

Facilitation of Traditional Medicine Industry through Science and Technology Park for Growth Development of the National Drug Industry

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Abstract

Traditional medicine has long been used to treat diseases based on experience and the cultural heritage in the field of health. With the development of technology, traditional medicine has become more widely recognized and a widely traded commodity. Demand for traditional medicine has increased higher than for other pharmaceutical products. In the production of traditional medicine, we need to pay attention to specific rules that need to be applied because it deals with the health of living beings. In making traditional medicine, there are guides that have been made involving Good Manufacturing Practice (GMP) for herbal medicines. Currently there has been much growth in traditional medicine industries but the growth has been limited. The start-up companies who are attempting to enter the traditional medicine industry often find themselves in difficulty since they lack facilities, infrastructure, and expertise in the technologies involved.

Science and Technology Park (STP), LIPI, Indonesia which is an institution that promotes industrially based research activities, can help to foster the development of an appropriate traditional medicine industry based on quality standards. STP LIPI plans to develop a pilot plant for use in the traditional medicine field. The plant is expected to help the community and the industry to develop a national traditional medicine industry.

Introduction

Traditional or herbal medicine has been recognized widely around the world. According to the World Health Organization (WHO), countries in Africa, Asia and South America used traditional medicine as support for primary medicine. 80% of Africa's population use traditional medicine for primary healing.

The National Agency of Drug and Food Control (NA-DFC), Republic of Indonesia (ROI), defines traditional medicine according to Article 1 of the Ministry of Health ROI Regulation No. 246/Menkes/Per/V/1990 traditional medicine is material or material ingredient in the form of plant material, animal material, mineral material, galenic preparation or mixtures of those ingredients, traditionally used for healing based on experience or empirical experience.

NA-DFC states that a medicine could be categorized as traditional or herbal medicines firstly if it contains 100% nature ingredient without the slightest addition of a chemical ingredient. Secondly, Article 15 of Government Regulation ROI No. 69 of 1999 which governs Label and Food Advertising, states that "description on Label, written or printed using Indonesian language, Arabic numbering and Latin alphabet." These

regulations are binding not only to traditional medicines produced domestically, but also applied to imported traditional medicines.

NA-DFC classifies traditional medicine into three of types of preparations, namely jamu, standardized herbal medicine and phytopharmaca.

a. Jamu (Empirical Based Herbal Medicine)

Jamu is material or material ingredient in the form of plant material, animal material, mineral material, galenic preparation or mixtures of that ingredients, traditionally used for healing based on empirical data. There are thousands of jamu preparations circulating in Indonesia.

Table 1. Jamu products in Indonesia

No.	Jamu
1	Air Mancur
2	Sido Muncul
3	Nyonya Meneer
4	Buah Naga merah kapsul
5	Sari Pinang serbuk
6	Akar Ginseng serbuk
7	Jamu Tradisional Wali Songo kapsul
8	Jamu Amat Kwat cairan obat dalam
9	Jamu Gali-Gali cairan obat dalam
10	Asam urat jamur mas cairan obat dalam
11	Pegal linu Mahkota Dewa cairan obat dalam

Table 2. Examples of SBHMs in Indonesia

No.	Product	No.	Product
1	Virugon	9	Reumakeur
2	Diapet	10	Hi Stimuno
3	Stop Diar Plus	11	Prisidii
4	Fitogaster	12	Irex Max
5	Sanggolanggit	13	Lelap
6	Fitolac	14	Kiranti Pegal Linu
7	Sehat Tubuh	15	Kuat Segar
8	Glucocarp	16	Kiranti Sehat Datang Bulan

b. Standardized Based Herbal Medicine (SBHM)

Standardized Based Herbal Medicine (SBHM) is a preparation of natural medicine that has been already approved to be safe and shown to be effective scientifically through preclinical trials and standardized raw materials. Only forty one Indonesian SBHM preparations are being sold in Indonesia.

c. PhytopharmaClinical based Herbal Medicine

Phytopharmaca are preparations which satisfy criteria such as safety, efficacy based on clinical trials, standardization of the raw materials used, and the applicable quality requirements. There are only six Indonesian Phytopharmaca products available in Indonesia

Table 3. List of Phytopharmaca in Indonesia

No.	Product
1	Nōdiar (anti diare) PT Kimia Farma (POM FF 031 500 361)
2	Stimuno (peningkat sistem imun) PT Dexa Medica (POM FF 041 300 411, POM FF 041 600 421)
3	Tensigard Agromed (anti hipertensi) PT Phapros (POM FF 031 300 031, POM FF 031 300 041)
4	X-Gra (aphrodisiac) PT Phapros (POM FF 031 300 011, POM FF 031 300 021)
5	Rheumaneer (pengurang nyeri) PT Nyonya Meneer (POM FF 032 300 351)
6	Diabmeneer (kencing manis) PT Nyonya Meneer

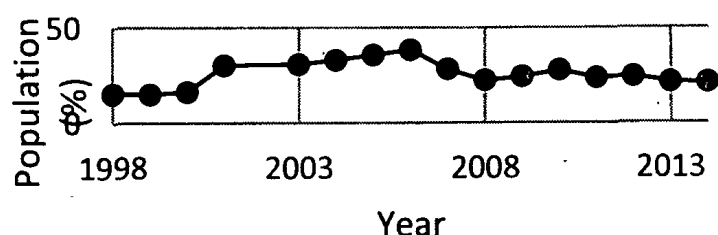


Fig. 1. Percentage of Indonesian Population using Traditional Medicine Parts of plants for traditional medicine that can be utilized - roots, rhizomes, stems, fruits, leaves, and flowers. Also sold in the market in the form of capsules, powders, liquids, simplicia and tablets.

Until now, the national seed crop that has been clinically tested are only the ones shown below.

1. Salam leaves (*Syzygium polyanthum* (Wight.) Walp.)
2. Sambiloto (*Andrographis paniculata* (Burm.F.) Nees)
3. Kunyit (*Curcuma domestica* Val.)
4. Red ginger (*Zingiber officinale* var. *rubrum*)
5. Jati belanda (*Guazuma ulmifolia*)
6. Temulawak (*Curcuma xanthorrhiza* Roxb)
7. Guava (*Psidium guajava* L)
8. Java chili (*Piper retrofractum* Vahl.)
9. Noni (*Morinda citrifolia* L.)

Traditional medicine is more appropriate for metabolic diseases such as diabetes mellitus, gout, cholesterol, cancer, etc., and is not suitable for acute illnesses or diseases which need to quick action with rapid response. This is because traditional drugs take longer than synthetic drugs to show effects.

Jamu has a greater chance because of the opulent biodiversity of Indonesia. Indonesia is widely known as a mega center of biological diversity (biodiversity) consisting of tropical plants and marine biota, the second largest in the world after Brazil. In the territory of Indonesia there are approximately 30,000 species of plants, 7,000 of which are considered to have efficacy as drugs and a total of 2,500 species of them are medicinal plants.

Over the years the uses of traditional medicine continues to be on an increasing trend, both for maintaining health as well as in medicines (Fig. 1). It is also supported by various research and technological advances that prove traditional medicine has a very good effect on health. Simultaneously traditional medicine that is proven to be efficacious and safe scientifically is driven to be used in health care

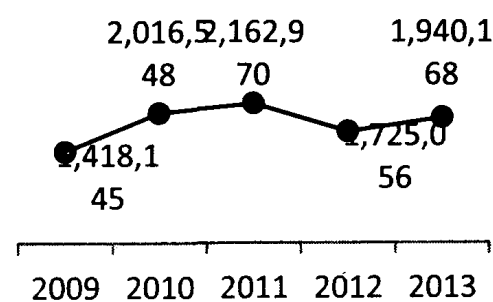


Fig. 2. Export value of global...

For business opportunities, traditional medicine looks promising. This can be seen from the increase in the traditional medicine world export market from 2009 to 2013 which grew by 4.82% per year

On the other hand, new business actors in traditional medicine industries still encountered obstacle in creating quality and highly competitive products because they have minimal facilities, inadequate infrastructure and lack of expertise in the technology used. In order to help develop the traditional medicine industry, LIPI through Science and Technology Park (STP) plans to build a Pilot Plant for Traditional Medicine. This Pilot Plant will be built by following guidelines of Good Manufacturing Practice for herbal medicines (Indonesian acronym CPOTB) so that it can be adopted by traditional medicine industry.

Methodology

This paper uses qualitative methods with literature study, interviews and focussed discussion and analyzing data descriptively. Literature study was conducted by finding references from written resource such as books, journals, articles, and official website of government institutions or organizations. Interviews were planned to access information on the research topic from experts in the area through discussion. Focussed discussions were conducted with Republic of Indonesia (ROI) Ministry of Health and ROI National Agency of Drug and Food Control, LIPI's researchers and businessmen in the traditional medicine field. The next step was filtering the data and information retrieved from these approaches and analyzing them descriptively to be used as an input in the development of a pilot plant in traditional medicine atn STP LIPI.

Result and Discussion

In Indonesia, therapy using traditional medicines plays an important role in the health care of the people. The use of traditional medicine is widespread and Jamu is the Indonesian term for indigenous medicine usually prepared from herbal materials. Jamu is produced mainly with traditional techniques, which are non-mechanized or only semi mechanized. There are three sources of jamu:

1. Preparation from fresh plant materials.
2. Home industries (smallholders and family business) whose products consist mainly of aqueous extracts and dried plants materials. They are distributed in simple packaging and bottles by independent vendors. The vendors carry baskets on their back and sell the medicine, called jamu gendong, door to door.
3. Large scale commercial preparation and distribution (jamu industry) where the product

is in the form of pills, powders, tea, tonics, topical oils, and cream.

To ensure the quality of traditional medicine, CPOTB has to be implemented on all aspects concerning the manufacture of traditional medicine with more attention paid to the process of production and handling of raw materials. The products will then always meet the quality requirements that have been established for the intended use. The quality of the product depends on the starting materials, production processes and quality control, buildings, equipment and personnel involved in the process. Details are found in the Regulation of Head of NA-DFC No. HK.00.05.4. 1380 - About CPOTB.

Any industry that makes traditional medicines must fulfill the technical requirements of CPOTB. Startup companies which aim to commence a traditional medicine industry often experience difficulties in applying CPOTB because of their lack of knowledge on managing industries on commercial scale. In addition, tools and infrastructure must also comply with requirements. These requirements also apply to LIPI in its efforts to develop a Pilot Plant for Traditional Medicines.

The Regulation of Head of NA-DFC Number 35 Year 2013 on Procedure for Certification of CPOTB specifies that the CPOTB certificate can be given to an Industry in Traditional Medicine (IOT), Industry to Extract Natural Materials (IEBA), or a Small Business in Traditional Medicine (UKOT). Based on discussions we find that if the Pilot Plant facility in Traditional Medicine is owned by Government, in this case LIPI, then the finished product produced cannot be commercialized because the facility cannot obtain CPOTB certification as LIPI is a research institute and not an industry.

According to the International Association of Science Parks, a science park is an organization managed by specialised professionals, whose main aim is to increase the wealth of its community by promoting the culture of innovation and the competitiveness of its associated businesses and knowledge-based institutions. Development of Pilot Plants in Traditional Medicines is relevant for improving the performance of traditional medicine industries in the surrounding area. A Pilot Plant can facilitate researchers to develop traditional medicine products from laboratory scale to pilot plant or even larger scale. In addition, the facilities provided may be used by traditional medicine

startup companies to perform technical validation of the technologies developed to obtain efficiency in scale and reduce risk of failure. When the industry is ready to undertake commercial scale production, they can adapt a process successful in the pilot plant for their production.

Eventually, facilitation conducted by STP LIPI is expected to increase transfer of technology in the area of traditional medicine that is scientifically proven and to grow various startup industries which are able to produce good products according to the requirements. The potential for traditional medicine in Indonesia is very large with traditional medicine export value in the period January - June 2014 being US \$ 29.13 million, an increase of 600% of the export value for January - June 2013. Indonesia's export growth for traditional medicine during period 2009 -2013 increased by 6.49% per year. With the opulence of biodiversity in Indonesia, opportunities to develop traditional medicines can be improved by the facilities provided by the Pilot Plant of Traditional Medicine which is owned by STP LIPI.

Pilot Plant

Because of differences in the production process for each finished product in traditional medicine industries, it is difficult for the Pilot Plan of Traditional Medicine LIPI to facilitate diverse processes for several different products. The Pilot Plant of Traditional Medicine LIPI has therefore to sort out traditional medicine products with high marketability. Based on data on market share of traditional medicines shown in Tables 1 and 2, it is seen that Ginger and Spices, Nesoi are the main alternative commodities that can be facilitated as traditional medicine, because they have a market share of more than 60% of both export and import market share of herbal products in Indonesia).

Conclusion

Demand for traditional medicine have increased every year far more than for other pharmaceutical products. Startup industries in traditional medicine often experience difficulty in applying for CPOTB since they lack facilities, infrastructure, and expertise in the technologies involved. The Pilot Plant of Traditional Medicine provided by STP LIPI can help industries to adopt appropriate technology for producing traditional medicines satisfying regulatory requirements. Furthermore product development from laboratory scale to pilot scale can be used as reference for industry to better

manage the risks faced in transfer of technology both to pilot scale and to commercial scale.

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Table 4. Indonesia Traditional Medicine Export Primary Product

No.	HS	COMMODITY	2013			% TREND 2009-2013	JAN - JUN 2014			% CHANGE 2014/2013	
			TONS	US\$ 000	% SHARE		TONS	US\$ 000	% SHARE	QUANTITY	VALUE
1	091010	Ginger	22,472	14,909	63.59	22.44	33,922	25,809	88.58	2,176.81	1,616.85
2	091099	Spices, Nesoi	1,188	4,343	18.52	-12.02	563	1,844	6.33	50.95	43.54
3	091030	Tumeric (Curcuma)	1,947	2,101	8.96	-16.17	444	699	2.40	18.11	21.36
4	091091	Mixtures of Two or More Spices Provided for Separated in Different Headings of This Chapter	729	1,603	6.84	67.15	220	620	2.13	11.7	2.63
5	091020	Saffron	794	490	2.09	47.34	274	166	0.57	-9.87	-13.40
		TOTAL	27,129	23,446	100.00	6.49	35,422	29,137	100.00	1,193.15	600.54

Table 5. Indonesia Traditional Medicine Import Primary Product

No.	HS	COMMODITY	2013			% TREND 2009-2013	JAN - JUN 2014			% CHANGE 2014/2013	
			TONS	US\$ 000	% SHARE		TONS	US\$ 000	% SHARE	QUANTITY	VALUE
1	091010	Ginger	6,308	5,927	81.55	117.59	1,007	929	60.25	-78.19	-78.26
2	091099	Spices, Nesoi	634	796	10.95	20.11	334	444	28.79	-6.21	22.55
3	091030	Tumeric (Curcuma)	249	475	6.54	73.77	170	145	9.43	24.33	-46.53
4	091091	Mixtures of Two or More Spices Provided for Separated in Different Headings of This Chapter	10	70	0.96	34.32	2	15	0.98	-31.87	31.38
5	091020	Saffron	-	-	-	-	3	8	0.55	-	-
		TOTAL	7,201	7,268	100.00	82.23	1,516	1,542	100.00	-70.34	-68.65

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