able to produce a large amount of traditional medicine and can distribute traditional medicine throughout Indonesia. The high public interest in traditional medicine also triggered the emergence of traditional medicine with a considerable variety so that the public is presented with various choices of brands, properties, and forms.

As it is known, the pharmaceutical market is the most important component of the system of pharmaceutical provision of the population. There is a variety of interests at the pharmaceutical market, among them the issues of drug availability are the most important and socially significant<sup>7</sup>. In today political complex systems supervision is necessary and undeniable. But how to supervise and its system are different between countries<sup>8</sup>. The registration procedure of drug products may slightly differ from countries/regions.

The primary challenges in drug registration process are observed and for success in the region is knowledge of the drug registration process and submission content of a region is essential for the effective planning and execution of global regulatory strategy<sup>9</sup>.

As a form of Intellectual Property Rights, branding is an identity or identification that distinguished products from one company to another<sup>10</sup>. Brands play a role in the world of trade, particularly in promotional and marketing activities, which are used to introduce the image, quality, and reputation of the goods or services traded. Therefore, brands are often identified with the image, quality, and reputation that has been attached to the product or service<sup>11</sup>. The development of trade in this era of globalization, causing the need for brands' legal protection, increases. This is because the brand's legal protection is expected to positively impact healthy business competition as a decisive factor for investors to invest in the world of trade. In the Indonesian legal system, brands as part of Intellectual Property Rights are regulated in Law Number 15 of 2001.

## MATERIAL AND METHODS

This research uses a qualitative research method with a normative juridical approach method. A normative juridical research method is research on positive legal principles written in the legislation and aims to conceptualize it as a written method. Soerjono Soekanto stated that only legal research is done by examining library materials or secondary data called normative legal research. Literature studies do data collection to collect legal materials, such as laws, law books, and legal research journals related to this study's topics<sup>12</sup>.

## RESULTS AND DISCUSSION

Medicinal plants are worldwide valued sources of new drugs. Traditional medicine are indigenous medicine which are used to maintain health and to prevent, diagnose, and treat illnesses contrarily as of allopathic medicine centered on theories, beliefs, and experiences<sup>13</sup>. Failure of some synthetic drugs and its side effects have prompted many researches to go back to ancient healing methods which use herbal medicines to give relief. Many of the thousands of plant species growing throughout the world have a direct pharmacological action on the body. Herbal treatment is a natural form of healing or alternative therapy where herbs and plants are used in the form of extracts, pills, syrup or powder to cure ailments or diseases of human beings and in some cases animals too<sup>14</sup>.

Traditional medicine still recognized as the preferred primary health care system in many communities, with over 60% of the world's population and about 80% in developing countries depending directly on medicinal plants for their medical purposes. This is due to a number of reasons including affordability, accessibility and low cost. History has revealed that most of the people of the world have been using plants, animals, micro -organisms and minerals for treating their illness. Traditional herbal medicines in last one decade have gained importance in various developed countries. One-Third of the American adults, Seventy four percent population of United Kingdom<sup>15</sup>.

Traditional medicines are based on utilization of natural products which are of great importance. Many forms of medicines have been used by civilizations since a decades and are still very much in practice. Traditional forms of medicines like – Ayurveda, Unani, traditional Chinese medicine (TCM), Kampo, Traditional Korean Medicine (TKM) have given beneficial results and are valuable for the human benefits<sup>16</sup>. Traditional system of medicines which normally consists of herbs, are under active research worldwide and a number of traditional formulations are showing promising results in preventing and treating diseases<sup>17</sup>.

Based on Law Number 39 of 2009 Concerning Health, traditional health services must be fostered and supervised by the government to be accountable for their benefits and safety and not contrary to religious norms because everyone has the right to get safe, quality, and affordable health care. Therefore, to provide consumer protection, namely the public against the circulation of traditional medicine that does not meet the requirements of quality, safety, efficacy, it is the obligation of the state to protect the community contained in Law Number 8 of 1999 on Consumer Protection<sup>18</sup>. The government established an agency in charge of supervising drugs and food, namely the National Agency of Drug and Food Control (NADFC) based on the Presidential Decree Number 103 of 2001 concerning the Position, Duties, Functions, Authorities, Organizational Structure, and Working Procedures of Non-Departmental Government Institutions<sup>19</sup>. Based on the legislation, NADFC carries out government duties in the field of drug and food supervision, namely: Assessment and preparation of national policies in the field of drug and food supervision; Implementation of certain policies in the field of drug and food supervision; Coordination of functional activities in the implementation of NADFC tasks; Monitoring, providing guidance and guidance on the activities of government agencies and communities in the field of drug and food supervision; and Implementation of coaching and general administration services in the field of general planning, administration, organization and management, staffing, finance, archives, law, press, equipment, and household<sup>20</sup>.

The objects of supervision carried out by NADFC include: Drugs, are finished drugs including biological products, which can be single or are a mixture of active substances, including narcotics and psychotropics, additives, contraceptives, and medical devices containing drugs. Traditional medicine is an ingredient or herb ingredients in the form of plant ingredients, animal ingredients, mineral ingredients, galenic preparations, or a mixture of such ingredients that have traditionally been used for treatment based on experience. Cosmetics are ingredients or preparations intended for use outside of the human body (epidermis, hair, nails, lips, outer genital organs) or teeth and mucosa of the mouth especially for cleaning, fragrance, changing appearance. Dietary Supplements are concentrated products containing one or more vitamins or minerals, consumed in small amounts measured and not in the form of common foods and marketed in the form of, among others capsules, tablets, powders or liquids intended to suffice the intake of vitamins and/or minerals from a normal diet. Food and beverages

are processed foods by certain means or methods with or without additional ingredients.

Based on the supervision object's description, NADFC also has a responsibility for the public's safety at large from the circulation of drugs and foods that are dangerous and unfit for consumption. NADFC must go down directly in supervising the circulation of these illicit substances because by the Main Duties and Functions that exist, namely monitoring, providing guidance and guidance on government agencies and communities' activities in the field of drug and food supervision.

In the Regulation of the Head of the National Agency of Drug and Food Control Number 14 of 2014 concerning Organization and Working Procedures of Technical Implementation Unit in the Environment of the National Agency of Drug and Food Control Article 10 of The Field of Examination and Investigation has the task: Carrying out the preparation of plans and programs; Evaluation and preparation of reports on the implementation of local inspections; Sampling for testing; and examination of production facilities, distribution and health agencies as well as investigation of cases of violations of law in the field of therapeutic products, narcotics, psychotropics, and addictive substances, traditional medicine, cosmetics, complementary products, food, and hazardous materials<sup>21</sup>.

In carrying out the preparation of plans and programs, the Field of Examination and Investigation makes a supervision plan loaded in the form of a work plan that will contain the quantity of supervision, the time of supervision, and the object of supervision. Then in the evaluation and preparation of reports on the implementation of local examinations in the Field of Examination and Investigation in carrying out supervisory duties can make reports of supervision results in the field as a form of accountability to superiors, the report can be in the form of written reports and unwritten reports. After that, an evaluation is carried out to identify the findings of supervision whether violations are found, and solutions provided for those who commit violations.

The Field of Examination and Investigation conducts sample testing. In conducting supervision of the Field of Examination and Investigation is authorized to test the object of supervision to the laboratory, whether the regulations supervise the samples. Sample testing includes the quality of the supervision object, the quality, and composition of the surveillance object. Then the Field of Examination and Investigation in conducting local inspections to production facilities and distribution facilities. The examination is carried out to see if the production facilities and distribution facilities circulate the supervision object by the provisions that have been determined starting from the permit, quality, and composition of the supervision object. The Field of Examination and Investigation conducts sample testing of production facilities and distribution facilities to see the manufacturing process and what content is in traditional medicine.

The Examination and Investigation Field consists of Examination Section, which performs local examinations, sampling for testing, examining means of production and distribution of therapeutic products, narcotics, psychotropics, addictive substances, and traditional medicine, cosmetics, complementary products, food, and

hazardous materials. Investigation Section has the task of investigating cases of violations of the law in therapeutic products, narcotics, psychotropics and addictive substances, traditional medicine, cosmetics, complementary products, food, and hazardous materials.

In conducting supervision in the Field of Examination and Investigation applies two stages of supervision, namely pre-market supervision and post-market supervision. Pre-market supervision is supervision carried out before the product is circulating in the market, standardization, coaching, and auditing the way traditional medicine is made. The second supervision is Post Market supervision which is supervision carried out when drugs circulate in the market. Under supervision, traditional medicinal products that can be granted circulation permits must meet the following criteria: Using materials that meet safety and quality requirements; Made by applying The Good Traditional Medicine Manufacturing Method; Meet the requirements of Indonesian Herbal Pharmacopoeia or other recognized requirements; Efficacious as evidenced empirically, hereditary, and/or scientifically; and Tagging contains information that is objective, complete, and not misleading<sup>22</sup>.

In supervising the circulation of traditional medicine, NADFC is based on the Regulation of the Minister of Health of the Republic of Indonesia Number 007 of 2012 concerning The Registration of Traditional Medicine and Regulation of the Minister of Health of the Republic of Indonesia Number 006 of 2012 concerning Traditional Medicine Industry and Business. With the issuance of the regulation is expected, the circulation of traditional medicine can follow the rules. Traditional medicine registration aims to protect the public from the circulation of traditional medicine that does not meet the requirements of efficacy, safety, quality, and benefits. Drugs that have a circulation permit must meet the criteria set by the National Agency of Food and Drug Control (NADFC). Traditional medicines circulated in Indonesia's territory must have a circulation permit granted by the Agency's Head. The granting of circulation permits is carried out through a registration mechanism by the established procedures.

To register a brand there are several requirements that must be met, here are the conditions: Photocopy of deed of establishment of a legal entity in accordance with the provisions of the legislation; The board of directors and commissioners of the supervisory body; Photocopy of ID card of the board of directors and commissioners of the supervisory body; The statement of the board of directors and commissioners of the supervisory body has never been involved in violation of the laws and regulations in the field of Pharmacy; Photocopy of evidence of land tenure; Photocopy of business premises license; Company sign letter; Photocopy of trading company license; Photocopy of Tax Registration Number; Location approval from the city district government; A plan or development that refers to the beginning of The Good Traditional Medicine Manufacturing Method and approved by the Head of the Agency; Original statement of willingness to work fully from the pharmacist in charge; Photocopy of the appointment letter of the responsible pharmacist from the head of the company; Photocopy of Pharmacist Registration Letter;

and Schedule of the plan to establish an industrial bank installation of machinery or equipment.

Administrative Requirements include<sup>23</sup>:

**Local:** Photocopy of business license of Traditional Medicine Industry/Small Industry of Traditional Medicine; Photocopy of diploma, Work Permit of The Technical Responsible Pharmacist who has been known or Assignment Letter from the Regional Office of the Ministry of Health of the Republic of Indonesia locally where the industry is located; and Pharmacist's Statement Letter as Insurer.

Technical Answer: Examples of Traditional Medicine Listed; Print-ready Tagging Design; and Examples of Simplicia/ raw materials. License, requirements are the same as local products, accompanied by License Designation Letter and Free Sale Certificate (original) from the country of origin authorized by the Representative Officer of the Republic of Indonesia's Government in that country.

Import, the same requirements as the Applicant's Product other than traditional medicine industry can also be registered by a Business Entity and accompanied by Letter of Appointment from the manufacturer of the country of origin; Free Sale Certificate (origin) from the country of origin authorized by the Representative Officer of the Government of the Republic of Indonesia in that country; Laboratory test certificate appointed by the National Agency of Drug and Food Control; Toxicity Test Data for Traditional Medicine whose safety is not yet known.

Technical Requirements: Local: Formulation/Efficacy; Composition: the name of the raw material and the amount; Efficacy/Usefulness: efficacy/usefulness of traditional medicine, supported by the efficacy/usefulness of raw materials supported by a library list; and How to Use: How to use and dosage/dose traditional medicine (detailed); warning, attention, restrictions/recommendation, length of use.

Quality and Technology: How to Manufacture, the number of products planned for one-time manufacture complete with the number of raw materials used, all stages of manufacture/Standard Operational Procedures; tools or machines used; Source of acquisition of raw materials; Raw Material Quality Assessment; description/organoleptic, macroscopic, microscopic, and physics-chemical tests are adapted to the type of raw materials (extracts); Finished Product Quality Assessment: certificate of analysis of finished products includes the examination of physics, chemistry, microbial contamination, and metal contamination; and Methods and Results of Stability/Durability Testing.

Import: The requirements are the same as local products, by attaching data from the original industry (original or legalized photocopy).

Tagging: At least the tagging/etiquette contains Traditional Medicine Name; Packaging size (Net Weight/net contents); Registration Number, name, and address of the industry (at least the name of the city and country); Composition (Latin name of raw material); Efficacy/Usefulness; How to use; Warnings and contraindications (if any); Production code number; and Expiry.

## CONCLUSION

Traditional medicine is one of the traditional health potions that are identical to the people of Indonesia. As we already know, Indonesian society is a society that never escapes from traditional medicine. These traditional medicines are identical to Indonesian society itself. In the case of registering traditional medicine, brands must be done by the prevailing laws and regulations because Indonesia is a country that recognizes the existence of laws. Besides, this form of supervision on the registration of traditional medicine brands must be done by the National Agency of Drug and Food Control (NADFC) properly and correctly not to cause problems that will later harm the responsible party.

**Conflict of interest:** The authors declare no conflict of interest.

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