

SY2 NATURAL PRODUCTS AS DRUGS: EVALUATION OF EFFICACY AND SAFETY

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The market for herbal medicines or herbal supplement varies greatly from countries to countries, with consumer acceptance and awareness, delivery forms, availability of products and regional regulations playing roles in influencing the growth of the market. In Thailand, there has been a much greater interest in herbal medicine. The consumption of Thai herbs as natural means for improving health and beauty is increasing tremendously year after year. Several herbs have been introduced for various indications including the exotic one such as Kwao Krew. In addition, the burden of health care expenditure coupled with economic crisis, provide strong incentives for government to encourage the population to maintain health by means of disease prevention and using Thai herbal products to substitute western medicine, which will decrease import drugs.

Even though, product safety and efficacy are paramount concern to general public, manufacturer and the government, the control and register of traditional drugs that are mostly from nature are less stringent than those of the modern drugs in the latest Drug Act 1987 (B.E. 2530). Herbs listed in the official pharmacopoeia of Thai traditional medicine may be registered without having to submit product efficacy and safety data. The guidelines for registration only require proofs that they have been employed in the Thai traditional medicine in the past. This kind of acceptance is to take it for grant that all claims that have been made are valid, which is not always true. The utilization of crude extraction and modern delivery forms pose another problem in terms of registration and question of efficacy and safety. It is not clear about how to deal with this type of formulations. At least some reasonable guidelines are needed to regulate and control of these herbs formulated in modern forms. This coupled with a prevailing assumption that "natural" is safe, a long history of "traditional" use and economic factors such as cost, time and lack of proprietary protection have led to lack of motivation and laissez-faire passion attitude toward safety assessment. However, Thai FDA has set criteria and standard to GMP evaluation for manufacturers of traditional medicines using ASEAN Guidelines. The major objective is to ensure that consumers will receive efficacious, safe and good quality products. The question still remains that this GMP standard is voluntary not an enforcement. Nevertheless, as the industry continues to grow and the use of natural products accelerates, there is an increasing likelihood that these products will come under greater scrutiny by consumer advocates, regulators and the public at large.