

ESTABLISHING REGULATIONS OF HERBAL MEDICINE ON THE BASIS OF PANCASILA AS AN EFFORT TO INCREASE SOCIAL HEALTH LEVEL

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ABSTRACT

Health is basic human right that bases on non-discriminative and participative principles in which the implementation is well-directed and integrated that covers promotivepreventive, curative, and rehabilitative principles. It is integrated and sustained as it bases on the health paradigm that basically prioritizes promotive and preventive efforts as well as includes curative and participative efforts so that it is necessary to have a systemization that is health oriented as stated in Law no 36 year 2009 on health. To level up social health level, it is necessary to have sort of tools that one of which is medicines. One of well-known medicines among society is herbal-medicines that within generations used as diseasemedicine. Such herbal-medicines needs good governance so as toprovide protection and profit for customers, society, and states. It is necessary to systemize by certificate the activity of manufacturing to the activity of marketing. Pancasila regulation system is a system that bases on three main pillars such as religiously-behaved, humanistic, and nationalistic, democratic, and social justness. Pancasila is cultural and philosophical source of fundamental values.It is therefore the strategies of constructing legal system should be initiated from culturally-constructed system (national legal tradition). Pancasila values are the spirit or the principles of constructing national legal system so that the herbal-medicines governance and regulation reform should base on the Pancasila legal system construction.

Key words: constructing herbal-medicines systemization, Pancasila, social health Level.

INTRODUCTION

The national purpose of Indonesia as stated in the preamble of Indonesia constitution 1945 is to protect all the people of Indonesia and all the independence and the land that has been struggled for, and to improve public welfare, to educate the life of the people and to participate toward the establishment of a world order based on freedom, perpetual peace and social justice. To achieve that national purpose, it is necessary to implement sustainable development that is basically series of directed and integrated national development including integrated national health development that covers promotive, preventive, participative, and rehabilitative principles.

Health is basic human right and is one of main element of welfare that is necessary to realize according to national goals as stated in Pancasila and the preamble of Indonesia constitution 1945. Therefore, each activity and effort to level up social health level should be implemented on the basis of non-discriminative, participative, protective and sustainable principles that in turn will be crucial to construct Indonesia human resource, the tenacity improvement, national capacity building, and national development.

The first effort to level up social health level is mainly initiated from disease medicine then leads to the health integration for all Indonesia people by involving them to participate. This effort of course covers integrated, sustainable, promotive, preventive, curative, and rehabilitative principles.

However, it remains perspective that views this matter (social health) as less important and belongs to long-term investment in implementing national development. Therefore, it is necessary to view that social health is an integrated and sustainable activity to take care of and is a main factor and precious investment in which the implementation is based on a new health paradigm that is well-known as a healthy paradigm; it is a paradigm that prioritizes a promotive and preventive effort by not ignoring curative and rehabilitative principles. In this regard, it is necessary to regulate that matter that mainly covers healthy insight. Such that regulation is as law no 36, year 2009 on health.

Based on law No 36 year 2009 on Health on general provision states that "health is a health condition, physically, mentally, spiritually and socially so that enabling any person to live a productive life socially and economically".

Meanwhile, on chapter 1, article (11) states that "health efforts refer to any activity and/or a series of activities carried out integrally and continuously to maintain and promote the community health degree in the form of prevention of disease, health promotion, disease medication, and health recovery by the government and/or the people".

Traditional medicine has long been well-known in the society far from the first modern medicine came to Indonesia. The traditional medicine system is one of elements of culture that has long been cultivated and preserved in the society whether in rural society or urban society as national heritage. In this modern era, this traditional medicine is still an alternative way to treat a certain disease because it costs cheaper than modern medicine.

According to Ministry of Health Care of Indonesia provision no 1076 year 2003, traditional medicine is a medicine and or cure by a method and medicine that refer to hereditary skills and experience that is empirically and accountably assessed and applied

in accordance with social norm and tradition. This profession is called traditional healers. Generally, these healers are divided into two categories such as traditional healers by potion and traditional healers by skills. The former healer is *sinsheor tabib* and the latter is acupuncturist, reflexologist, spa-therapist, and magician, etc. Traditional medicine by potion is well-known as *herb (herbal)*. This traditional potion is well-known as *herbal potion* in Indonesia. This is often used to cure unknown diseases or is used in term of urgent condition where modern medicine is not available and unreachable. People tend to choose this alternative to cure and heal a variety of diseases since it is economically reachable. But in fact, the herbal medicine offered in the market is more expensive than patent medicine (medicines). It also raises in the society the issue of side effect that herbal medicine has less side effect than the patent medicine does though it is not fairly judged because not all herbal products have been assessed and registered to the Indonesia National Agency of Medicine and Food Control (BPOM). As stated before, that the use of medicine is as an effort to level up social health level, it is therefore necessary to construct good governance and regulation on herbal medicine in order to avoid negative impact to the social health that may occur because of the use of that medicine.

As stated before that herbal medicine is the most wanted alternative among society since it is believed that it contains no side effect as it is made of natural ingredients. Furthermore, this alternative is relatively cheap than patent medicines that attract people to choose this alternative as we know that mostly Indonesian people are under middle economic class. Nevertheless, it is also possible that this social opinion goes wrong since herbal medicine nowadays has not been scientifically and clinically assessed by the Indonesia National Agency of Medicine and Food Control (BPOM) and health care department that are legally authorized, especially on the content and dosage of the herb that in turn lead them (society) to suffer more dangerous diseases.

In this regard, it needs a regulation that herbal medicine which is manufactured or produced as an alternative medicine should be legalized (patent right) at Director General of Intellectual Property Right. By this policy, it is hopefully able to reduce negative possibility of occurring side effect in the future. The procedures of legalizing cover some activities that one of them is having legalized form of accepted product from the Indonesia National Agency of Medicine and Food Control (BPOM). Therefore, it is important to synchronize a systematic and integrated system of good governance of herbal medicine that covers the requirement of the provider to legalize the product (herb) to HKI. By legalizing that herbal medicine, it is hopefully able to have legal protection not only to the inventor of the product but also to the customers.

By considering social importance and the importance of economic growth as well as conserving hereditary tradition that one of which is producing herbal medicine (product), it is crucial to systemize good governance and regulation on the basis of fair (justness) and dignity. In short, the regulation and the reorganization of good governance of herbal product ranging from selecting ingredients, production process, packing to the distribution and marketing, should consider terms and conditions determined by the Ministry of Health Care of Indonesia. These cultural hereditary products and skills belong to local wisdom that need to be cultivated because it is a source of values of Indonesia culture that drive to develop states on the basis of Pancasila. And the society especially the providers of the herbal product is state's potential that need to be cultivated. Therefore, it is better to moderate between alternatives that lead to produce productivity rather than destructing these potentials.

DISCUSSION

1. The Notion of Legal Health.

As stated in chapter 1 article 11 that leveling up social health is by medicines or medicine. On chapter 1 article 8 Law no 36 year 2009 stated that medicine refers to material or combination of materials, including biological product used to affect or investigate physiological system or pathological condition with respect to stipulation of diagnosis, prevention, cure, recovery, health promotion and contraception, for mankind. One of well-known medicines in the society is traditional medicine or herbal medicine. Traditional medicines are ingredients or ingredients in the form of plant material, animal ingredients, mineral, extract (*galenic*), or a combination of such ingredients that have been hereditary for treatment, and may be applied in accordance with the norms and tradition in the community.

As stated in the preamble of the constitution 1945 that the purposes of Indonesia are to protect all the people of Indonesia and all the independence and the land that has been struggled for, and to improve public welfare, to educate the life of the people and to participate toward the establishment of a world order based on freedom, perpetual peace and social justice, therefore the independence of Indonesia shall be formulated into a constitution of the Republic of Indonesia which shall be built into a sovereign state based on a belief in the One and Only God, just and civilized humanity, the unity of Indonesia, and democratic life led by wisdom of thoughts in deliberation amongst representatives of the people, and achieving social justice for all the people of Indonesia. The health as one of and general welfare element should be applied by some efforts in order to accomplish integrated national health development.

In chapter 28H article 1 the constitution 1945 of Indonesia explicitly stated that Every person shall have the right to live a physically and mentally prosperous life, to have residence, and to obtain a proper and healthy living environment as well as to obtain health services. This statement states and implies that health is a basic human need and is right of all Indonesian citizen. On the other hand, legal is a medium to protect all human importance that include implementing health for all citizens.

Law is a set of rules that contain principles. It is the overall rules in which all people should obey. It regulates all aspects of human life including health. And in order to support social health enhancement, it is necessary to formulate a regulation as the body of law during which changed as health law. Health law is a regulation which is concerned with health services.

Leenen (in Guwandi) states that “health law is all regulations that are concerned with health services and its application to the civil law, administration law, and criminal law”.¹ Guwandi also cited Van DerMijn’s opinion that health law is a set of regulations that is concerned with treatment and also its application to the civil law and the administration law. In his paper as cited by Ministry of Health Care states “.....health law as the body of rules that relates directly to the care of health as well as applications of general civil, criminal and administrative law”. This theory is universally applicable around all states. The formulation of health law is not only centered to the regulations but also covers international regulations and agreements, international principles, traditions, jurisprudence, and doctrine. Therefore, the sources of health law involve written law, doctrine, and jurisprudence but objectively health law covers all aspects that relate to health care. Health law regulates two main importance and concerns such as service receivers both personal cash and group cash. The second is the service provider such as hospital, district health care, and clinics as well as health practitioners such as doctor, nurse, midwife etc. that is necessary to include in the regulation.

2. The Notion of Traditional Medicine.

Traditional medication and cure have been well-known in Indonesian society long before modern method came. In Indonesia we know that traditional medication is as an element of culture that grows and develops in rural and urban setting within generations. At first, this medication seemed to be mystical that is rooted to animism. Along with human development, this method is influenced by some cultures such as India, China, Arab, and Europe. Moreover, today’s community would rather choose this method as an alternative to cure deceases. People tend to consume traditional medicines rather than patent modern medicines that is produced by pharmacy company that has been certified and assessed by the Indonesia National Agency of Medicine and Food Control (BPOM). People also tend to choose this method since it is relatively and economically reachable and cheap. This condition is inevitable because it has no standard to set the price into standardized prices as regulated by government and it does not have clinical standard. According to law no 36, year 2009 on health, traditional medicine refers to material or ingredients in the form of plant substance, animal substance, mineral, extracts, or combination of such substances which have been used for medication for generations, and may be applied according to the prevailing norms in the society.

Traditional medicine is divided into three:

- a. Traditional medicine refers to material or ingredients in the form of plant substance, animal substance, mineral, extracts, or combination of such substances which have been used for medication for generations, and may be applied according to the prevailing norms in the society.
- b. Every people who provide traditional health service using equipment and technology should secure permit from the authorized health institution.
- c. Phytomarmaka is medicine preparation (raw) that has been accounted for secure in which the raw materials consist of *galenic* that is permitted by authorized institution.

1. Establishing Regulatory System on Patent-Based Herbal Medicine in the Basis of Justice of Pancasila to Increase Social Health Level

1.1. The Regulation of Paten-Based Herbal Medicine Management.

Talking about the history of the development of patent, it is important to back to 16 centuries on which the patent was labelled, called “Oktoroi”. The patent was not as recognition of a certain product or right but rather as a king protection for foreign people who brought certain knowledge and skills to create an innovation. In other words, patent was not as a recognition of a new invention. Its first recognition as an invention and the principles of patent began when the regulation of Monopoly in England first published. While in Indonesia it was applied before its independence (Oktrooiwet) in 1910 and was valid since 1912. However, after Indonesia was independent, this policy was not valid since its authority was in Netherland.

Along with the ratification of international treaty, technological development, industrial and trade development, Indonesia needs to regulate patent policy to protect inventors before law as well as to create a good atmosphere of business competition.

1.2. The Notion of Patent

According to chapter 1, article 1 law no. 13 year 2016, patent shall mean an exclusive right given by the State to an inventor for his invention in the field of technology, for a certain time, in which he shall himself exploit the invention or give his approval to any other person to exploit the same. While the invention shall mean an inventor’s idea that is poured into an activity of solving a specific problem in the field of technology, either in the form of a product or process, or an improvement and development of a product or a process. In chapter 1, article 3 law no 13 year 2016 states that inventor shall mean a person or several persons acting together implementing an idea poured in an activity resulting in an invention. An invention can be applied in an industrial matter only if the invention can be applied in the industrial matter as described in the proposal (Chapter 8 law no 13 year 2006).

1.3. The Concept of Herbal Medicine Management.

Indonesia which has a variety of natural resources, cultural diversities, and traditional knowledge and skills, especially in the field of traditional medicine or herbal medicine needs to have good governance in order to protect and provide worthiness for its community and state.

Good governance is a process, tradition, policy, and institution that affect supervising, managing, and controlling a certain product. Relating to this herbal medicine governance, it is necessary to regulate this process to warrant that the product manufactured gives a positive impact and worthwhile for society specially to increase social health level. Pre-marketing and

¹Guwandi, 2004, *Hukum Medik*, BalaiPenerbit FKUI, Jakarta, hlm.15.

manufacturing product regulation through authorized institution and proved by a certificate, will protect both providers and customers.

1.4. Establishing Pancasila-Based Herbal Medicine Systemization

Talking about Pancasila-based herbal medicine systemization cannot be separated from what Pancasila law system is. Pancasila law system is a law system in which rooted to Indonesian culture, tradition, and philosophy and belongs to world civilization. Pancasila law system is an authentic and original law system. It has to base to three principles;

- a. Religious values-oriented (religious moral)
- b. Humanistic values-oriented (humanism)
- c. Social values-oriented (nationalistic, democratic, and social justice)

Since Pancasila contains fundamental cultural and philosophical values, therefore legal system of national development should establish and root to its own culture as the fundamental spirit. Basically, Pancasila as fundamental sources establish and reform its legal system from its fundamental ideas. We can argue that to reform and establish herbal legal system should refer to its fundamental sources (Pancasila). Barda states that legal system establishment should base to the three principles as the application of Pancasila.

Establishing good herbal medicines governance and management should be religious values-oriented, it means that the regulation being established should base to the essence of religious values that direct to beneficence about what is right and wrong. It means that providers who produce herbal medicine should consider this principle to avoid customers' loss and disadvantages. One of things can do is that by registering its patent. By registering the patent of the product and innovation, it means that the providers have legalized and fulfilled the administration and clinical assessment requirement of the products as well as to protect its innovation and products from haphazard claims.

Second, good governance establishment should also be social-oriented. It means that to promote this legalization among providers should use smooth approach by persuading them rather than to confront with them in order to ease them to deal with this requirement. Furthermore, the legal system that will be established should also cover social justice. It means that it should provide social justice not only to the providers but also to the customers by labelling the ingredients and contents of the product. Loving our own hereditary products needs nationalism and patriotic attitude as well as to provide the producers an opportunity to develop these hereditary products that leads to the responsibility of keeping democratic atmosphere by also considering the progressive eras.

CONCLUSION

Traditional medicine is an ingredient or a basic ingredient or an extract ingredient that is among generations used to cure or heal on the basis of experience and is applicable among society in accordance with social norm and tradition. Constructing regulation and good governance system of herbal products cannot avoid Pancasila legal system. Pancasila legal system is an authentic and original legal system. Pancasila legal system should base on three principles;

1. Theologies values oriented (religious moral)
2. Humanistic values oriented (humanism)
3. Social values oriented (nationalistic, democratic, and social justness).

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