



Seminar document

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Efficiency and Safety of Herbal Products Academic seminar

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### Ways of Herbal Research and Development

Herbal research and development is a multidisciplinary research, which is relevant to many organizations, including government and private sectors. In order to solve both health problems and market demands, we should promote herbal research and development in different ways, as follows:

**1. Herbal raw materials** — We should promote research in agricultural fields, so as to increase output per area of herbs. We must study how to plant and harvest properly, making good quality raw materials with high quantities of active ingredients. We also must study how to reproduce them using tissue cultures, along with preventing and protecting plants from pests, without using chemical pesticides. Research and development of technology is necessary to support herbal raw material production. While **Good Agricultural Practice (GAP)** and **Good Harvesting Practice (GHP)** are needed for plantations (Production of herbs in industrial fields). Part of raw material production is very important but is usually overlooked by manufacturers. In fact, if raw materials are not high quality enough, the value of the final product will also be poor.

Government organization should be a Focal Point, in order to promote herbal research and development, together with herbal plantations to meet the demand of the market. The Ministry of Agriculture, the Faculty of Agriculture of private universities, the Ministry of Public Health, such as the Medical Science Department, Government Pharmaceutical Organization and Thai Traditional Medicine Institute, should cooperate, to give advice. For example, identify the type and quantity of herbs, which agriculturists should plant, to meet the demands of the market.

**2. Preclinical research and development** — This section is applicable for pharmacology and toxicology of herbs in testing on animals or other test methods. The objective of this part of research is to study indications, mechanisms and safety of herbal drugs.

Pharmacological studies uses high cost, specialized apparatus and many researchers from different organizations, such as The Faculty of Pharmacy, Medicine, and Science from different universities all over Thailand, the Medical Science Department, etc. Therefore, those studies of pharmacology, along with studies on the mechanism of action, should work as a Collaborative Research Project. If each organization focuses on their particular expertise and they combine those works, the best possible result would be gained.

Moreover, each organization should follow the **Good Laboratory Practice (GLP)** to reach the international standard of study. Quality and standard assurance is a global trend, so we must improve our quality to compete with others.

**3. Clinical Research and Development** — Thailand has a lot of herbs, which could be developed into herbal products. Unfortunately, only a few herbs have passed clinical research and development. As there are not enough toxicity studies, the ethical committee will not permit clinical studies on safety grounds. Therefore, government organizations should support toxic studies, along with clinical trials to assure that it safe for humans. Moreover, supporting the mechanism of action for active ingredients in herbals is also necessary. If all of this can be done, we will have enough scientific results to demonstrate the efficiency and safety of herbal products, which will lead to herbal product industries for export.

For clinical trials, heads of the project must ask for permission from the ethical committee of the hospital where the project will be carried out and / or the ethical committee of Ministry of Health, before the study can be started. And the study must strictly follow **Good Clinical Practice (GCP)**

**4. Quality control of raw materials and herbal products** — This is specific for Botanical chemistry of herbs. The objectives are to find the active ingredients, identification and development of analytical methods for each component to be able to detect both quality and quantity.

Methods, in which we improve, include methods prior to production, at the time of production and after finishing the process.

Finally, stability tests are needed for the finished product. At the present, the Medical Science Department, Herbal Research Institute, and Drug Research Unit have finished botanical chemistry and pharmacognosy studies of many herbs and have made already completed monographs of 21 herbs, which are published in the Thai Herbal Pharmacopoeia (2 volumes).

In addition, another important item is the using of a Micro Limit Test to check for microbes that might contaminate the finished product. This is to assess the quantity of microbes to not be greater than the upper limits. We also have to test for pesticides, heavy metals, and aflatoxin contamination.

In addition to pharmacology and toxicity studies, quality control also utilizes a number of specific apparatus and countless experts. Government organizations should cooperate with the private sector to support studies in this field, including the promotion of researchers to use their expertise doing the best possible research, for our Country.

**5. Production of herbal products** — Finding ways to prevent products from contamination by microorganisms during processing is required for herb production. Studies should find the best way to destroy any microbes found in raw material, not to employ Gamma Rays to irradiate finished products. Some manufacturers, especially those from the countryside, are not affluent enough to utilize this method.

Formulators, utilizing new technologies, should increase the effectiveness of herbal drugs. To elevate the standard of our drugs and supplements, we should follow the **Good Manufacturing Practice (GMP)**. Private manufacturers should be the focal point of production research and development; because of they have more skill and more expertise than the government.

**6. Marketing** - Marketing research is no less important than other research. Market research which should be supported, is to find the demand for herbal products, inside and outside the country, calculating a break event point of each herbal product and find ways to promote the marketing, both inside and outside of the country. The focal point of this should be done by private organizations, together with the Ministry of Commerce and the Faculty of Pharmacy of Chulalongkorn University where a lot of research has been done.