WIPO ASIAN REGIONAL SEMINAR ON INTELLECTUAL PROPERTY ISSUES IN THE FIELD OF TRADITIONAL MEDICINES

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DISTRIBUTION AND CONSUMER PROTECTION OF TRADITIONAL MEDICINES BASED ON SCIENTIFIC PROOF

Document prepared by Prof. Dr. Goeswin Agoes, Professor in Pharmaceutical Technology,
Institut Teknologi Bandung, Indonesia
Introduction

Before the monetary crisis, drug consumption per capita in Indonesia was about US$4.50 to 5.00. At present, drug consumption has dramatically decreased and is predicted to be only about US$2.00. Drugs are mostly consumed in big cities and at Community Health Centers in rural areas where medical doctors assisted by nurses and midwives practice diagnosis of diseases.

In rural areas, several disease treatment alternatives are available. People in rural areas frequently visit druids (dukun) instead of medical doctors, therefore in this society druids still play an important role in disease treatment. The use of medicinal plants either boiled in water (decoct) or used fresh are commonly used in this society. The medicinal plants are also frequently used as fresh vegetables, taken with food especially by women for body maintenance.

At a more sophisticated level, people take drugs obtained from plants as a liquid extract prepared by extraction using water. A mixture of different liquid extracts obtained from plants is commonly available in Indonesia and is called jamu gendong. The jamu gendong is widely consumed regularly by housewives or blue-collar workers, to maintain health or to treat various non-serious diseases.

At the moment, jamu is processed and produced on an industrial scale by jamu industries. These industries produce a mixture of varieties of plant herbs (simplicia) packaged in sachets. The users then boil the content of the sachet in hot water before use and take the liquid extract or both the liquid extract and the simplicia.

In modern dosage forms, jamu is introduced into hard gelatin capsules and consumed in the form of capsules. Plant extracts can also be processed to make liquid dosage forms such as syrups, and solid dosage forms such as powders, pills or tablets, or liniments. These modern dosage forms can be categorized either as drugs (which have to conform to drug registration requirements) or as traditional drugs (which have to be registered at the Directorate of Traditional Medicines, Indonesia).

The coverage of drugs obtained from plants by the Indonesian society is wide enough. Besides traditional medicines obtained from Indonesian plants, in the meantime, cosmetics containing natural resources are commercially available and exported to several countries.

Besides Indonesian traditional medicines, drugstores in big cities provide traditional medicines imported from China, which require approval by the Directorate of Traditional Medicines. These Chinese traditional medicines (not necessarily made in China) are commonly consumed by many people living in big cities as alternative medicines. One big concern of these Chinese traditional medicines is that they, in some cases, contain synthetic chemicals (not obtained from plants) and can be dangerous for consumer health. For consumer safety reasons, the Indonesian government does not allow any traditional medicines to contain synthetic chemicals.
Status of Traditional Medicines

The system of alternative treatment in Indonesia has been developed empirically and is not the same as that of alternative treatments in India and China. These two countries possess different traditions for treatment methods using plant *simplicia*.

At higher levels of education in Indonesia, Faculties of Pharmacy offer pharmacognosy as one of the major courses and conduct many researches concerning the study of bioactive compounds isolated from plant *simplicia*. On the other hand, Faculties of Medicines offer pharmacology of modern drugs but only cover a little information concerning traditional medicines. Both Faculties of Pharmacy and Faculties of Medicines conduct research activities regarding the pharmacology of medicinal plants. The former perform experiments to test pharmacology effects using animal models, while the latter use human beings.

Due to the lack of scientific data concerning traditional medicines, medical doctors are reluctant to use medicinal plants for patient treatment. The medical doctors do not want to put their patients at risk, since there is no assurance of the safety of traditional medicine usage. In addition, the Faculties of Medicines in Indonesia do not possess courses in traditional treatment in their curriculum.

Traditional medicines have been approved as alternative treatments in Indonesia. Several books such as Materia Medica Indonesia (1977), Cara Pembuatan Simplicia (Methods to Simplicia Preparations, 1985), Cara Produksi Obat Tradisional yan Baik (Good Manufacturing Practices for Traditional Medicines, 1991) have been published and used as references.

Standardization of Traditional Medicines

One limitation of the use of crude drugs obtained from plants, animals and minerals, is the ignorance of active principles. If some active principles are discolored, variations of chemical contents may occur. Since there is no assurance for the quality of these crude drugs, their usage can be a concern, especially in modern medicines. However, due to some limitations of modern treatment and the unwanted side effects of some synthetic drugs that may occur, people tend to take drugs obtained from natural resources believing them to be safer.

Isolation of the active components of crude drugs was initiated a long time ago and has been developed over the last 75 years. For instance, morphine has been isolated from opium, and quinidine from the bark of Conchona. This indicates that active principles can be isolated from natural resources and retain their pharmacological effects. The purpose of the isolation of active compounds is especially for phytochemical study, then followed by pharmacological study to determine their activities. The knowledge of these active compounds obtained from crude drugs is very helpful in disclosing many pharmacology activities that have not been recognized before and this will enhance the use of traditional medicines.

In many cases, the pharmacology effects are not given by one compound, but rather by a mixture of active compounds in crude drugs. The information on standardization of plant *simplicia* in Indonesia is available in Materia Medika Indonesia. However, the
standardization only includes the description of *simplicia* but does not include the determination of markers contained in the *simplicia*. In addition, the standardization of extracts and other galenic dosage forms are not available. At the moment, the scientific community suggests that one marker for plant extracts is not enough. This is especially true when several components, but not one component in extracts are needed for the pharmacology effect.

### Distribution of Alternative Treatments

Alternative treatments have significantly contributed to the improvement of public health, especially at a time of monetary crisis where society’s capability to afford modern drugs is very limited. The Indonesian government actively conducts campaigns for alternative treatments and performs education for medical doctors to use drugs obtained from natural resources.

Some organizations, such as PERHIBA (Perhimpunan Peneliti Bahan Alam, the Association of Natural Resources Researchers) also help campaigns for the use of medicinal plants, publish books about medicinal plants, and conduct training to grow medicinal plants in house fields. Every week, several newspapers publish articles about the usage of medicinal plants available in Indonesia. Many medical doctors are eager to develop and use medicinal plants to treat their patients. The sole problem in the medicine field for using traditional medicines is the proof requirement that the active components contained in medicinal plants are useful, safe, not toxic and effective.

Due to this problem, developing countries like Indonesia which are not able to conduct research or provide the scientific proof of pharmacology activities in the near future need information technology for monitoring as well as dissemination and development of traditional knowledge (in using medicinal plants) for public treatment. This is highly required to assure the medical field and the people in big cities regarding the use of medicinal plants as drug alternatives. The proofs of pharmacology activity that are available at present are mostly based on empiric experience. The scientific proof then becomes the most important thing to obtain in order to eliminate the concern of using medicinal plants as drugs for alternative treatment. International collaborations then become important to enhance the development of drugs obtained from medicinal plants.

### Traditional Medicine Industry

Most *jamu* and pharmaceutical industries obtain the *simplicia* from wild type plants grown by common people. This causes some problems since the quantity of *simplicia* on an industrial scale is very limited, the quality is varied and there is also possibility of fraud with similar plants. Only big Jamu industries can afford to possess medicinal plant plantations located out of Java, because in Java the field price is quite high. Availability of medicinal plants can be a problem on an industrial scale and this is one of several factors that can slow down the development of traditional medicine industries.

Medicinal plant plantations on an industrial scale require research into whether domesticated plants grown in a new habitat different from the original will produce the same types and level of active ingredients. We have to learn from experience i.e. the difference and similarity of wild type and domesticated ginseng.
It may be possible that the marker for *simplicia* and extracts obtained from medicinal plants grown for industrial purposes will be different from those from wild type plants that usually do not require special treatment and attention.

**Property Rights of Medicinal Plants**

The Government owns the property right of all of the diversity located in the country including medicinal plants. This is an important issue to address especially for developing countries, like Indonesia, that until now have not conducted enough research and exploration of medicinal plants. This property right will protect the diversity in one country from illegal action conducted by foreign researchers and countries. For this reason, the Indonesian government owns the property right of biodiversity in Indonesia. International agreement stating that the government is the one that owns the property right of all of the biodiversity located in one country is required. The regulation of intellectual and property rights has also to be agreed. This will protect the developing countries from losing the most valuable prosperity for their social welfare.

For the internal needs of one country, it might be better to categorize medicinal plants as drugs in modern terms, i.e. as food:

1. health food, for medicinal plants that have been commonly consumed as food;
2. over the counter (OTC) drugs, for medicinal plants that have been known and commonly taken for health purposes, such as for health maintenance or for treatment for common non-serious diseases;
3. ethical drugs, for medicinal plants that give potent effects and can endanger human health if consumed or used inappropriately.

It is very important to establish international collaboration and technology information systems to distribute information concerning the research of medicinal plants, pharmacology effects and the side effects that may occur in the misuse of medicinal plants.

**Concluding Remarks**

There are many efforts to promote traditional medicines in Indonesia, for instance the regular publication of articles in newspapers, the establishment of organizations such as PERHIBA, and the publication of books concerning medicinal plants. In addition, the Department of Health conducts many campaigns for the use of medicinal plants as alternative treatments. The Pharmacy Student Association, Institut Teknologi Bandung, conducts regular activities that assist people living in a village located near Jatiluhur. These activities include training concerning a healthy life, and the fight against illiteracy. The village people also learn to grow and benefit from medicinal plants for alternative treatments.

When national and society needs are to be considered:

1. It is necessary to protect the biodiversity of medicinal plants in order to achieve maximum benefit for the prosperity of Indonesian society, preventing them being carried illegally to foreign countries.
2. In order for the medicinal plants to be accepted in the medical field as alternative drugs, pharmacology research and the safety test of active ingredients have to be carried out.

3. Information technology for monitoring, dissemination and development of traditional knowledge, medicinal practice and biodiversity resources should be recognized to develop the use of medicinal plants as an alternative treatment.

4. Patent criteria for drugs from medicinal plants have to be discussed in detail in order for researchers and industry to benefit from the opportunity of developing medicinal plants as alternative drugs.

References