The Current Situation of the Herbal Medicinal Product System in Thailand

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Abstract This report aimed to review and update current situation of herbal medicinal product (HMP) system of Thailand and provide recommendations for sustainable development of HMP system. Research papers and official database and documents of public and private agencies on related subjects were compiled and brainstorming of experts in the field was then performed to formulate recommendations. It was found that although government policy to promote the use of HMPs in public health services was issued for more than 40 years, inputs of HMP system, i.e.
Introduction

Herbal medicine (HM) is truly rooted in Thai culture since ancient times and it is presently incorporated into health services. It not only has benefits to health, but is also acknowledged for its economic and cultural value.\(^{(1)}\)

In 2018, sales of herbal medicinal products (HMP) in Thailand were 42.4 billion baht with 11% annual growth rate from 2017. Herbal topical analgesic is the fastest growing market segment with a 14% annual increase (data from Ministry of Commerce). The value of HMP manufacture has gradually risen throughout the period of 2008–2016 according to statistics from the Thai Food Drug and Administration (TFDA). This data infers that HMP has been and will become more accepted among consumers. The integration of Thai traditional medicine (TTM) including HMP into the mainstream health system is a policy of the Thai Ministry of Public Health (MoPH). However, it may not meet the demand of prescribers because 40% of HMP prescription in the government hospitals were outside the list of HMP in the National List of Essential Medicines (NLEM) so far (data from Health Data Center of MoPH).

This article explores current situation of inputs and the HMP management in Thailand. Policy recommendations are then given in order to improve the efficiency and sustainability of HMP.

Method

The last report on the Drug System of Thailand was published 17 years ago in 2002, this research in 2019 therefore aims to provide up-to-date information on the HM system of Thailand. It is a part...
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of the Health Systems Research Institute project for the “Situation analysis of medicine system of Thailand” with the scope depicted in the conceptual framework below (Figure 1).

The report presents the inputs including policy, HMP industry, infrastructure supporting the industry, research and development (R&D), and human resources. The 4 main components of HMP management: selection, procurement, distribution and use were gathered from researches and the official database and documents of public and private agencies. Finally, experts in the field of HMP undertook brain–storming and analysis of the data, giving comments and formulating suggestions.

Results

1. Inputs

1.1 Policy

The Alma–Ata Declaration on Primary Health Care initiated by WHO in 1978, calls on Member States to use indigenous medicine and HM as a part of Primary Health Care (PHC), and this was a turning point for Thailand to bring back Thai traditional knowledge into health services. The R&D in HMP especially folk remedies was later extensively conducted by researchers of the MoPH and universities leading to a wider use of single herb remedies in public health settings. In 1999, the List of HMP in the NLEM was announced, later covered by the public health insurance system and TTM practitioner positions as government officers and employees in the MoPH was established. This led to the gradual increased used of selected TTM formulas and single HMP from the NLEM in the health service system.

Over the past five years (2015–2019), the Thai government has paid high attention to support local wisdom and the development of innovative Thai herbal products. This endeavor was sated in the 2017 Constitution of Thailand and emphasized the role of government to promote and support the development of TTM wisdom to maximize its benefit for the good health of all Thai people. Additionally, several measures have been established to promote the use of traditional knowledge including HMP. These include the Master Plan on Thai Herbal Development (2017–2021), the first comprehensive plan to promote the herbal industry with the goal of becoming the Association of Southeast Asian Nations (ASEAN) region leader in exporting herbal raw materials and products. At local regional level, four ‘herbal cities’; herbal product development centers are specified in the plan, later expanding fourteen provinces through-
out the nation. A lack of continuous budget support for implementing this plan is the major obstacle to achieve the above-mentioned goals. So far, there is no comprehensive evaluation on how this plan help improve efficiency and effectiveness of herbal industry.

1.2 HMP industry

Based on MoPH Notification on “Specifications of Criteria and Procedures for the Production of Traditional Medicines (TM) According to the Laws on Drugs B.E. 2559” (2016), Manufacture of HMP can be divided into three categories based on sales volume and risk of HMP to health (oral or external use, dosage forms or manufacturing technology). For category A manufacturer who produce ‘high risk’ oral products or whose production volume of oral HMP products is worth more than 20 million baht per year, Good Manufacturing Practice (GMP)– Pharmaceutical Inspection Co-operation Scheme (PIC/S) production standard is required, those who do not meet the earlier criteria and are in categories B and C producing other oral and topical HMPs, must follow the Fundamental Manufacturing Practice (FMP) to ensure the quality of their products. Currently, the manufacturing standard for HMP is consideration by TFDA due to the change of law regulating HMP according to the Drug Act to Herbal Product Act B.E. 2562 (2019).

To date, there are 71 HMP manufactures which 47 and 24 were certified GMP PIC/S and FMP, respectively (data from TFDA on July 2019). Most of them are small and family-run businesses with insufficient capacity for R&D. While the domestic production value of HMP has increased over a ten-year period, import value has remained stable over the same period of time (data from TFDA) (Figure 2). This implies that the HMP industry has achieved self-reliance at a certain level but still needs to tackle some challenges in order to improve efficiency.

In addition to private manufacturers, the state-run

Figure 2 Production and import value of HMP for human during 2008–2016
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enterprises such as Government Pharmaceutical Organization (GPO) and Defense Pharmaceutical Factory (DPF), and some hospitals under MoPH or universities, also play a role in the production of HMP. A report from the Department of Thai Traditional and Alternative Medicine (DTAM), shows there are about 90 government hospitals producing HMP, with varied production capacity regarding the number and dosage forms of HMP items. Of these, with the support of DTAM, 47 are WHO GMP-certified production facilities (data from a meeting for policy dissemination on June-7, 2017). This is in order to preserve health wisdom that meet the health needs of local people.

The development model of the HMP value chain is explicit in Surat Thani province, one of the herbal cities located in the South, making the ‘Surat Model’ an example to follow for other provinces. In addition to contract farming at the upstream level, a whole range of measures is carried out throughout the value chain to support the production and utilization of HMP and provision of TTM services. Part of the provincial UHC capitation received is allocated for the production and distribution of HMP for all hospitals in Surat Thani and other provinces.(5)

1.3 Infrastructure

1.3.1 Supply of herbal raw materials

Both the quality and quantity of herbal raw materials are one of the main challenges for Thai HMP industry. There are around 13-15 large traders who are wholesalers, importers and/or producers of HMP in Bangkok.(2) Many herbs are scarce or are not native plants of Thailand and hence herbal raw materials derived from such herbs need to be imported.(6,7)

Herb prices are unstable and vary according to production quantities and demand. As mentioned previously, contract farming is one way to solve this problem but it requires both side to honour the contract made. At present, some traders have begun classifying herbal raw materials and set the price based on their qualities; however, the majority of farmers still have no bargaining power.(2)

1.3.2 Quality standards and laboratory service

The quality of HMP available that fail to meet national pharmacopeia standards is another main concern. The 2018 report of the Department of Medical Sciences (DMSc) shows findings of research conducted in 140 items of HMP sampling from the market where only 86.43%, 96.43%, 97.86% met the standard specifications of microbial, heavy metal and pesticide limits, respectively.(8)

For many decades, the DMSc, DTAM and TFDA have continuously put effort into establishing suitable standards to support the HMP industry, such as production standards for different levels of manufacturers, Thai Herbal Pharmacopeia (THP), Thai Herbal Preparation Pharmacopoeia (THPP) and selected Monographs of Thai Materia Medica. In addition, DMSc and Regional Medical Sciences Centers can also provide laboratory services for manufacturers to analyze and issue certificate of analysis for HMP manufacturers.

1.4 R&D on Thai Herbs

R&D is crucial to move the HMP industry forward and create innovative products in accordance with Thailand 4.0 strategy. Figure 3 shows research budgets and the number of research projects on Thai medicinal plants (2014–2018). Figures remained stable during 2015–2017 but markedly increased in 2018 as a result of the First National Master Plan on Thai Herbal Development (data from National
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Research Council of Thailand, Agricultural Research Development Agency, Thailand National Nanotechnology Center and Department of Thai Traditional and Alternative Medicine).

When breaking down the value chain into downstream, midstream and upstream levels, it was found that midstream is more attractive to researchers as seen in Figure 4. Studies on pharmacological activities and

Figure 3 Number of research projects on Thai medicinal plants and budget during 2014–2018

Figure 4: Researches on Thai herbs according to the value chain of herbal products

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- taxonomical & ethnobotanical study development of herbal database
- development of herbal agricultural & harvesting practice
- development of high-quality herbal raw material and quality control process
- development of herbal formulation and dosage form, preparation of herbal extracts
- Pharmacological and clinical study
- development of quality control & manufacturing process
- post-marketing study, pharmaceutical administration and pharmacovigilance
- Other, e.g. community enterprise promotion
formulation development of herbal products have been the first and the second priority issues conducted during 2014–2018.

1.5 Human resources

TTM and Traditional Chinese Medicine (TCM), particularly acupuncture, are officially recognized in Thai health system; however, there are much more personnel in TTM than those in TCM in public health settings. Based on the data of MoPH, as of 1 September 2019, there were 2,813 TTM practitioners working in MoPH. Meanwhile, of 59 provincial health offices responding to the 2017 survey conducted by the Institute of Thai–Chinese Medicine DTAM, there were 220 medical doctors trained in acupuncture and 70 of them working in MoPH hospitals.

Medical doctors normally prescribe research–based single HMP whereas TTM and TCM practitioners prefer to prescribe multi–ingredient HMP. At health center level, MoPH also promote prescribing selected items of HMP in NLEM by community health nurses. In pharmacies, patients can receive various HMPs from pharmacists without prescription.

Vadhnapijyakul and Suttipanta (2014) conducted a survey in 139 hospitals and found that 97.4% of prescribers were physicians. Of interest, around 69.9% of TTM practitioners did not perform diagnosis and prescribe HMP because they were not authorized to do so by the hospitals. Around 20% of medical doctors seldom referred patients to TTM practitioners for further treatment. The research also found that hospitals did not have a sufficient supporting system for TTM, for example not qualified working area for HMP production and TTM services. TTM practitioners were high variation in positions, number and educational degree in each hospital.

Realizing the significance of HMP as a part of health services, health professionals and relevant agencies have organized trainings to build capacity on integrating TTM into health care services. Topics include basic principles of TTM for medical doctors, clinical research methodology for TTM practitioners provided by the DTAM, and production and rational use of HMP for pharmacists organized by pharmacy council.

2. HMP product management

2.1 Selection

Consultation, review of product dossier, and registration and licensing of HMP is an important process for regulatory and TM authorities (TFDA, DTAM) to screen and select safe, effective and quality HMP into the market. Regarding Drug Act B.E. 2510, drugs are classified into 2 types; modern drugs (MD) and traditional drugs (TD). TD is the remedies recorded in classical textbooks or used by local people. This Act limits development of traditional remedies as it specifies that these remedies do not need to follow science. Data from TFDA showed that the number of TD registered are increasing with slowing growth as seen in Figure 5.

To minimize the limitation of Drug Act on TD, National Drug Committee in 1998 classified TD into four subtypes, i.e., TD, modified TD, herbal drugs with semi–purified compound and modern drugs (pure compound) from herbs. However, in practice there are only two subtypes; traditional drug (TD) and scientifically developed HD (SDHD). Only 13 SDHD could be registered compared to 7,610 TD during 2009–2018 as shown in Table 1.
Figure 5 Cumulative number of registered traditional drugs for human during 2009–2018

Table 1 Two types of HMP registered with TFDA during a ten-year period (2009–2018)

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To ensure more appropriate regulatory measures for HMP, Herbal Product Act B.E. 2562 (2019) was launched in February 2019 to separate HMP from modern drugs. Regarding the new act, herbal products including HMP will be approved to the market via three channels; registration, notification and listing based on risk assessment. Currently, the act is in the process of bye–laws development. In the near future, enforcement of HMP will be changed to this act and there will be more items of HMPs launched to market faster than usual due to the improved process of notification and listing. Based on the risk assessment principle of new law, the distribution channel of HMPs may be changed; this makes preparing TFDA staffs for product approval and post marketing surveillance is vital for the future HMP system.

The NLEM is the effective benefit package list used by three main public health schemes; Civil Servant Medical Benefit Scheme (CSMBS), Social Security Scheme (SSS) and Universal Coverage (UC). Presently, there are 74 items of HMP included in NLEM or just 10% of the list. The number has remained the same since 2014 due to insufficient evidence to support the efficacy and safety of HMP, in comparison with modern drug (MD) which increased almost every year.

In health settings, the Pharmacy and Therapeutic committee (PTC), has a role in approving all drugs including HMPs to be used in the hospitals but they do not have much knowledge on HMP as the majority of PTC members are modern medicine professionals. From the survey of 139 hospitals in 2014, approximately 24% had inadequate items of HMP for treatment. Among these hospitals, about
only 16 items of HMP were available, with the capsule being the most common dosage form found. Hence, the main challenge is insufficient items of HMP to meet the health need.\(^{(15)}\)

DTAM has also selected some TTM formulae from various credible sources and included into the ‘National Thai Traditional Formulary’. The purposes of this formulary are to promote industrial and hospital production of the selected items, to promote their utilization in health service facilities, and to be used as textbooks for teaching.

### 2.2 Procurement

The import and export data of herbs from the Ministry of Commerce are available but it was unspecified as to how much was used for medical purpose. Therefore, only statistics of export and production values retrieved from TFDA is presented in Figure 5.

The total value of HMP procurement is not available. Government Procurement and Supplies Management Act B.E. 2560 requires state agencies, including public hospitals, throughout the country to follow procedures with the aim of increasing transparency in the government’s procurement processes. Government hospitals have to buy any drug not exceed the standard price, by generic name and at least 60% of procurement budget for the items in NLEM.\(^{(16)}\) Majority of HMP purchased is under NLEM and only 25 items of HMP have the standard price compared with 293 items of the modern drugs.

### 2.3 Distribution

HMPs are available in both public and private health facilities. Only over-the-counter (OTC) remedies or non-prescription medicines which are considered safe and effective enough for commonly found minor conditions are sold without prescription according to the Drug Act B.E. 2510. Although there are limited distribution channels of HMPs as mentioned earlier, they are still found in non–pharmacy stores. A survey by Boodawong B et al.\(^{(17)}\) showed that 436 items of HMPs from a total number of 2,991 drugs were available in 613 groceries in 8 provinces. These stores received their supplies from several sources such as wholesale dealers (32.5%), drug stores type 1 (31.5%), drug stores type 2 & 3 (14.7%) food trucks (11.5%), department stores (7.7%) and others (2.6%). Routes of distribution were direct delivery, postal service and medicine trucks. Information about the HMP distribution channel at national level is lacking.\(^{(7)}\)

Interestingly, HMP is increasingly available online, although legally it is not permitted. The Euromonitor International 2019 (data from Ministry of Commerce) showed that some items of HMP, such as herbal balm, herbal inhaler and cough pills have gained more popularity among tourists. These online sales and distribution channels for tourists should also be taken into consideration under the Herbal Product Act B.E. 2562.

### 2.4 Use

Data on the public use of HMP among insurers of three public health schemes are presented in the Table 3. Among the three schemes, service users under UC consumed more HMPS compared to the other two schemes; and UC covers about 75% of Thai population. In 2018, utilization of HMP was reimbursed as 274.60 MB.

Statistics of the Health Data Center in 2016–2018 showed an increase of HMP use in term of items and numbers of prescription. HMPs in NLEM was
prescribed at approximately 60% of all HMP prescription (59.02%, 61.18% and 63.27% in 2016, 2017 and 2018 respectively). People over 60 years old used HMPs the most (32.53%) compared with other age groups.

Although patients are able to access to HMPs from health settings, many of them self-medicate with HMPs without informing health professionals. Tantipidoke R, et al. found three patterns of HMP use; use of HMPs before starting allopathic medicine, concurrent use of HMPs and conventional drugs and use of HMPs as a complementary treatment. (18) Another study shows that only 50% of users had knowledge on HM while 21.6% of them used HMPs with no medical indications. (19)

Adulteration of HMPs with modern medicines, especially with steroids, is commonly found in rural communities. During 2008–2009, DMS investigated 1,584 HMP samples from all over the country. Finding showed 283 samples (17.87%) were adulterated with modern medicines and that tablets were the most frequently adulterated dosage form. Notably, 47% of adulterated samples, more than one modern medicines were detected. The modern medicines identified were steroids, NSAIDs, antihistamines, and psychotropic substances. Samples from the northeastern part of Thailand were found to be the most adulterated. (20)

At the local level, during 2005–2009, 136 of 626 samples or 21.7% of HMPs from the Public Health Regions 4 and 5 were adulterated with steroids, equivalent to the average dexamethasone 0.319 mg/g, ranging between 0.010–1.119 mg/g. Capsule dosage form had the highest amount of steroids (1.081–1.119 mg/g). (21)

Safety monitoring of HMPs
In Thailand, the Health Product Vigilance Center (HPVC) under TFDA is responsible for safety surveillance of health-products and the adverse product reaction (APR) reporting system. From HPVC statistics, only 3,583 records, out of all 761,921 records (0.47%) related to herbal products during 2000–2018.

Thai vigibase, the national APR database collecting report throughout the country, showed that there were 1,216 records with 1,983 incidences that may be associated with herbal products during 2006–2015. About 20.2% of this figure were serious APR. The top five herbs (accounting for more than 10% of APR) were Andrographis paniculata, Curcuma longa, Derris scandens, Cissus quadrangularis and Centella asiatica, while oral traditional recipes for musculo-skeletal conditions were the cause of highest APR records.

Discussion
During the past two decades, the promotion of HMP use has strongly been implemented by the MoPH due to the national policy on the integration of TTM into health service system and because the goal of HMP development is to achieve drug security. Coverage for HMPs in public health schemes and additional on-top capitation from National Health Security Office (NHSO) for the provision of HMP services in health service facilities, have been the main driving force. In the future, various measures such as investment in R&D for both HMPs and raw materials (22), encouragement of qualified traditional practitioners and folk healers, (23) development and implementation of the evidence-based clinical practice.
guidelines (CPG), public empowerment on the use of HD for self-care to relief common minor diseases and symptoms should also be strengthened in order to achieve sustainable HMP system.

Access to medicine is the main output of HMP system. According to the medicines access framework from a WHO–Management Sciences for Health (MSH) consultative meeting held in Ferney-Voltaire in 2000, access to medicine can be measured in four dimensions of availability, accessibility, affordability and acceptability.

Out of the four aspects of access to medicine, acceptability on HMP is not a problem because HMP is a part of Thai culture. Regarding the availability of and accessibility to HMPs, there are currently about 20,000 items of HMPs available in the market (TFDA statistics), but there are only 74 items included in the NLEM. Collection of solid clinical evidence to support the selection of HMPs into the NLEM should start at the health setting level. With support from the DTAM, clinical trials with collaborating hospitals can then be conducted to determine efficacy and safety of new items of HMPs for future addition into NLEM. The consideration of the PTC is a critical step to make HMPs available for patients, technical support from the DTAM will be helpful to provide backup data for TTM practitioners in each public hospital and propose herbal remedies to PTC.

HMPs available in the health services covered by the health insurance systems in Thailand are currently only those named in the NLEM; however, these HMPs solve only common minor illnesses or symptoms. Only a few hospitals encourage TTM practitioners to prepare herbal remedies based on TTM theory and local health wisdom for their patients. Some hospitals have therefore made an attempt to increase herbal medication availability in their settings to accommodate the practice of TTM practitioners. For example, Kabchoeng hospital in Surin province has 36 herbal preparations and occasional extemporaneous preparations used for ten groups of symptoms, including emergency care for treating venomous snake bites. Prapokklao hospital in Chantaburi province operates psoriasis clinic to serve patients who do not respond well to modern medicine. The treatment results show improvement in slowing the progression of disease.

Lastly, affordability of healthcare services should be taken in to account, if there are more HMPs added to public health insurance, through affordability at individual level is not a problem now. Of note, inequity of accessibility to HM among service users under the three public health insurance systems should be addressed for example, the prescription of personalized HM formulas can be reimbursed from CSMBS only.

Challenges

The main challenges facing the HMP system which urgently need to be addressed are the quality of raw materials, quality of finished products, and promoting practice of health professionals. To improve consumer and patient accessibility to quality HM products, the standards of raw materials and finished products should be enforced more strictly during registration and procurement process. The substitution of HMPs to modern medicines should be endorsed as a national policy to upgrade quality of HMP value chain. The farmers and manufactures will have a clear list of HMP target to cultivate and produce whereas the DTAM and TFDA will plan better on researches
of the specific HMPs. At the same time, government investment in basic infrastructure, such as central laboratories to conduct quality tests or even product stability test, routine market surveillance and strengthening the capabilities of HMP businesses are also required. These will create trust among health professionals especially physicians wishing to prescribe HMPs for their patients.

The findings of this study show that HMPs in NLEM have not met the demand of prescribers; medical doctors and TTM practitioners yet. Therefore, addition of more new herbal remedies in NLEM and allowing individualized multi-ingredient HM preparations to be covered by all public health insurance schemes are top priority issues.

**Conclusion**

In conclusion, Thailand’s present HM system can serve only basic medical needs or act as a complement to western medicine. To upgrade HMP to be a main-stream service, compiling TTM theory and folk medicine, promoting TTM practice, improving the quality of herbal raw materials and finished products, and well as research and development throughout value chain of HMPs are strongly recommended.

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บทคัดย่อ: สถานการณ์ปัจจุบันของระบบยาจากสมุนไพรในประเทศไทย

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รายงานนี้มีวัตถุประสงค์เพื่อรวบรวมสถานการณ์ปัจจุบันและจัดทำข้อเสนอแนะเพื่อพัฒนาระบบยาจากสมุนไพรที่ยั่งยืน โดยรวบรวมและวิเคราะห์ข้อมูลจากฐานข้อมูล และเอกสารของหน่วยงานที่เกี่ยวข้อง รวมถึงงานวิจัยต่าง ๆ ที่สังเคราะห์และระดมสมองผู้เชี่ยวชาญ ผลการศึกษาพบว่า ประเทศไทยมีนโยบายการพัฒนาจากสมุนไพรเพื่อใช้ในการดูแลสุขภาพของประชาชนที่ชัดเจนมากกว่า 40 ปี แต่ปัจจัยสำคัญที่ส่งผลต่อการพัฒนาและส่งผลกระทบโดยตรงต่อการจัดการยา คือการคัดเลือกยา พบว่าที่ผ่านมาการขึ้นทะเบียนยาเป็นไปเพียงเล็กน้อย แต่ยาพัฒนาจากสมุนไพรถูกเบิกจ่ายผ่านระบบหลักประกันสุขภาพของรัฐทั้งสามกองทุน มีมูลค่าประมาณ 274.6 ล้านบาท ในปี พ.ศ.2561 ความเร่งด่วนในการพัฒนาระบบยาจากสมุนไพร คือ คุณภาพผลิตภัณฑ์ และการมียาจากสมุนไพรที่ต้องการต้องมีคุณภาพตามความจำเป็นทางสุขภาพ