





## Brief history of Thai traditional medicine

The Kingdom of Thailand has its own system of traditional medicine called “Thai traditional medicine” (TTM). Historical evidence shows that Thai people began to use herbal medicine for the treatment of various symptoms and diseases and health promotion since the Sukhothai period (1238-1377). TTM knowledge was gradually developed, systematized, revised, recorded, and passed on from generation to generation throughout the country’s history, from Sukothai to Ayutthaya (1350-1767), Thonburi (1767-1782), and the early Rattanakosin period (1782-1916), as a means of health care for the Thai people. Unfortunately, the influence of Western medicine, which was introduced into Thailand by missionaries and western physicians since the reign of King Rama III (1787-1851), gradually increased and eventually led to the abandonment of the systematic teaching of TTM in the medical school in 1916. This sparked the decline in TTM acceptance, especially among people in the urban areas, and the status of TTM practitioners in the country’s health care system for over 60 years.

The revival of TTM began around 1978 after the proclamation of the Alma-Ata Declaration when the World Health Organization (WHO) urged its member countries to include traditional medicine and medicinal plants in their primary health care (PHC) program. Thailand’s Ministry of Public Health responded to WHO’s call by including such a policy to promote the use of medicinal plants in PHC since the time of the 4th Health Development Plan (1977-1981). Government policy on the promotion of the use medicinal plants and Thai traditional medicine in the country’s health care system has continued until today as stated in the 5<sup>th</sup> - 10<sup>th</sup> (present) National Health Development Plan (2007-2011).

In 1989, the Ministry of Public Health established the “Collaborating



Center for the Development of Thai Traditional Medicine and Pharmacy” which was later upgraded to the division level in 1993 as the “**Institute of Thai Traditional Medicine**” (ITTM). Through the years, the Institute has organized several activities to develop TTM in various aspects. In October 2002 as a result of the Bureaucratic Reform Act, the “**Department for the Development of Thai Traditional and Alternative Medicine**” (DTAM) was established as a new department under the Ministry, comprising ITTM, Division of Alternative Medicine, and the Office of the Secretary. This clearly showed the commitment of the government to promote TTM as another means of health care for the Thai people.

### **What is Thai traditional medicine?**

According to the “**Protection and Promotion of Thai Traditional Medicine Knowledge Act B.E. 2542**” (1999), Thai traditional medicine is defined by law as “the medical processes dealing with the examination, diagnosis, therapy, treatment, or prevention of diseases, or promotion and rehabilitation of the health of humans or animals, midwifery, Thai massage, as well as the preparation, production of Thai traditional medicines and the making of devices and instruments for medical purposes. All of these are based on the knowledge or textbooks that were passed on and developed from generation to generation”.

#### **The four elements (Tard) of the body**

According to TTM which is based on Buddhism, the human body is composed of four elements (*tard* in the Thai language), i.e., earth, water, wind and fire. When the four elements of the body are in equilibrium, it will be healthy. In contrast, if an imbalance in these elements occurs, i.e., if there is a deficit, an excess, or disability in any of the four elements, a person will become ill. Moreover, the imbalance in the four internal elements and illness can also be due to an imbalance in the four external elements as well.

#### **The Practice of TTM**

The arts and the practice of TTM can be divided into four main areas, i.e.

1. **Medical practice** involving the diagnosis and treatment of diseases or symptoms.



2. **Pharmacy practice** involving the use of medicinal materials derived from plants, animals or minerals as traditional medicines and the art of compounding those ingredients into various dosage forms of TTM recipes.

3. **Traditional midwifery**, and

4. **Nuad Thai or Traditional Thai massage**.

### **Treatment of diseases and symptoms and health promotion using TTM**

TTM is considered a holistic medicine. The treatment and health promotion emphasizes adjusting the balance of the body elements and various factors, e.g., *tard chao ruan* (dominant element of one's body), seasons, where one lives, external elements have also been taken into account in order to give appropriate treatments. Treatments prescribed for patients are based on the four fields of TTM practice, e.g. herbal medicine preparations, traditional Thai massage, post-partum care, mother and child care, as well as some rites and rituals, if necessary.

## **National policy on Thai traditional medicine and the implementation**

**The 10<sup>th</sup> National Health Development Plan (2007-2011) and “Sufficiency Health System” Strategic Plan** were formulated under the 10<sup>th</sup> National Economic and Social Development Plan of which the framework and the direction for the development of the country's macroeconomics have been based on King Bhumibhol Adulyadej's philosophy of **“Sufficiency Economy”**.

**The “Sufficiency Health System” Strategic Plan** aims at achieving good health, good service, sufficiency life style and peaceful society. One of the desired characteristics of sufficiency health system is the use of technology appropriately and wisely with the emphasis on the use of Thai traditional medical knowledge and being self-reliant. The development of alternative forms of health care by knowledgeably blending Thai wisdom with international wisdom is one of the six strategies of the 10<sup>th</sup> National Health Development Plan.

In addition, on 12 June 2007 the Cabinet approved “**National Strategic Plan on the Development of ‘Tai’ Wisdom<sup>1</sup>, ‘Tai’ Ways of Health<sup>2</sup> B.E. 2550-2554 (2007-2011)**” which determines the directions and the roles of indigenous medicine, Thai traditional medicine and alternative medicine in the national health system and requires the participation from various sectors involved to implement the plan. This National Strategic Plan is composed of five strategies related to indigenous medicine, Thai traditional medicine and alternative medicine, namely: -

1. Knowledge development and management
2. Development of health service system
3. Human resource development
4. Thai traditional medicines and herbal medicines development
5. Protection of Thai traditional knowledge related to indigenous medicine, Thai traditional medicine and Thai herbs.

The Strategic Plan also sets up goals for each strategy to achieve at the end of 5-year period (2011), institutes responsible for collaborating or implementing each strategy, and implementation plans, and budget needed.

The implementation plans of the five strategies by the Department for Development of Thai Traditional and Alternative Medicine (DTAM), Ministry of Public Health can then be divided into five main areas, namely:-

1. TTM knowledge development and management
2. Development and promotion of the use of TTM services in the national health system
3. Development of human resource as quality TTM practitioners and teachers
4. Development of quality Thai traditional medicines and herbal medicines
5. Protection of Thai traditional medicine knowledge and Thai herbs.

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<sup>1</sup> **‘Tai’ Wisdom** means knowledge, technology, practices and biodiversity existing in Thailand that cover the context of Thai traditional medicine, Thai indigenous medicine and alternative medicine.

<sup>2</sup> **‘Tai’ Ways of Health** mean pathways that lead to health and allow people to be free from sickness, unhappiness, and all kinds of stress.



The followings are the details of the work that DTAM and various other government offices in and outside the Ministry of Public Health have done so far under the five implementation plans.

### *1. Development of Thai traditional medicine knowledge through researches*

In order to successfully integrate TTM into the national health care system and to gain acceptance from health personnel and the public, it is necessary to conduct pre-clinical and clinical researches to obtain scientific evidence to support efficacy, safety, and quality of traditional medicines, herbal medicines, and traditional procedure-based therapy. Hence, knowledge generation through R&D is the one of the five main strategies of DTAM for the development of TTM and various activities have been conducted, namely: -

- Establishment of **research network of TTM** between DTAM, Department of Medical Sciences, universities, and hospitals and training courses on clinical research on traditional medicine in order to promote more clinical trials on TTM to support the addition of more herbal and traditional medicines in the National List of Essential Drugs.



- Establishment of “**Ethics Committee on Research in Human Subjects in the Field of Thai Traditional Medicine and Alternative Medicine**” since 2003 to review clinical trial protocols on TTM and CAM. Researchers who wish to conduct clinical study on herbal medicines or traditional or alternative therapy in humans in the state-run hospitals must submit clinical trial protocol to be reviewed and approved by this Ethics Committee, of which DTAM serves as the secretariat office, prior to conducting the study. The committee developed its own guideline and also follows WHO guidelines on evaluation of traditional medicine as well as refers to GCP guidelines when considering the clinical trial protocols. GCP is the gold standard for conducting clinical trial on traditional medicine in hu-

mans in Thailand. The Ethics Committee was recognized by the Strategic Initiative for Developing Capacity in Ethical Review or SIDCER, a capacity building initiative of WHO/TDR.

- Establishment of the “**Institute of Thai Traditional Medicine Research**” as the clinical research unit of the Institute of Thai Traditional Medicine





- Provision of research funding from “**Thai Traditional Medical Knowledge Fund**” for research projects on TTM to researchers outside DTAM

At the national level, since the 4<sup>th</sup> National Economic and Social Development Plan (1977-1981), every Thai government has broadly stated in the country’s public health policy to support research and development of medicinal plants in order to increase their use in the health care system and reduce the import of modern medicine to help the country’s economy. According to the policies of the National Research Council of Thailand (NRCT) and the Ministry of Public Health, researches on the body of knowledge of TTM and R&D of new herbal drugs from medicinal plants are regarded as another important area of health research of the country. Collaborative research projects that pool experienced researchers and resources from various research institutes and are product-oriented and complete-cycled in nature are given higher priority for funding over basic researches. NRCT therefore appoints a subcommittee consisting of experienced academics and researchers to look over the scientific merit, feasibility, cost effectiveness and the outcome of those submitted research projects.

Over the years, R & D projects on the development of herbal medicines have been conducted in many schools of medicine, pharmacy and science of most universities. Based on the number of publications of research papers with Thai authors in the area of research and development of medicinal plants, 395 papers were published in foreign and Thai scientific journals during 2000-2003 and 31 of which (7.85%) were clinical trials conducted by university hospitals and public hospitals. Hence, there appears to be many competent Thai researchers, especially in the universities, to conduct collaborative multidisciplinary research on herbal medicines and traditional procedure-based therapies.

## ***II. The integration of Thai traditional medicine into the national health care system***

### **List of Herbal Medicinal Products**

One of the key policies to integrate TTM into the treatment of diseases has been the **selection of herbal medicinal products into the National List of Essential Drugs** in order to promote their use in the





List of Herbal Medicinal Product  
A.D. 2006

public health facilities. As of the year 2010, there are 19 items of herbal medicinal products listed in the National List of Essential Drugs (A.D. 2006) B.E. 2549. Of those 19 items, 11 are herbal medicines of which their use is based on traditional knowledge, while 8 items are single herbal medicines that have been scientifically developed. Currently, a Working Group was appointed by the Subcommittee on the Development of the National List of Essential Drugs to select many more herbal medicines for

inclusion into the National List of Essential Drugs and the Hospital Formularies of Herbal Medicinal Products so that doctors would have more herbal medicines to choose from in place of modern medicines.

In addition, as a part of health service system, the following **TTM services are also covered by the Universal Health Care Coverage Scheme (UCS) of the National Health Security Office**, namely: -

1. The treatment and diagnosis with
  - 1.1 Thai traditional medicine
  - 1.2 Applied Thai traditional medicine
2. The treatment and rehabilitation with
  - 2.1 Traditional herbal medicines or traditional recipes comprising of medicinal plant materials
  - 2.2 Therapeutic massage for treatment and rehabilitation
  - 2.3 Herbal steam bath for therapeutic purpose

Recently, under the UCS, the National Health Security Board has approved the allocation of more budgets (from 2 Baht to 6 Baht) per capita for the TTM treatments with therapeutic Thai massage (4.50 Baht) and herbal medicines in the essential drug list (1.50 Baht) starting from fiscal year 2011.



Traditional medicines and herbal medicines in the National List of Essential Drugs



Herbal steam bath for therapeutic purpose



Therapeutic massage and hot herbal compress for treatment and rehabilitation

Moreover, in order to successfully integrate TTM into the examination and treatment of diseases, Institute of Thai Traditional Medicine, DTAM took the following measures to establish the standards of TTM services in the health care system, namely: -

- Setting up of the “**Standards of TTM Service Facilities under**

the **Ministry of Public Health**” that cover the standards of followings; -

- Facilities, equipment and environment
- Personnel
- Job description
- Quality assurance
- Provision of services
- Setting up of **“Clinical Practice Guideline (CPG) of Thai Traditional Medicine”** based on 9 organ systems and CPG of commonly used procedure-based TTM therapies
- Setting up of **“ICD-10 of Thai Traditional Medicine”** and preparation of computer program for recording and reporting TTM services using ICD-10-TM program for future planning and improving of TTM service system. The trial-run phase of utilizing ICD-10 TM computer program to record and report TTM services in the health care system is currently underway with 25 provinces initially participated when the trial run was started in 2009.

- Preparation of the **list of traditional medicines** that can be used in the health service facilities.

According to the evaluation of the standard of Thai traditional medicine services by ITTM during fiscal year 2008, the numbers of health service facilities that provide TTM services that meet the standards of DTAM were as follows: -

Regional / General Hospitals	95/95 (100%)
Community Hospitals	689/726 (94.9%)
Health centers	6368/9868 (64.5%)
<b>Total</b>	<b>7152/10680 (66.9%)</b>





Based on the data of the Bureau of Health Inspection, it was found that in the fiscal year 2009, the percentage of people covered by health security systems that received treatment or rehabilitation by TTM and CAM in the public health service facilities was 9.03%. The value of herbal medicinal products used in all levels of public health service facilities in the fiscal year 2009 was 267,328,236 Baht which was 1.57% of the value of total medicinal products (modern medicines and herbal medicines combined). The percentages of the value of herbal medicinal products as compared to the value of total medicinal products at each level of health service facilities were as follows: -

Regional / General hospitals	0.2%
Community hospitals / Health centers	2.3%

### ***III. Development of human resource in TTM - training programs and existing human resource***

#### **3.1 Educational systems**

The educational systems of Thai traditional medicine (TTM) can be divided into two major types based on the types of practitioners, namely: -

***3.1.1 The systems producing “Thai traditional medicine practitioners” (original type).*** The education in this system can be either by ‘**apprenticeship with an authorized licensed practitioner**’ or by ‘**studying in a Thai traditional medical institution certified by Profession Commission in the branch of Thai traditional medicine**’. Under the apprenticeship system, a person who wishes to be registered and licensed as a Thai traditional medicine practitioner must have two documents; i.e., the Apprenticeship Form showing the information and signatures of the ‘student or apprentice’ and the ‘teacher’ who will provide the training and pass on the knowledge and the starting date of training and Certificate of Completion of Training or Apprenticeship on the practice of Thai traditional medicine from a teacher who works in a training institution or a health service center certified by Profession Commission. The training in each field of TTM must be given by an authorized teacher of that particular field at a specified period of time, namely: -

- For the field of Thai traditional MEDICINE, at least 3 years of training
- For the field of Thai traditional PHARMACY, at least 2 years of training
- For the field of Thai traditional MIDWIFERY, at least 1 year of training
- For the field of Thai traditional MASSAGE, at least 2 years of training

A person must submit the above documents to the Profession Commission in the branch of Thai traditional medicine showing his/her completion of the training in either one of the above field, in not less than the specified period of time, to be qualified for taking a licensing exam in order to become a registered and licensed practitioner in that particular field.

**Training and education in Thai traditional massage or Nuad Thai.** Under the Ministry of Public Health Notification issued on 1 February 2001, therapeutic Thai massage is regarded as a branch of TTM. As a result, the registration and licensing of TTM practitioners in the field of Thai massage, the conditions and the regulation of practice will be according to the Practice of the Art of Healing Act B.E. 2542 (1999). The Profession Commission in the branch of Thai traditional medicine developed the standard curriculum for the profession of TTM in the field of Thai massage requiring total duration of training of not less than 2 years (800 hours) before being eligible for licensing examination. Thai massage training institutes must also be certified by the Profession Commission if





their training curricula comply with the standard curriculum.

**Curriculum for Thai traditional medicine assistants.** For the training of “**Thai traditional medicine assistants**” who are allowed to practice certain task of TTM practitioners in health service facilities under the supervision of other licensed practitioners, the Profession Commission in the branch of TTM developed and officially announced the 330-hour training curriculum for TTM assistants in 2007, training in Thai massage is the main part of this curriculum.

**Regarding the study of Thai traditional medicine under a certified Thai traditional medical institution,** as an interest in TTM and alternative medicine among Thai people greatly increased since the early 2000’s, increasing numbers of universities have responded by offering four-year Bachelor degree education in TTM. University graduates still have to take separate licensing examinations to become licensed traditional medicine practitioners in each of the four fields of TTM practice.

**3.1.2 The system producing “Applied Thai traditional medical practitioners”.** This education system is by **certified academic educational institutions only**. The four-year curriculum includes some basic science and basic medical science knowledge, e.g. anatomy, physiology, biochemistry, pathology, pharmacology, botany and pharmacognosy as prerequisite courses, together with the lectures and clinical training of Thai traditional medicine, pharmacy, court-type Thai traditional therapeutic massage, and midwifery. Licensed applied TTM practitioners can therefore practice in every field of Thai traditional medicine. In addition, they are allowed to use some simple modern medical equipment, e.g. stethoscope, thermometer, sphygmomanometer, for physical examination of the patients in order to better diagnose the patients and rule out if they have serious illness that require immediate modern medical treatment. However, they can prescribe only traditional medicines and order only traditional therapeutic procedures for their patients.

As of the year 2010, there are 13 universities teaching Thai traditional medicine at a bachelor degree level that are certified by the Profession Commissions. Of these, 5 offers BS degree in TTM and 8 in

applied TTM.

### **3.2 Regulation of the practitioners in the field of Thai traditional medicine**

Regarding the regulation of the standard of the education and training and the practice of Thai traditional medicine, under the Practice of the Art of Healing Act, the ‘**Profession Commission in the branch of Thai traditional medicine**’ and the ‘**Profession Commission in the branch of applied Thai traditional medicine**’ are responsible for the licensing examination, registration, and issuing or revoking the license of TTM and applied TTM practitioners, respectively. In addition, the commissions are also responsible for the control of professional practice by setting up the standards of professional practices, standards of professional curricula, reviewing and approving the teaching curricula of academic institutions, and considering professional misconduct of practitioners and appropriate measure of punishment.

**Number of licensed practitioners as of September 2009.** The cumulative numbers of licensed TTM practitioners were as follows: -

TTM practitioners in Thai traditional medicine	17,001
TTM practitioners in Thai traditional pharmacy	23,409
TTM practitioners in Thai traditional midwifery	5,735
TTM practitioners in Thai massage	332
Applied Thai traditional medicine practitioners	660

## ***IV. Development of quality Thai traditional/herbal medicines: production standard, regulation, and registration***

### **4.1 Classification of traditional or herbal medicines**

According to the Drug Act 1967 (B.E.2510), drugs are classified into two major groups, namely: -

1. Modern Drugs
2. Traditional Drugs

“Traditional drug” means a drug intended for use in the practice of the traditional medicine or the cure of an animal disease, which appears in a pharmacopoeia of traditional drug, notified by the Minister as a traditional drug, or a drug of which formula has been registered as that of



a traditional drug.

***Types of registered herbal medicines***

Thai FDA classified herbal medicinal products into four categories, namely:

**1. Traditional drugs.** These are Thai traditional medicines or traditional Chinese medicine of which the indication, therapeutic claims, dosage and administration are based on traditional knowledge that have been passed on from generation to generation or from traditional textbooks recognized by the ministerial regulation. The dosage forms of traditional drugs are not different from traditional dosage forms.

**2. Modified traditional drugs.** These are traditional medicines of which the indication, therapeutic claims, dosage and administration are based on traditional knowledge as in the first group but the dosage forms have been modified into modern dosage forms, e.g. capsules or tablets, for the ease of use and an increased compliance.

**3. Modern herbal medicines or Phytopharmaceuticals.** These are herbal medicinal products that are composed of active plant materials in the form of semi-purified compounds derived from scientific research and are classified as modern medicines. The indication, therapeutic claims, dosage and administration of herbal drugs are usually based on clinical trial evidence. This group of drugs is usually made of standardized herbal extracts prepared into various modern dosage forms.

**4. New drugs.** These are new drugs from herbs developed through complete drug development process and are in the form of purified isolated active substances of which the chemical structures were identified as new chemical entities; hence, this group of drugs is classified as modern medicines.

According to this classification, most of Thai traditional medicines and herbal medicines fall into the first three categories of herbal medicinal products.

**4.2 Standards of raw materials: GAP, National Pharmacopoeia**  
• **Good Agricultural Practice (GAP) standard for medicinal plants that are the sources of commonly used crude drugs.**

Currently, the Institute of Thai Traditional Medicine in cooperation with the Department of Agriculture and Cooperatives, university



professors, as well as several state-run hospitals and nearby communities that grow and supply herbal materials for the community hospitals for the production of herbal medicines are working together to develop GAP standards for the cultivation of commonly used medicinal plants to ensure the quality of the herbal materials. GAP standards of 37 commonly used medicinal plants will initially be prepared.



• **Thai Herbal Pharmacopoeia.** Recognizing the importance of good quality crude drugs on the quality of finished herbal medicinal products, the “**Thai Herbal Pharmacopoeia**” was published by the Subcommittee on the Establishment of Thai Herbal Pharmacopoeia under the supervision of the Thai Pharmacopoeia Committee, of which the Department of Medical Sciences (DMSc), Ministry of Public Health serves as the secretariat office. The Subcommittee is composed of DMSc officers from the Office of Drugs and Narcotics and the Medicinal Plant Research Institute) and professors in phytochemistry, botany and pharmacognosy from various universities. Subcommittee members and related institutes have conducted researches on various commonly used medicinal plants collected from all over the country to set up their quality specifications and analytical methods of active constituents. So far three volumes and one supplement issue of the Thai Herbal Pharmacopoeia covering 34 monographs of Thai medicinal plant materials and herbal preparations have been issued since 1998. More than thirty monographs are being prepared and are expected to be published in the future.





• **Monographs of Selected Thai Materia Medica** In addition to Thai Herbal Pharmacopoeia which focuses on the standard specifications and analytical methods to determine the quality of herbal materials, another type of reference on medicinal plant materials and crude drugs commonly used in Thailand called “**Monographs of Selected Thai Materia Medica**” have also been developed. The purpose of this reference is to inform TTM students and practitioners and manufacturers of Thai traditional medicines about the appearance and the characteristics of authentic herbal materials and medicinal plants that are the source of herbal raw materials so that the right ones will be used for the production of traditional medicines to guarantee their therapeutic efficacy. “The Subcommittee on the Preparation of Thai Materia Medica”, appointed in 2004, comprises of experts from DTAM, DMSc, FDA, the Forest Herbarium, the Royal Institute, phytochemists, pharmaceutical botanists, and pharmacognosts from various universities. Volume 1 of this reference series covering 54 monographs was published in 2008 and Volume 2 is in under publication and is expected to come out in 2011, while monographs of Volume 3 are under preparation.



#### **4.3 Production standard: GMP requirement**

GMP standard for the manufacture of traditional medicines was set up and Thai FDA and various government offices concerned as well as universities have given training courses on GMP and quality control on raw materials and herbal products for local manufacturers regularly. As of April 2010, 15 manufacturers of traditional medicine are certified ASEAN



GMP Guidelines issued by FDA

GMP and 27 received GMP certificate. Even though currently GMP standard for the manufacturing of traditional medicines is not fully enforced, FDA requires that traditional medicines submitted for registration must pass the tests for microbial contamination from accepted laboratories. Report of the assay for microbial contamination from certified lab must be submitted when filing for registration of traditional medicine product. According to Thai Herbal Pharmacopoeia 2000, traditional medicine must not have the following pathogenic microbial contamination: -

*Staphylococcus aureus* in 1 g or 1 ml of traditional medicine preparation

*Clostridium* spp. in 10 g or 10 ml of traditional medicine preparation

*Salmonella* spp. in 10 g or 10 ml of traditional medicine preparation

Moreover, traditional medicines must not have heavy metal contamination. Arsenic, cadmium and lead in traditional medicine products must not exceed 4, 0.3 and 10 ppm, respectively.

FDA, DTAM and Faculty of Pharmacy, Mahidol University have collaborated in assisting local manufacturers to adjust their production processes and facilities and quality assurance system to Good Manufacturing Practice (GMP) level by providing training courses on GMP and quality control on raw materials and herbal products for local manufacturers regularly. DTAM has also provided financial and technical support for 18 hospitals to upgrade their standard of herbal medicine production to GMP level. Moreover, with the grant from the Ministry of Finance, Faculty of Pharmacy, Mahidol University has established and published the procedures for the quality control of 19 herbal preparations in the National List of Essential Drugs for the local manufacturers of herbal medicines.

DTAM is now conducting a feasibility study on the building up of a “**National Herbal Manufacturing Plant**” in an attempt to help local SME manufacturers, who are unable to upgrade their production facilities to GMP level, to continue manufacturing their herbal medicinal products with GMP standard. This manufacturing plant will help pass on Thai wisdom on the production of effective and quality traditional medi-



cine recipes to the future generations.

In addition, DTAM is also in the process of establishing “**Central Market for Herbal Medicinal Materials**” in Bangkok to serve as the trading place of raw materials for the production of herbal medicinal products so that demand and supply of the raw materials can be monitored and the production will match the demand of each type of raw materials and prevent the shortage or over-supply of herbal materials.

#### **4.4 Registration of traditional medicinal products**

The registration of traditional medicinal products, the licensing of traditional medicine manufacturers, and post-marketing surveillance are the responsibility of Thai Food and Drug Administration (FDA), Ministry of Public Health. Herbal medicines that are prepared from single or several herbal materials into different dosage forms have to be registered with the FDA prior to manufacturing and selling. Medicinal plant materials or crude drugs are exempt from registration in order to make it easy for the public to use herbs for health care. Prior to the production of any traditional medicine, the manufacturers must apply for manufacturing license from the FDA and have their manufacturing facilities well prepared and well equipped for the inspection by the FDA. The information submitted by the manufacturers for the registration of traditional medicines will be considered by the subcommittees appointed by the Drug Committee. Duration of registration of traditional medicines is about 160 working days.

Similarly, the importers of traditional medicines must apply for import license from the FDA first. Licensed importers can then file for the registration of the traditional medicines that they would like to import into Thailand.

#### **4.5 Number and value of registered traditional medicinal products**

Regarding the number of traditional medicine recipes for humans registered with FDA, during 1983-2009 there are a total of 12,302 recipes registered, of which 11,435 (93.0%) are locally made and 867 (7.0%) are imported. Comparing with modern medicine for humans, during the same period of time, there are a total of 26,048 modern medicines registered of which 19,981 (76.7%) are locally made and 6,067 (23.3%) are imported. Table 1 shows the local production value and import value of

**Table 1** *The production value of locally produced traditional medicines for humans and import value of traditional medicines for humans during 2000-2008.*

<b>Year</b>	<b>Production value of traditional medicine for humans (Million Baht)</b>	<b>Import value of traditional medicine for humans (Million Baht)</b>
2000	675.337	124.587
2001	736.906	146.584
2002	868.883	167.537
2003	1203.390	202.700
2004	1388.669	199.286
2005	1,484.838	394.101
2006	2,197.26	244.251
2007	2,183.73	270.48
2008	2,543.15	330.62

*Source: Drug Control Division, Thai FDA*

traditional medicine for humans during the years 2000-2008.

Comparing with modern medicine, in 2008 the production value of traditional medicines for humans (2,543.15 million baht) was only about 7.20% of that of locally made modern medicines (35,322.85 million baht) and about 4.0% of the imported value of imported modern medicines for humans (64,148.13 million baht). Meanwhile the imported value of traditional medicines for humans in the same year was 330.62 million baht; therefore, the production and imported values of traditional medicines for humans (2,873.77 million bath) were only 2.88% of those of modern medicines for humans (99,470.98 million bath). This is partly because most of the traditional medicine manufacturers in Thailand are small to medium scale and only a few are large-scale industry. Moreover, the price of modern medicines is much higher than that of traditional medicines. Therefore, both the public and private sectors still have a lot of work to do to improve this industry and to encourage doctors to prescribe more herbal medicines in place of modern medicines, where appropriate.

With regard to the export of traditional medicines, according to the information from FDA, during 2000-2002 the lowest export value of locally made traditional medicines was 30 million baht, and the highest export value was 39 million baht.



## *V. Protection of Thai traditional medicine knowledge and Thai herbs*

It is well known that the issues of the protection of traditional knowledge (TK) and genetic resources (GR) and the equitable sharing of the benefits derived from TK and genetic resources are currently being in hot debate between developed and developing countries in both CBD (Convention on Biodiversity) and WIPO (World Intellectual Property Organization) arenas.

Thailand was at the forefront to make the first move to draft and issue a sui generis law to protect her TK and genetic resources called **“the Protection and Promotion of Thai Traditional Medicine Knowledge Act B.E. 2542”** in 1999. The Act serves as a measure to promote public awareness of the value of Thai traditional medicine knowledge and herbs as well as to increase public participation on the conservation, development and sustainable use of TK and GR related to TK. The Act protects the traditional medicine formulae, scriptures and textbooks on TTM, Thai



medicinal plants that are valuable for research, or have economic value, or may be extinct, as well as places of origin of medicinal plants.

DTAM is responsible for the implementation of the Act and serves as the secretariat office of the **“Protection and Promotion of Thai Traditional Medicine Knowledge Committee”**. The Committee, Sub-Committees and DTAM are responsible for

1. the compilation and categorization of the information on TTM knowledge including TTM formulae and textbooks on TTM,
2. the registration and protection of traditional medicine formulae or textbooks that are regarded as ‘national’, ‘general’ or ‘individual’ properties using information technology for data entering, retrieval and networking,
3. giving advice to the Minister of Public Health to notify in the Government Gazette the species of medicinal plants to be treated as “controlled medicinal plants” for the protection of medicinal plants that are valuable for research, or have economic value, or may be extinct,
4. giving advice to the Minister of Public Health to establish places of origin of medicinal plants in natural ecological system or where biological diversity exists or can be affected by any act of humans as “conservation areas” and to prepare the action plan called “Herbs Protection Management Plan” and propose to the Council of Ministers for approval in order to protect medicinal plants and their places of origin.

### **Future trends in the development of TTM in the country**

The integration of TTM into the national healthcare system and national health security scheme is still at the beginning period. More researches must be conducted on traditional therapies and herbal medicines in order to provide scientific evidence to support more traditional medicines and therapies into the health service system. The establishment of **“Thai Traditional Medicine Research Institute”** is hoped to accelerate clinical research projects in TTM and the development of the model of TTM hospital and TTM services in the country.

The strengthening of herbal medicine industry and the improvement of the quality of traditional and herbal medicines is another major challenge for both public and private sector. Various national and regional



(ASEAN) standards must therefore be set in the near future, e.g.

- GAP standards for the cultivation and post-harvest handling of commonly used herbs,
- Quality specifications and monographs of commonly used herbal medicinal materials in the National Herbal Pharmacopoeia,
- GMP standards for the manufacturing of quality traditional medicine, and
- Standards and quality of traditional medicine, etc.

### **Suggested areas of regional collaboration**

It is hoped that bilateral collaboration with countries that have a long and successful experience on the use of traditional medicine in the health care system and multi-lateral collaboration among ASEAN countries via the process of “ASEAN Harmonization”, ACCSQ TMHS PWG and regional collaborative projects on traditional medicine will help Thailand improve the quality of traditional medicine practices and medicinal products even further so that TTM will later gain recognition and acceptance by ASEAN member countries and the rest of the world in the future.

Possible areas of future regional collaboration that Thailand would like to participate in are on: -

- Human resource development
- Research & development on traditional medicine
- Knowledge & resource sharing
- Development of the quality standards of traditional medicinal products and raw materials
- Development of the standards of traditional medicine services
- Promotion of traditional medicine into the primary health care