SY1 NATURAL PRODUCTS AS DRUGS: EVALUATION OF EFFICACY AND SAFETY

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Since 1980, the Office of Primary Health Care System, Ministry of Public Health, had proposed herbal drugs as Essential Drugs which can be used as one of the strategies to achieve "Health for All for the year 2000". A medicinal plants demonstration garden had been set up at the health station and information about the selected medicinal plants for simple illnesses, for example, constipation, dyspepsia, and insect bites was disseminated. Most of these medicinal plants are prepared and used in the traditional style. The selection of these plants is based on folklore supported by scientific research and can be easily found in the community.

Since the last decade, there has been a resurgence of interest in herbal medicines in western societies. It is generally believed by the lay public that herbal remedies are safer and less toxic to the human body than synthetic drugs. The medicinal plant industries have become billion dollar businesses. There is an urgent need for good quality products worldwide. However, a large variety of medicinal plants continues to be gathered from their wild form in the country of their origin both for local consumption and export. The large-scale exploitation of plants to meet the sudden surges in demand of selected herbs and herbal products results in the threat of virtual extinction, at least in easily accessible forest ranges. Cultivation of medicinal plants is obviously needed. Decisions on the priority species to be cultivated must depend on factors such as the climate conditions, the most abundantly used species, species that have export potential, species utilized for curing diseases for which modern therapy is disproportionately costly, and species utilized for curing diseases which have no effective therapy in modern medicine. The aim of medicinal plant cultivation is to obtain produce with high yields of active chemicals and acceptable limits of trace metals. In addition to the selection of the best species, environmental factors are also important. Soil (type, texture, pH, fertility and drainage) altitude, seasonal variation in temperature, atmospheric humidity, day-light hours, rainfall pattern, and time of harvesting play significant roles. For example, Mentha species demand a minimum of 14 h. day light at harvest time to produce a high methanol content in the oil. The menthol is converted into menthone under cloudy weather which spoils the quality of the oil for commercial purposes; the most appropriate time to harvest *Andrographis paniculata* to obtain high yield of andrographolide is before flowering.

From these examples, it can be realized that even under controlled conditions, the contents of bioactive compounds can vary. Undoubtedly, medicinal plants obtained from different localities are expected to have varied percentages of active compounds. In Thailand, most medicinal plants are collected from natural sources and the majority are used without further analysis of the active ingredients.

Therefore, it is anticipated that their therapeutic efficacy can be variable. The first step in evaluation of the therapeutic efficacy of herbal drugs is quality control of medicinal plant materials. WHO has recently published internationally recognized guidelines for assessing the quality of medicinal plant materials. Herbal medicines have been used for thousand of years. Their popularity has declined in many countries due to the inconvenient dosage form and variable therapeutic effectiveness. However, in some countries both modern drugs and herbal drugs have been offered to patients at the same hospitals.

Since herbal drugs have been used by humans for so long, it has led to the assumption that they are relatively safe and effective. It is true that the majority of herbal drugs have been used by humans for generations, so their efficacy and safety have been confirmed by their continued uses. However, precautions should be taken in herbal drug preparation by using new methods that may affect the efficacy and safety of the traditional herbal drugs. Furthermore, concurrent use of herbal drugs may mimic, magnify, or oppose the effect of modern drugs, for example, bleeding when warfarin is combined with ginkgo (*Ginkgo biloba*), and exacerbation of extrapyramidal effects with neuroleptic drugs and betel nut (*Areca catechu*).

To evaluate the efficacy of herbal drugs requires suitable testing models so that the results can be extrapolated to humans. There are several semipurified compounds and pure chemicals that exhibit antimalarial activities in the *in vitro* culture of *Plasmodium falciparum* but which are toxic in rodent models *(P. berghei)*. Some herbal preparations do not exhibit antimalarial activity in *in vitro* testing but can prolong the survival time of *P. berghei*-infected mice. During the past three decades, most pharmacological studies of natural products emphasize the testing and finding of pure compounds isolated from herbal drugs. It is anticipated that these new chemicals may be the lead for discovery of new classes of drugs for specific diseases. This approach is not a successful way to confirm the efficacy of herbal drugs, especially, antimalarial drugs. There is a need to develop research on the pharmacology of traditional medicine, to identify which preparations provide optimal bioavailability of traditional herbal drugs with minimal side effects.

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