

PRODUCT CERTIFICATION AND LEGAL PROTECTION TO ENHANCE INDONESIAN TRADITIONAL HERBAL PRODUCTIONS*

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Abstract

This study is aimed to empower traditional herbs producer and help legal protection of Indonesian traditional medicines, implementing Participatory Research and juridical-sociological approaches. Data were collected through literary, questionnaire, interview and Focus Group Discussion. The first year study revealed that Herbal Producer Association worked with all members, persuading government offices to get product certification and effective trademark licenses. In the second year study the researchers and Producers Association trained and facilitated vendors to endorse trademark, label registry, and markets shares. Producers maintain traditional medicine management, because product certification is hard to achieve.

Keywords: *product certification, legal protection, traditional herbs.*

Intisari

Penelitian ini bertujuan untuk memberdayakan produsen jamu/OT dan membantu perlindungan hukumnya, dengan memanfaatkan pendekatan penelitian partisipatoris dan sosiologis yuridis. Data dikumpulkan dengan literatur, kuesioner, wawancara dan Focus Group Discussion (FGD). Pada tahun pertama organisasi gabungan pengusaha jamu (GP Jamu) bersama-sama dengan seluruh anggotanya mendorong pemerintah untuk perolehan sertifikasi produk izin edar dan merek secara efektif. Pada tahun kedua, peneliti dan gabungan pengusaha jamu melakukan pelatihan guna perolehan izin edar, pendaftaran merek, dan peningkatan pemasaran. Para pengusaha jamu tradisional perlu terus menerus didampingi karena perolehan izin edar terkesan sulit.

Kata Kunci: sertifikasi produk, perlindungan hukum, obat tradisional.

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A. Background

Issues on nation heritage on traditional knowledge and traditional culture expression come from the function of genetic resources traditional knowledge and folklore (GRTKF) by foreign countries in using medicines that the raw materials originates from developing countries including Indonesia. Economically, in case of developing countries, Indonesia has received injustice treats that the traditional raw materials were seized and patented by foreigners and it purchases back the products in a sky-high cost. Indeed, Indonesia should receive big royalty because genetic sources is its own origin and is legally protected. This is the fact that Indonesia should protect the genetic resources beyond national regulation, international consensus and iconize genetic sources as nation's heritage. This way, herbs and phytopharmacy including drugs and traditional medicine (*jamu*) should be empowered and protected applying motto "promote and protect". A central issue on misappropriation of GRTKF in Indonesia and international trades and the execution of The Asean Economic Community (AEC) and Asean-Chine Free Trade Agreement (ACFTA) legally abolish Indonesian traditional medicines, and traditional medicines from Chine are freely traded in Indonesian markets.

Recently, problems of Indonesian indigenous herbs are of twofold. **First**, natural resources as raw materials of *jamu* or traditional herbs are affluent, but skilled human resources to produce traditional herbs are short. **Second**, empowerment program to train producers of traditional medicine to accomplish good and right management, standardized quality of product, marketable product, and networking are lamented. This way, trainings on economic values of traditional medicine, law empowerment, and auspices to achieve intellectual rights, certified circulation from Health Department and promotion through advertisement are prepared. A considerable research to develop prospect and potential of

traditional medicines that convince sustainability, policy and strategies to increase traditional medicine in the markets in East Java and Central Java has been conducted.

This study empirically discovers that substantial efforts have been conducted by Herbal Producer Association (Gabungan Pengusaha/GP). Members of the association and producers are persuaded aspiring prospects and potentials, roles of government and related offices, regulation effectiveness to reveal trade licence, registered label and advisory.¹ Recently most herbal producers (Obat Tradisional) prepare product just to provide CPOTB for trade licence; motivation to achieve Standardized Herbal Product (Obat Herbal Terstandar/OHT) is still far from target. Only 1-2 producers achieve and get OHT every year in Jawa Tengah and Jawa Timur². Economically, a core problem that requires advisory and implementation guides to achieve sustainable production, capital, marketing and promotion, networking and management is top urgent. Urgency also exists for empowerment, standardized health (hygienical and laboratory, standardized CPOTB), and legal standing (regulation, policy, label, and consumer protection). Efforts are needed to increase expertise of the human resources, trainings and advisory from related institutions, including Office of Drug and Food Monitoring (POM), Office of Industry and Trade (Perindag), Health Office, Office of Cooperation and Medium Scale Trade, Provincial Office of Intellectual Property Rights, Office of Agriculture, universities, and GP to implement Empowerment, Promote, and Protect Model. The Legal issues are as follows: **First**, how is the way to promote and protect OT production through product certification?; **Second**, what is the effort of protecting the brand relates to OT distribution license granted?; and **Third**, how is the problem brand mark on OT production?

¹ Interview with Stevanus Handoyo, Secretary of GP Jamu Jawa Tengah, 15 July 2015.

² Interview with Minarni Purnomo, Director of GP Jamu Jawa Timur, 26 August 2015.

B. Research Methods

This study uses qualitative approaches to describe and analyse potentials and prospects of the development of traditional herbal products, spending a two-year observation. This article uses normative empirical method on knowing participants need about legal understanding of product certification. This study is based on participation and self-development, treats *jamu* producer as research participants. Participants of this study included 100 producers and 70 consumers of herbal medicine from East Java and 150 producers and 80 consumers from Central Java. Promote and Protect model is implemented relying upon Participatory Research Approach (PRA) and juridical-sociology approaches. Data were collected through: (1) literary; (2) questionnaire answers from the respondents; and (3) direct interview and Focus Group Discussion (FGD), involving producers, head of organizations, head of government officers in the country and provincial levels, policy makers on traditional/herbal medicines.

C. Research Result and Discussion

As an economic corridor, Java has its urgent role to “Stimulate National Industry and Service”; potential to become invest asset particularly for the *jamu* and traditional medicine (OT). So far, traditional medicines are produced from generation to generation; even, plenty of vendors in Central Java and East Java serve *jamu* using traditional services, carrying the *jamu* on the back. Centers of *jamu* as a home industry product, such as Madura (East Java), Cilacap (Central Java) still produce the *jamu* in trivialities. These *jamu* and traditional medicines are served and blended in a simple package from centuries ago, and are sold without medical guarantee and legal protection. Potential production factor that is not maximally achieved produce low quality of the product. This way, competitors exist from herbal companies of famous labels or patented foreign herbal companies that probably absorb the nature of Indonesian indigenous knowledge on

traditional medicines. Justice is part of *rechtsidee*, and it is not fair that Indonesia as the origin state of genetic resources whose intellectual property rights are protected and should receive royalty, is treated as consumer of a high cost its own traditional medicine. Biopiracy has long been implemented, but academic community and practitioners do not defend and involvement of the government and related offices is low. The needs of communal society on Indonesian indigenous medicines never receive enough attention.

Most producers of traditional medicines in East Java and Central Java are medium scale industries, however, potentials and opportunities to develop the products into industrial herbal medicines are prospective in the future. Added values and competitive sense should be accomplished to the development of sustainable and justice products to defend from bio piracy. Weaknesses of the traditional medicine production that include technology, economy, health, law, social and management should be overcome. Based on economic interest, Indonesia has been treated in injustice manners because raw materials of traditional medicines originate from the country, but the benefits of the medicines are seized, given foreign labels, and it is sold and bought in a sky-high cost by Indonesian.

Immediately, Indonesian genetic sources should be protected through national regulation and international agreements, even, it should be the icon of heritage of Indonesian country. OT should evolve to OHT and finally as Phytopharmacy. Indonesian traditional medicines deserve nobility, sustainability, and legal protection under “promote and protect” model, refusing adagio of advanced countries that say traditional knowledge is common heritage of mankind, through protection of Indonesian indigenous heritage using legal protection. Current issues pertaining to misappropriation of GRTKF in Indonesian context and international trades include the implementation of ACFTA and AEC that make Indonesian producers of traditional medicines are fear of the dominance of traditional medicines from

China that would control Indonesian markets.

IKOT/UKOT should be professionally managed prior to compete in broader industrial markets. Industrial concern must attend an interaction process among technology, innovation, trade licenses and mark. Various approaches for empowerment are required in a single sector and regional sectors. To accurate empowerment *jamu* producers include, human resources development, capital, partnership, and development of small scale center and supervisory on a certain unit and certain are through Effort Collective Group (GP). To compete in the very tight global market that will happen in home country market, business competitors should increase efficiency and competitive products, also spin off. This study confirms that empowerment strategies serve more benefits conducted through participatory approach.³

Slow evolvement of OT to OHT, certification, label protection and production factors affect market potentials. Tantri claims company management is affected by internal and external factors.⁴ External environment consists of indirect factors, i.e. economy, social, politics, and technology and direct factors, i.e. competitive position of the company, consumers profile, suppliers, creditors and employers. Internal environment comprises of internal elements in the company that links each other that should work harmonically, and support mutually in a comprehensive process and provide sustainable evaluation. In addition, a company should develop R&D to see markets and to innovate new products, development of regulation implementation and politics pertaining to production factors, and plans company development based on SWOT analysis.⁵ Business research is undertaken to reduce uncertainty and focus on decision making.⁶

Leadership of UKOT/IKOT is confused for some extents, e.g. owner and company leader who works as an operator of a home industry that should be managed professionally. In addition, the need of medicine is considered top urgent because she controls external function of the company. This way, a strong organizational structure should be provided to enhance management and sustainable company. David suggests organizations should take a proactive rather than a reactive approach in their industry, and they should strive to influence, anticipate and initiate rather than just respond to events.⁷

Beside professional organization, strategies to cope markets should be applied. The strategies are include: (1) giving free sample product, (2) to do social relationship as it takes a war, (3) using internet, and (4) to make jokes. In addition, innovation should be implemented together with sense of marketing, including: a principle of sustainable marketing holding that a company should define its mission in board social terms rather than narrow product terms.⁸ Company should define it. Purwaningsih confirms that producer is responsible to his product up to the products are bought by the consumers.⁹

Politics and legal standing implemented in the policy regulation affect the sustainability of production factor. For example, the existence of MEA needs political will from the government to protect traditional medicine as an industrial of traditional knowledge basis that is the heritage of the ancestors. Government interferes to protect imbalance competition between traditional medicine products of IKOT/UKOT and industrial pharmacy of herbal products and herbal medicine from China. The competitors come from in home country and foreign countries that cost of production is lower

³ Soenyono, 2011, *Pemberdayaan Masyarakat Miskin*, Jengala Pustaka Utama, Surabaya, p. 101.

⁴ Francis Tantri, 2013, *Pengantar Bisnis, Cetakan 4*, RajaGrafindo Persada, Jakarta, pp. 133-134.

⁵ Suko Susilo, 2009, *Ekonomi Politik dan Teori Pembangunan*, L-SOD, Depok, p. 5.

⁶ William G. Zikmund, et al., 2013, *Business Research Methods, Ninth Edition*, South Western, Cengage Learning, Texas, p. 51.

⁷ Fred R. David, 2013, *Strategic Management, Fourteenth Edition*, Pearson Education Limited, Edinburg Gate, p. 51.

⁸ Philip Kotler & Gary Armstrong, 2014, *Principles of Marketing, Fifteenth Edition*, Pearson Education Limited, Edinburg Gate, p. 619.

⁹ Endang Purwaningsih, 2015, *Hukum Bisnis*, Ghalia Indonesia, Bogor, p.75.

and the selling cost is cheaper. Producers of the traditional medicines face problems on the products but also get problems on intellectual protection and its marketing. Market does not serve invisible hand to create harmony, but tool of measurement to judge values of product objectively should also be available.

1. Promoting and Endorsement of Traditional Knowledge

Traditional medicine is one of the traditional knowledge. Traditional knowledge is defined is the work of indigenous people, in terms of food, *jamu*, medicine, art and technology that are used from generation to generation from the ancestors. Traditional knowledge is owned by all traditional people that is protected and sustained but it has not been accurately protected in the intellectual right law. As plenty of traditional knowledge from Indonesia is patented by foreigners, Indonesian people are open their eyes to protect and exploit in justice way. Task Force on genetic resources, traditional knowledge and expression of folklore of the Ministry of Law and Human Rights has some functions as follows: (1) inventory of various genetic resources and its benefits, traditional knowledge and expression of folklore that have been public domain; (2) to inform and publish exchange information electronically for public uses about genetic resources and their utilities, traditional knowledge and expression of folklore that have been public domain so that others cannot process for patented rights; (3) to prepare advices to draft Plans of Law Regulation on the procedures to possess genetic resources, its relationship with intellectual rights, and justice share on the benefits to use the resources; and (4) to support solution on the problems pertaining to intellectual property rights to use genetic resources and justice share of the benefits to use the resources.

Problems pertaining to probability of how traditional medicine would be patented are still controversy because label and patent rights and their protection are law construction adopted from

liberal countries to protect their individual works. The main goal is to guarantee the monopoly use of the work. Based on liberal concept, individual ownership is absolute reserving collectivity in the Indonesian Customary Law. In the customary law, property has social function for public uses; even traditional community will be proud of having work that is admired and used by other traditional community. In addition, customary law conceives that property is concrete and cash; so that patented rights are somewhat strange for the customary community.¹⁰

Conceptually, community empowerment using participatory approach is explained as follows: (1) mapping on area potentials, including natural and human resources, socio-cultural condition, availability of socio-economy facilities and economic potentials; (2) analysis to the results of mapping to select alternatives of trade development; (3) visibility analysis toward identified trades and selecting a certain work to focus for core work, supporting work, related work, and institutions that support the work development; and (4) expected output pertaining to absorption of labours, local economic development, growth of investment, and to decrease number of the poor.¹¹ The main characteristic of community empowerment focuses on the policy of indigenous development using human resources potentials, institutions and local physics. This way, community empowerment can be applied through integrating efforts to mobilize actors, organizing resources, optimizing available institutions, forming new institutions and selecting strategies actions to support area development.

To focus regional and sectoral development, using Basis of Economy basis, primary factor to determine economic growth of an area directly relates to demand of goods and services from other areas. According to Location Theory is also prominent to determine and develop industrial territory; producers tend to use work location that gives maximum benefits and minimize production

¹⁰ Endang Purwaningsih, 2012, *Hak Kekayaan Intelektual dan Lisensi*, Mandar Maju, Bandung, p. 64.

¹¹ Soenyono, *Op.cit.*, p. 101.

cost, that is location nearby with raw materials and markets. Building of landmark is also urgent for marketing strategy.¹²

So far, food and beverage industry particularly traditional medicine or *jamu* is commonly managed by individuals for home industry basis. This small scale industry is operated by family members and cooperative mutual work. Small scale trade is characterized by no clear job description between administration and operation, low access to the creditor institution, no legal standing and most of them work on food industry, drinks, and tobacco. Some have improved from medium scale industry to a company that has legal standing and is profit oriented in terms. The company runs step by step at the first time, but it must work strongly; markets significantly grows better. Traditional medicine would be a good alternative supplement if it fills standardized medical criteria. This way, local and national government offices, such as Disperindag, Ministry of Law, BPOM, Health Office, Directorate General of Intellectual Rights and traditional medicine organizations wake from deep sleeps. Problems on chemical-drug materials in Cilacap is recently overcome by BPOM, but the producers should not be left. Some *jamu* produced by Aneka Sari Cooperation from Gentasari Cilacap, are in the process of trade licence, expecting BPOM persuasively works with the cooperation and uses participatory approach to overcome problems of the producers. Traditional medicines in Cilacap are now powerless; trade licence is in process, requisites to fill standardized herbal medicines are hard to achieve. To have registered labels is a hard work for the traditional producers. In addition to this problem, an example is present from Madura from which circulation of traditional medicine is affected by the popularity of the strength of Madura traditional medicines. Some traditional medicines in Madura have achieved registered trade and licence to trade. This problem complies with government efforts to facilitate producers in

Cilacap empowerment to increase quality of *jamu*, legal protection and information on health cares.

Rate percentage on an increase of UKOT/IKOT to be PT within recent 5 years is 42%; producers that follow the program consist of 1-3 years 16% and 3-5 years 12%. Most producers claim that standardized criteria to increase UKOT into PT are too high and very hard to achieve.

Other problem pertains to increase OT into OHT where rate percentage distribution is achieved as follows: more than 5 years 44%; 3-5 years 18%, 1-3 years 14%, and the other 24% strongly claim that they do not know where and when increase OT into OHT. In terms of supervisory programs, producers expect to receive supervisory from government office 70%, university 12%, and the other 2%. In all, the status to increase OT into OHT is perceived badly needed by 40%, necessary 38%, moderate 20%, less necessary 19%, and not necessary 6%. Helps from government are strongly expected by 62% and importantly expected by 38%.

2. Product Certification and Intellectual Property Protection for Trade Licenses and Mark

The practices of small scale trade and communal, products of traditional medicines or *jamu* should be increased its process using laboratory certification to achieve herbal medicine category. Standardized herbal medicine efforts, together with effort to increase market shares and their quality by giving trade label and licenses would provide more opportunity to promote *jamu* into domestic and export commodity. Export commodity should be certified its quality, medical assurance, competitive, and intellectual legal protection. Indonesian export commodity has been identified as low innovation on the packages and quality from year to year. This way, business agents on traditional medicines should be more careful and more creative to identify the demands of the exported market potentials in a certain country. Researches on market characteristics are strengthened exposing business

¹² Paul J. Peter & Jerry C. Olson, 2013, *Consumer Behavior and Marketing Strategy*, Salemba Empat, Yogyakarta, p. 135.

agents to export new commodities that previously Indonesian traders cannot trade to countries whose economic atmosphere will grow better. In addition, business agents who focus on export commodity, should reorient their trade to domestic demands. Good economic growth and better growth of purchase capacity will place domestic market better potential. Moreover, incoming import commodities in Indonesian markets that increase tight competition should be considerably monitored. To prevent from the increase of tight global competition that penetrate into domestic market, producers should improve efficiency and competitive values of the products.¹³ OT has largely been consumed by domestic consumers and the increase of turnover is potential to penetrate foreign markets. Requisites for standardized trades relevant to CPOTB with medical assurance as well as label popularity would be top priority prepared by *jamu* producers.

Decree No. ST. 04.03.43.12.13.4439 on Fastening License for Small Scale Trade of Traditional Medicine provides significant difference of regulation between regulation of Health Ministry No. 246 Year 1990 and Health Ministry No. 006 Year 2012 especially regulation of packages produced by UKOT and CPOTB; emphasizing that UKOT needs enough time span for self-preparatory and a substantial breakthrough is required to achieve license of UKOP faster as stated below:

1. Small Scale Trade on Traditional Medicine in terms of capsule and liquid (UKOT 1). Decree of Health Ministry 006/2012 regulates that UKOT 1 should confirm requisites of CPOTB proved by CPOTB certificate issued by BPOM. To make the license appropriate, UKOT 1 should exhibit Letter of Agreement on Building Ground Plan of the UKOT. Verification on fulfilment of CPOTB by BPOM is conducted in line with Regulation of POM No. HK.03.1.23.06.11.5629 year 2011 on Technical Requisite to Produce Good

Traditional Medicine. UKOT 1 who do not yet develop its building or the development is in process based on the Agreement Letter of Grand Plan of UKOT and in preparation to serve document of quality system are recommended for CPOTB by showing Letter of Commitment to finish development of UKOT and quality system on CPOTB annexing schedule of finishing development no more than two years. Finally, UKOT 1 should apply certification of CPOTB not later than 1 January in the following year (1 January 2016).

2. Small Scale Trade of Traditional Medicine that produces other than COD and capsule (UKOT2). UKOT 2 applying completeness of license or new license should be verified their completeness of CFPOTB by the local BPOM referring to Guide of Implementation of Sanitation, Hygienic and Document issued by BPOM year 2013. UKOT 2 whose documents of CPOTB are in process can be recommended to fulfil CPOTB by local BPOM annexing Letter of Commitment to fill CPOTB and schedule of finishing no more than 1 year. Letter of Commitment signed by Head of local BPOM can be proposed for registration of traditional medicines.

Decree of BPOM No. PN.03.4.41.411.02.14.574 dated 6 February 2014 on Her-registration of Traditional Medicines and Health Supplement stating the effectiveness of electronic registration and the role of Head of BPOM RI No. 39 Year 2013 on Standardized Public Services in BPOM promulgated on 15 July 2013, indicates to extend trade license the same products with no package changes. Application should be proposed in a fastest of 60 (sixty) days or the latest within 10 days of effective work prior

¹³ Komite Nasional Ekonomi, 2012, *Prospek Ekonomi Indonesia 2012: Terus Tumbuh di Tengah Ketidakpastian Global*, Komite Ekonomi Nasional, Jakarta, p. 17.

to the expiration of circulation license. Traditional medicine and health supplement that the circulation license has expired and no registration to prolong is illegal and against the law.

Decree of BPOM RI No. HK.05.02.43.01.14.382 dated 24 January 2014 on Fastening of Industrial Traditional Medicines (IOT) and Industrial Extract of Natural Materials (IEBA) states a number of 82 (eighty two) industrial traditional medicines. Considering significant difference of regulation between Decree of Health Ministry No. 246/1990 and Decree of Health Ministry No. 006/2012 on the regulation of Core Plan of Development (RIP) and CPOTB, enough time span is available for IOT and IEBA for self-preparation and initiative to find breakthrough steps is possible to fasten of approval of licenses of IOT and IEBA as the following:

1. IOT and IEBA having CPOTB certificate for all kinds of production: (1) referring to recommendation of CPOTB issued by BPOM based on Decree of Health Ministry No. 006/2012 Article 17, IOT and IEBA having CPOTB certificate can be recommended to fill CPOTB as the certificate implies, and (2) to prepare from her-registration, IOT and IEBA should submit an application for Agreement of RIP, Office System Management, and Quality System of CPOTB.
2. IOT and IEBA that have had CPOTB certificate for some kinds of products are possible to recommend fulfilled CPOTB for all kinds of products as the certificate assures.
3. IOT and IEBA having no CPOTB certificate have to apply Agreement of RIP, Office System Management, and Quality System of CPOTB in line with Regulation of BPOM No. HK.03.1.23.06.11.5629/2011 on Technical Plan to Produce Good Traditional Medicines.

Announcement No. 03.41.411.03.13.905 on stages of implementation of e-registration of traditional medicines suggests that any industry of traditional medicines is subject to register company account. Registration of company account applies for all products including the first step product. Registration of company account for industry that has had circulation license was conducted no later than September 2013. Account registration is applied through *website.asrot.pom.go.id*. Successful online registers would receive information through register's email to submit documents to BPOM, the Directorate Evaluation of Traditional Medicine, Supplement, Food and Cosmetic for verification.

Members of Traditional Medicine Association of East Java, according to Ita from PT Balatif¹⁴ are loaded with problems on license and certification of CPOTB. Ita explained to register new product of OT the company should apply semi online process using company account prior to submission of hard copy documents to BPOM. The process has been disseminated by BPOM.

Product certification and intellectual legal protection is truly prominent when borderless product and capital circulation occurs to any direction. *Jamu* producers investing their capitals would use tangible or intangible assets. Producers of *jamu* would feel comfortable and safe if the products to invest are protected by regulation that support the company and is facilitated ease to find circulation license and registered label, giving opportunity to achieve brand-mark and well-known mark indicating marks of the *jamu* and their origin country Indonesia. Producers should also proficient to select which country the product would be sold having strong legal protection and legal enhancement on intellectual protection to defend traditional knowledge and indigenous people.

Government through offices involved to manage traditional knowledge is responsible to any exploitation of traditional medicine. So far, no protection is specially focused on the traditional

¹⁴ Interview with Ita, pharmacist of PT Balatif, Malang, 20 October 2014.

medicine problems and legal sanction to foreign producers seizing benefits through illegal ways of intellectual protection without permission of Indonesia traditional community.

Interviews with Hermansyah owner of PT ASIMAS,¹⁵ Danang of PT Sabdo Palon,¹⁶ and Agung of PT Gujati¹⁷ identify that the most obstacle to find legal protection is that there is no clear coordination between Directorate Intellectual Protection of label registration in BPOM and assessment section for OT, resulting label certificate registered in Ditjen KI is refused by BPOM for some reasons. Question is addressed saying who will be more competent to define label. Complaints are also addressed on the standardized process for OT as it is equalized with pharmacy instead more pharmacy companies have expanded their products to OT and herbal medicines.

Interview conducted on restructure of production factors (capital, human resources, and raw materials) with Moh. Chaeron¹⁸ of PT Meddia Herbal claimed that most problems come from capital, machines, and regulation. Hj. Siti Halimah of PT Lestari Jaya viewed that quality and quantity of human resources that are competent in OT are the most restriction, adding problems on government incentive to allocate capital with long and soft loan model. In addition, Agus Santoso of CV Herbal Indo Utama identifies problems on limited capital that should be provided more capital with soft loan facilities, inexperienced human resources with limited training incentive from government, and non-standardized raw materials. Artike Theresiani of PT Searang Herbal Indoplant confirmed that shortage of product is a result of limited raw materials. What makes the matter worse, more pharmaceutical industries diversify the product

by building new IOT/IEBA industries, making raw materials are utilized in more number and the available stocks decline faster. KH Tamam Qaolany from Jamu Tradisional Onta Emas suggests that most problems come from production factors including capital, pharmacist, human resources, and technology.

Solution expected to overcome the problems is suggested by Sarjuni of PT Agaricus Sido Makmur Sentosa-ASIMAS involving government role to prepare facilities of production, financial incentive to support investment, trainings for quality of product assurance, and cost for clinical laboratory for traditional medicines.¹⁹ Interview with Sabdha Agung of CV Untung Kumoro²⁰ suggests problems of standardized raw materials and inexperienced human resources as the main obstacles. Safrin and Puji Rahayu from PT Indo Abadi Sarimakmur maintained problems on regulation and clinical laboratory procedure are of top urgent.²¹ Regulation on traditional medicine trade is very complicated and clinical laboratory process is costly. Certification for CPOTB is considered very hard and complicated. Yesi R from PT Kaliroto identified problems on the restructuring production machines, facilities of production and limited capital are prominent for any traditional medicine company.²²

Problems to increase status of OT into OHT and spin off from UKOT to medium scale industry are administered from Moh. Chaeron of PT Meddia Herbal.²³ The problems exist because of limited capital and complexity of formal requisites and procedures to achieve status of OT into OHT. Hj. Siti Halimah added more problems, including capital, human resources, machines or technology, raw materials and management. Agus Santoso viewed that most problems come from limited

¹⁵ Interview with Hermansyah, Director of PT ASIMAS, Surabaya, 8 August 2015.

¹⁶ Interview with Danang, Director of PT Sabdo Palon, Solo, 26 August 2015.

¹⁷ Interview with Agung, Director of PT Gujati, Solo, 26 August 2015.

¹⁸ Interview with Moh. Chaeron, staff production of PT Media Herbal at Semarang, 15 July 2015.

¹⁹ Interview with Sarjuni, staff production of PT Agaricus Sido Makmur Sentosa-ASIMAS, Malang, 8 August 2015.

²⁰ Interview with Sabdha Agung, staff production of CV Untung Kumoro, Surabaya, 8 August 2015.

²¹ Interview with Safrin and Puji Rahayu, staff production of PT Indo Abadi Sarimakmur Gresik, Surabaya, 8 August 2015.

²² Interview with Yesi R, staff production of PT Kaliroto, Surabaya, 8 August 2015.

²³ Interview with Moh. Chaeron, staff production of PT Media Herbal at Semarang, 15 July 2015.

capital, unskilled human resources, and limited knowledge pertaining to certification of CPOTB. KH Tamam Qaolany added, most problem he faces is pharmacist that is not available. Sarjuni identified problems of large investment for facilities, high cost of clinical laboratory, and clinical laboratory to examine product quality, tight competition in free markets with imported products whose cost is lower and higher quality, are dominant obstacle to increase the company into a larger scale industry. Sabdha Agung claimed that most factors that restricts the traditional medicine industries to increase included hard and complexity of pre-treatments and during treatments for clinical laboratory of traditional medicines and finding markers for comparison. In addition, Yesi R described clinical laboratory to check extract quality and markers are of big problems, for instance, to accomplish 4 marker, producers should assure accurate content of each kind of element and it does cost very expensive. Similarly, Rifda Amalia claimed that to register OT into OHT is very complicated and high cost of clinical laboratory of the quality product obstructs producers efforts.

Specific policy to overcome problems on developing traditional medicines are expected to execute. Access to find capital should be simplified making it easier to conduct. Similarly, government should support with technology, simplify requisites and procedures to increase company status, and facilities to ease market shares for domestic and international scopes (Moch. Chaeron)²⁴. In addition, bureaucracy to proceed product license should be shortened and easier (Siti Halimah)²⁵. Incentive to access trainings and education from government to increase human resources' capacity building pertaining to certification of CPOTB, capital soft loan, technology, supply of standardized and achievable raw materials, and easy procedures to obtain product license is strongly expected (Agus Santoso)²⁶.

Artike Theresiani viewed problem in certification needs immediate solution. New traditional medicine industry should receive incentive to obtain license and CPOTB certificate more easily. Some industries admit that no incentive is received during the process of production as stated by Tamam Qaolany. He stepped in a lengthy process to obtain license of production and agreement to hire pharmacist. Sabdha Agung proposed policy on standardized raw materials supply is formulated and incentive to achieve low cost for clinical laboratory of traditional medicine products is provided by the government.

Findings of the study of the first and second year research strongly indicate that Association of Traditional Medicine has accommodated aspirations of *jamu* communities in East Java and Central Java. Mutual cooperation between the researcher and producers for advisory actions, trainings, efforts to obtain circulation licenses as CPOTB admits, label registration, and increase of marketing shares are successfully conducted. Producers of *jamu* joining in the association have been given empowerment and advisory for one occasion; but they would achieve independent confident for the next and the future. Producers should achieve target using their own efforts to enlarge markets, diversify their products, and increase their status from OT into OHT.

Problems remaining to solve involve serious attention to obtain trade licenses pertaining to CPOTB certificate that is considered exhausted, and label registration procedures that are not fully disseminated in a good package. Empirically, this study discovers that most producers of *jamu* do not have motivation to increase OT into OHT; producers tend to view complexity to obtain CPOTB certificate as requisite to achieve trade licenses is of a long and big obstacle to solve. Efforts to popularize well-known label is beyond the target, because they are imposed to bridge smooth trade and circulation

²⁴ Interview with Moh. Chaeron, staff production of PT Media Herbal at Semarang, 15 July 2015.

²⁵ Interview with Siti Halimah, staff production of PT ASIMAS, Surabaya, 8 August 2015.

²⁶ Interview with Agus Santoso, staff production of CV Herbal Indo Utama, Surabaya, 8 August 2015.

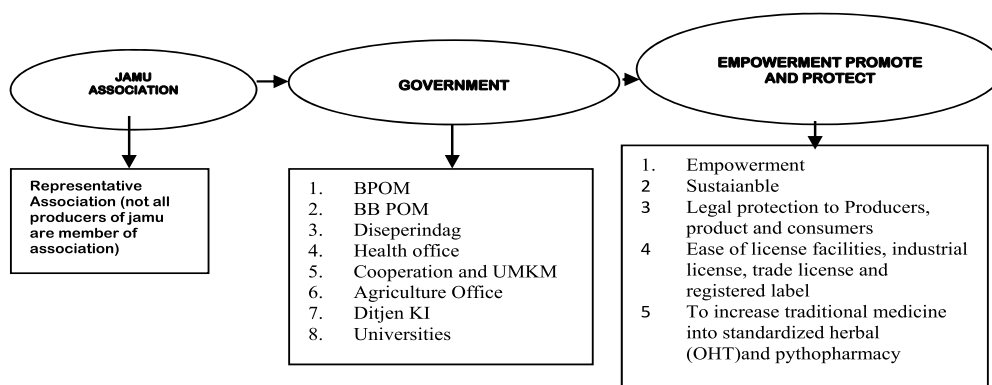
licenses and label licenses. In short, serious problems remaining unsolved should include: (1) most OTs have no trade and circulation licenses; (2) standardized OT to be equal with pharmacy decrease motivation; (3) most industrial pharmacy seizes traditional and herbal medicines; and (4) role

of Ditjen KI and BPOM to certify label licenses is confused.

3. Empowerment Model to Increase OT into OHT

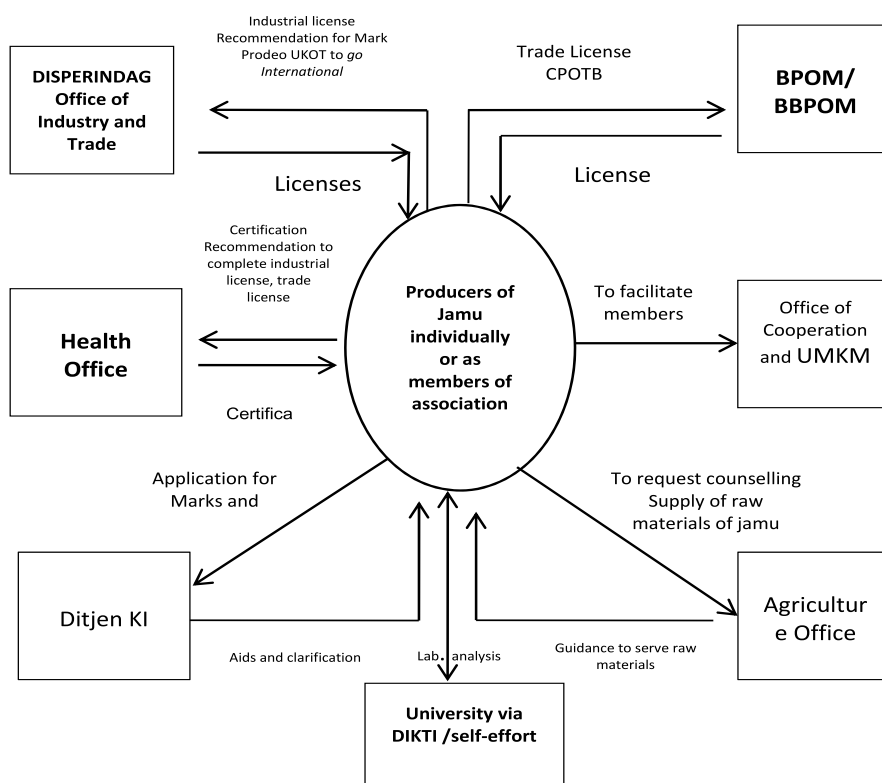
This model was developed from the first year research and was furnished in the second year.²⁷

Scheme 1. The Empowerment Model to Promote and Protect Herbal Productions



Source: Research Report MP3EI Ditjen DIKTI: Potensi dan Strategi Pengembangan Jamu/Obat Tradisional Menuju Obat Herbal di Jawa Tengah dan Jawa Timur, 2014-2015.

Scheme 2. The Role of Herbal Productions Link Institution



Source: Research Report MP3EI Ditjen DIKTI: Potensi dan Strategi Pengembangan Jamu/Obat Tradisional Menuju Obat Herbal di Jawa Tengah dan Jawa Timur, 2014-2015.

²⁷ Early Model resulted by the first year is as planned publishing at *Jurnal Masalah-Masalah Hukum*, Faculty of Law Universitas Diponegoro, October 2014.

In Product Certification Focus Group Discussion²⁸ Jornalis Uddin, a Foundation Chairman of YARSI Board, said that cooperation between YARSI with Herbs Entrepreneurs must be developed by involving the study center of herbs and *Halal* for the development of the laboratory that has existed. Researcher has also proposed that laboratory in YARSI University could be accredited. Herbs owner (PT ASIMAS of Malang), Hermansyah states that research conducted by the Team is more lead to industry or UKM rather than on the philosophy of traditional medicine or the herbs. Terminology of traditional medicine is considered incompatible with herbs or *jampi*, reminding given the herbs is not given claim to treat, so it is necessary to find legal solution related to the implementation and interpretation of traditional medicine/legal concept.

Sri Utami Barakah of PT Phapros Semarang states that: (1) traditional medicine produced industries is more expensive; (2) the proposed regulatory standard is made in order to go international; (3) there is still technical obstacle in obtaining marketing authorization; and (4) there is a sense of optimism on businessmen related to diversity and bio-diversification.

Stevanus, daily Secretary of GP Herbs Central Java stated that industry structure is not strong, in China 1200 industries have been integrated between the downstream and upstream. There are some obstacles: (1) the low quality of human resources in the industry OT; (2) lack of coordination for the raw materials needs; (3) cross-sector coordination is still weak; and (4) drafting regulations should involve all relevant stakeholders. Five parties that contribute to the development of herbs: (1) people; (2) health workers; (3) research (Research and Development of Health, Ministry of Agriculture and campus); (4) regulators; and (5) the business world. Budi Djanu, speaker from Legal Bureau of Food and Drugs Control Officers (BPOM) stated that the herbs

under the control of the deputies' 2 BPOM, until now there are still many brokers to register NIE. BPOM object is controlling products and BPOM had no authority to remove Herbs Brand/OT who has first obtained the certificate brand in General Director of KI. There is no necessity associated BPOM Brand new first then General Director of KI. BPOM is open to appeal against the refusal to. For the distribution license registration is different from the brand (distinguishing features), but BPOM requires safety, efficacy and quality.

Especially for traditional medicine, the word "efficacy" replaced "benefits". For *Halal* food is still being processed. Adi Supanto, speaker of Brands section of General Director of KI states that the latest Law about KI targeted April 2016, especially the incoming national legislation is the Trademark and Patent Law. The researchers concluded that there should be coordination between entrepreneurs/manufacturers of herbs/OT for the preservation of herbs as the nation's heritage, as well as protecting intellectual property, promoting and marketing as a potential industry as an icon of Indonesia with the assistance of the campus and related agencies for further facilitate the smooth running of their businesses towards the export market destination, even rising from OT to OHT. Offense between brand and distribution license should be addressed directly to the consultation with BPOM (not via brokers), and previously made the brand really does not offend/violate the trademark belonging to someone else, and then put forward the submission of NIE. However, it should be understood that the terms brands (distinguishing) adjusted by plus NIE BPOM terms of safety, efficacy, and quality to be more efficient and effective. BPOM does not hesitate to help if it is invited to help GP Herbs, because BPOM is not only giving services at the center but also picking up the ball (on site).

²⁸ Product Certification Focuss Group Discussion, YARSI University, Jakarta, October 22, 2015.

D. Conclusion

Conclusion of this study is based on the above findings and discussion and is stated as follows: **First**, Association of Traditional Medicine Producers has accommodated aspiration of *jamu* community in East Java and central Java, mutually work in the sinergical advisory with the researchers, conducting trainings together to obtain trade licenses based on CPOTB, label registration, and improving markets. Legal protection and involvement of the government are of top urgent to achieve sustainable production of OT. **Second**, serious attentions are badly needed to facilitate trade and circulation licenses pertaining to complexity and exhausted procedures of CPOTB certificate as well as less dissemination to obtain label registration. Producers of *jamu* producers of *jamu* do not have motivation to increase OT into OHT; producers tend to view

complexity to obtain CPOTB certificate as requisite to achieve trade licenses is of a long and big obstacle to solve. Efforts to popularize well-known mark is beyond the target, because they are imposed to bridge smooth trade and circulation licenses and label licenses. In short, serious problems remaining unsolved should include: (a) most OTs have no trade and circulation licenses; (b) standardized OT to be equal with pharmacy decrease motivation; (c) most industrial pharmacy seizes traditional and herbal medicines and (d) role of Ditjen KI and BPOM to certify brandmark and trade licenses are confused. **Third**, problems on label are actually surprising; in the market of OT, similar and almost similar labels are frequently obtained. Surprisingly, after the labels are confirmed producers having similar labels have been aware that the raw materials of both traditional medicine are also identical.

BIBLIOGRAPHY

A. Book

- David, Fred R., 2013, *Strategic Management, Fourteenth Edition*, Pearson Education Limited, Edinburg Gate.
- Komite Nasional Ekonomi, 2012, *Prospek Ekonomi Indonesia 2012: Terus Tumbuh di Tengah Ketidakpastian Global*, Komite Ekonomi Nasional, Jakarta.
- Kotler, Philip & Gary Armstrong, 2014, *Principles of Marketing, Fifteenth Edition*, Pearson Education Limited, Edinburg Gate.
- Peter, Paul J. & Jerry C. Olson, 2013, *Consumer Behavior and Marketing Strategy*, Salemba Empat, Yogyakarta.
- Purwaningsih, Endang, 2012, *Hak Kekayaan Intelektual dan Lisensi*, Mandar Maju, Bandung.
- _____, 2015, *Hukum Bisnis*, Ghalia Indonesia, Bogor.
- Soenyono, 2011, *Pemberdayaan Masyarakat Miskin*, Jengala Pustaka Utama, Surabaya.
- Susilo, Suko, 2009, *Ekonomi Politik dan Teori Pembangunan*, L-SOD, Depok.
- Tantri, Francis, 2013, *Pengantar Bisnis, Cetakan 4*, RajaGrafindo Persada, Jakarta.
- Zikmund, William G., et al., 2013, *Business Research Methods, Ninth Edition*, South Western, Cengage Learning, Texas.