

Thailand's Legal Framework Concerning Drugs

Kitti Pitaknitinun, B.Sc. (Pharm), LL.B., B.Econ., M.P.H. (Hospital Management), MA. (Leadership in Social Business and Politics)*

**Yupin Lawanprasert, B.Sc. (Pharm), M.S. (Environmental Health),
Dr.P.H. (Public Health Administration)****

Songsak Vimolkittipong, B.Sc. (Pharm), LL.B.***

** Ministry of Public Health, Thailand*

*** Faculty of Pharmacy Rangsit University*

**** Bureau of Drug Control Office of Food and drug Commettee*

Abstract This study aimed to explore and summarize current landscape of Thailand's laws and regulations concerning drugs and related legal problems. The study was conducted through documentary research and gathering of experts' opinion on key problems and recommendations. On governance of drug system, it was found that there were 39 pieces of associated laws concerning drugs which can be further categorized into 5 categories which are laws on pharmaceutical products control (4 pieces), laws on governance of healthcare professions and service (11 pieces), laws on consumer protection (5 pieces), laws on trade and commerce (10 pieces), and laws on others specific responsibility (9 pieces). On financing of drug system, the laws on trade and commerce have significant bearing on higher national drug expenses. Although Thailand has been implementing the universal health coverage program; but laws on health security is still unable to prevent bankruptcy due to high healthcare cost. On drug research and development and drug manufacturing, the laws on pharmaceutical product control does not have tangible measure promoting domestic drug research and development with the exception of recently passed Herbal Products Act B.E.2562. On drug selection, laws on pharmaceutical product control focuses on registration procedure which emphasizes effectiveness, efficiency, and safety of the product. Selection procedure was established for drugs listed in the National List of Essential Medicines which are then offered through benefit package of all health security funds. On drug procurement, Governmental Procurement and Inventory Management Act B.E. 2560 allows government departments to organize collective bargaining on district/provincial level, which departments under the Ministry of Public Health are particularly receptive to, resulting in reduction in drug expenses. Health security funds also negotiating drug prices on national level to procure essential drugs at reasonable price thus increase accessibility for the patients. On drug distribution, Drugs Act, B.E. 2510 and Health Facility Act, B.E. 2541 allows drug stores and private clinics, in addition to hospitals, to dispense prescription drugs. This alleviates workload and traffic in and to hospitals as patients may bring prescription to those alternative distribution channels. On drug utilization, At present grants preliminary recompense to patients who suffer from improper medical services according to health

security laws and also facilitates litigation for further compensation through consumer protection laws. As a recommendation to enable effective enforcement of laws concerning drug leading to intended result, agenda for rigorous enforcement, passing of new laws in certain issues, amendment to specific details which hinder the development of nation's drug system should be prioritized.

Keywords: drug, drug system, laws, drug act, laws concerning drug

Introduction

Drug is one of life's necessities, merit goods and key resource in health care. In B.E. 2556, Thailand's expense on drug is approximately 140,000 million bahts which equates to 24% of health expenditure.⁽¹⁾ Given such importance, efficient drug governance system is essential.

Laws is a system of rules which is imposed on a particular community to regulate rights, duties, and the relationship between its members⁽²⁾ to maintain order, deliver justice, and protect the public interest according to the need of the state,⁽³⁾ thus many pieces of laws were passed by the government to regulate drugs throughout their lifecycle.

Thailand has been having problems with high drug expenses, irrational uses and misuse of drug. Nowadays, there are a multitude of new technologies under development that will have a major impact on medical and pharmaceutical industry such as the use of artificial intelligence/machine learning,⁽⁴⁾ drug development from biological product, and gene editing.⁽⁵⁾ All of these will certainly change drug research and development and also affect the economy, monetary, and fiscal system in the future. For this, laws can be an accelerator or a hindrance to further progress.

From the importance of laws elaborated above, this study was conducted with the aim to explore and summarize current landscape of laws concerning drug,

its scope, and enforcement problems that can later be used to establish guidelines for new laws or amendment in benefit for Thailand.

Methodology

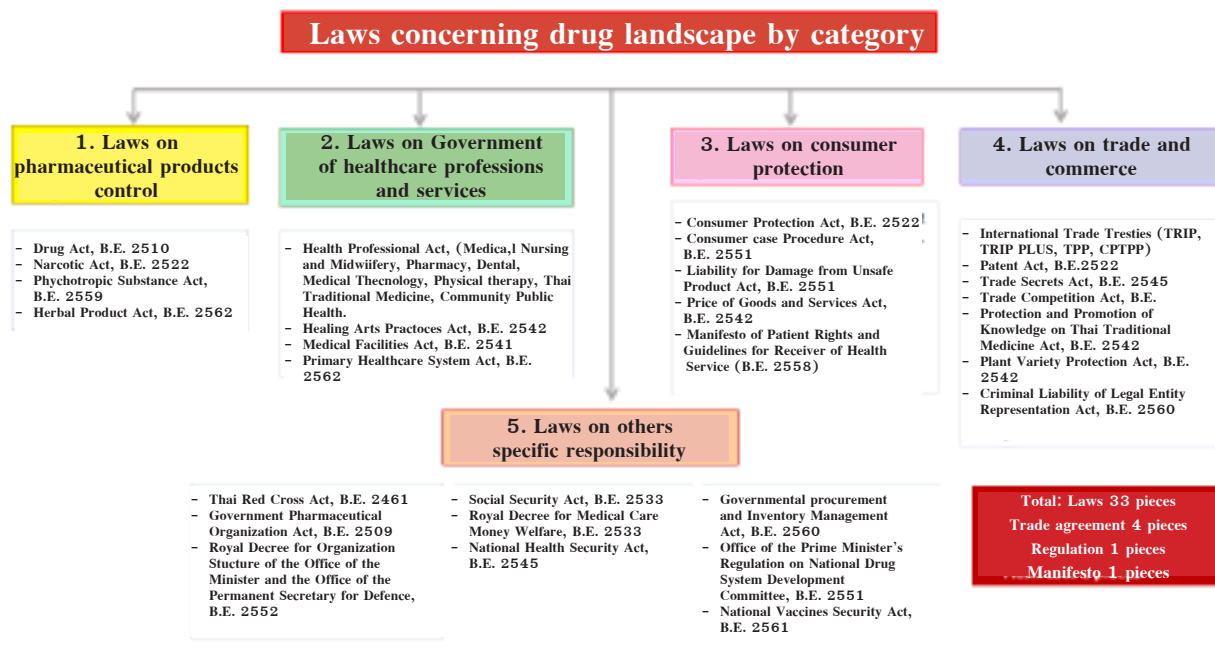
Through documentary research and categorizing laws into categories which are laws on pharmaceutical products control, laws on healthcare professions and services, laws on consumer protection, trade and commerce, and laws on others specific responsibility, these categories of laws were analyzed in different dimensions of drug management system including governance, financing, research & development and manufacturing, selection, procurement, distribution, and utilization. Data and recommendations were also gathered experts' opinions on specific problem.

Results

1. Current landscape of laws concerning drug

All components of drug system are interconnected from the drugs, prescribers, dispensers consumers or patients, to management. The study has found that Thailand have passed laws governing aforementioned components in total of 39 pieces. As shown in Figure 1, there are 4 laws on pharmaceutical products control, 11 on governance of healthcare professions and services, 5 on consumer protection, 10 on trade and commerce (including international treaties),

Figure 1 Landscape of drug laws category in Thailand



and 9 on others specific responsibility.

1.1 Laws on pharmaceutical products control

Intended purpose of laws in this category is to regulate manufacturing, trading, importing, and possessing of drugs, narcotics, psychotropic substances, and herbal products.

Key laws in this category are Drug Act B.E. 2510,⁽⁶⁾ Narcotic Act B.E. 2522,⁽⁷⁾ Psychotropic Substance Act B.E. 2559,⁽⁸⁾ and Herbal Products Act B.E. 2562.⁽⁹⁾

Laws on pharmaceutical products control category share similar principle focusing on controlling process of manufacturing, importation, sales, and possessing of narcotics and psychotropic substances. They primarily specify power and duty of responsible committees, licencees, and practitioners. They also regulate the application processes for manufacturing/sales/importation permits, drug registration process, categorization, advertising, post-marketing surveillance, and penalties.

While all drugs are regulated under Drug Act B.E. 2510, some drugs are also considered psychotropic substance or narcotic which make them fall under Psychotropic Substance Act B.E. 2559 and Narcotic Act B.E. 2522, respectively. These are laws that must be strictly complied with as they specify a far more severe penalties in comparison to Drug Act B.E. 2510. Activities regarding psychotropic substances and narcotics for medical uses require a permit under associated law in addition to one under Drug Act to proceed further.

In accordance to deregulation of cannabis for medical uses, a Ministry of Public Health's regulation exempts cannabis extracts with Tetrahydrocannabinol (THC) less than 0.01 percent by weight and products which has Cannabidiol (CBD) as main ingredient with THC less than 0.2 percent by weight from falling under schedule 5 narcotic apart from cannabis and hemp.⁽¹⁰⁾ There is also a Narcotics Control Committee's regulation⁽¹¹⁾ establishing specification for hemp

product which may be exempted from restriction as schedule 5 narcotic.

Problem regarding laws on pharmaceutical products control

1) Almost all laws under this category focus on effectiveness, quality, and safety of the product but lack provision on promotion of research and development in the manufacturing industry, and pricing standard. They also lack provision on businesses' liability to consumer on damage from product use.

2) Previous attempts to solve problem on distribution of dangerous drugs and misuse of drugs were to tighten the control by re-categorizing them to special controlled drug or psychotropic substance which require prescription or can only be used in medical facilities while there is no established common system to issue prescription that is recognized by all dispensers, lessen people access to drugs that may be more effective in their treatment.

3) Current registration regulation is too rigid to adapt to changing context or high technology drug and accommodate new kind of drugs.

4) Since Drug Act passed, the requirement for dispensing channels to always have a pharmacist on premises during operating hours cannot be enforced. After the grace period from B.E. 2522 that ends on 30 September B.E. 2529 which only require pharmacists to be on premises at least during 3 operating hours, there are still operators reporting 3 operating hours while actually operating longer.

5) There is no effective regulation to the growing problem of false or propaganda advertisement of products on mass, and social media which in many cases result in loss of life.

6) There is no effective law enforcement against

offenders in psychotropic substance contamination and intentional addition in dietary supplements. Cases include Sibutramine in weight loss products, and Sildenafil in virility supplements by claiming properties for male enhancement.

1.2 Laws on governance of healthcare professions and services

This category regulates healthcare professionals, practitioners of the healing arts, and service provision on both public and private sectors. Key laws are the following.

1) The 8 healthcare profession acts⁽¹²⁻¹⁹⁾ cover each health profession: medical doctors, pharmacists, dentists, nurses and midwives, medical technicians, physical therapists, Thai traditional medicine professionals, and community public health professionals. All acts aim to establish and enforce professionals' practice to comply with the respective standards and ethics, define the scope of each profession. These laws also have provisions on foundation of professional councils and committees, regulation of its members' compliance with ethics enforced through reprimanding, probation, and suspension or revocation of professional license according to given context.

2) Healing Arts Practices Act B.E. 2542⁽²⁰⁾ governs 7 branches of healing arts which are occupational therapy, communication disorder therapy, cardiovascular technology, radiological technology, clinical psychology, orthotics, and Chinese traditional medicine. Its basis and principles are similar to those of healthcare profession acts.

3) Health Facility Act B.E. 2541⁽²¹⁾ regulates standards and operation of health facilities in private sector but in public sector this law will be enforce only about Health facility characteristics and standard

under ministerial regulation.

4) Primary Healthcare System Act B.E. 2562⁽²²⁾ define the scope of primary healthcare services connecting households and communities to secondary and tertiary healthcare services and mandate primary healthcare access as a basic right for the citizens.

Problem regarding laws on healthcare professions and services

1) Healthcare profession acts and actual practice of each profession currently overlap and transgress the scope of other professions in, e.g., diagnosis, drug dispensing, blood sugar level check, blood pressure check. These negligences over adhering to scope of responsibility of each profession can lead to major conflict later between professions.

2) Article 40 of the Constitution of the Kingdom of Thailand states that occupational regulation must be kept to the necessary minimum, any law put into effect must not discriminate against certain group nor intervene in education institution's provision of education which leaves little room for professional councils to carry out their duty in protecting the people without implementing measures that can be considered intervention.

1.3 Laws on consumer protection

This category concerns itself around protection of the citizens in drug related issues and guarantees the rights of consumers receiving healthcare services. Key laws consists of the followings.

1) Consumer Protection Act B.E. 2522⁽²³⁾ defines consumer's rights and protection specifically regarding product labelling, advertisement, contracts, product and service safety. This law also allows Office of the Consumer Protection Board (OBCP) or other non-profit consumer organizations to represent the

consumer in a lawsuit.

2) Consumer Case Procedure Act, B.E. 2551⁽²⁴⁾ prescribes judicial method that facilitates exercising of consumer rights in order to timely alleviate the damage.

3) Liability for Damage from Unsafe Product Act B.E. 2551⁽²⁵⁾ specifies liability and mandates fair reparation from manufacturer of the unsafe product and related parties to victims suffering damage from its use.

4) Prices of Goods and Services Act B.E. 2552 requires price of products and charge of services^(26,27) which include drugs and medical supplies to be clearly displayed and also requires hospitals to declare cost and sale price of drugs, medical supplies, medical services, and other related services.

5) Manifesto of Patient Rights and Guidelines for Receiver of Healthcare Service (B.E. 2558), issued by the Ministry of Public Health and professional councils, guarantees patients' rights such as access healthcare services that is up to the standard, access to one's own medical information, receive second opinions, and data privacy. It also specifies guidelines for patients to follow when receiving service.

1.4 Laws on trade and commerce

This category mostly comprises of international trade treaties, laws and amendments that were passed in accordance with those treaties. They include:

1) Agreements on Trade-Related Aspects of Intellectual Property Rights (TRIPS)⁽²⁹⁾ and expanded agreements (TRIPS-Plus), Trans-Pacific Partnership (TPP), and Comprehensive and Progressive Trans-Pacific Partnership (CPTPP)⁽³⁰⁾ which Thailand has an obligation to comply with as a member of the World

Trade Organization. These agreements aspect concerning the protection of intellectual property is the primary factor that impact Thailand's drug system.

2) Patent Act B.E. 2522⁽³¹⁾ governs affairs regarding patent for invention covering new inventions, derivatives, and inventions with industrial application. Patents for both product and process are valid for 20 years from application date.

3) Trade Secret Act B.E. 2545⁽³²⁾ defines information that is a trade secret, scope of protection, violation, limitation period, and process of securing registered trade secret by government departments.

4) Trade Competition Act B.E. 2560⁽³³⁾ specifies business governance to ensure free and fair competition, prevent monopolization and unfair trade.

5) Protection and Promotion of Knowledge on Thai Traditional Medicine Act, B.E. 2542⁽³⁴⁾ protects and promotes Thai traditional medicine and use of herbal products through selection of herbs with economic value and warrant further research to be categorized as controlled herbs.

6) Plant Variety Protection Act, B.E. 2542.⁽³⁵⁾ promotes conservation and agricultural development of indigenous plant species with participation local communities to create sustainable utilization.

7) Criminal Liability of Legal Entity Representative Act B.E. 2560⁽³⁶⁾ holds the board, managers, or other people in positions of authority in the operation of a legal entity responsible for violations committed by the entity and be penalized to the sentence imposed by concerning laws.

Problem regarding Patent law

The repeal of compulsory licensing, and other patent-related measures and the dissolution of Drug Patent Committee whose authority covered drug price

regulation left Thailand without viable mechanism to oversee drug patents and its holder, effectively conceded complete monopoly to patent holders.

1.5. Laws concerning others specific responsibility

This category may be further divided into those concerning the foundation of drug research and development, and manufacturing organization which include: the Thai Red Cross Act B.E. 2461⁽³⁷⁾ established the Queen Saovabha Memorial Institute. The Government Pharmaceutical Organization Act B.E. 2509⁽³⁸⁾ established the Government Pharmaceutical Organization (GPO). The Royal Decree for Organization Structure of the Office of the Minister and the Office of the Permanent Secretary for Defence B.E. 2552⁽³⁹⁾ founds the Defence Pharmaceutical Factory (DPF).

Those concerning health security which include: Social Security Act B.E. 2533⁽⁴⁰⁾ provides security for employees. Royal Decree for Medical Care Money Welfare B.E. 2533⁽⁴¹⁾ provides security for government officials and their family. National Health Security Act B.E. 2545⁽⁴²⁾ provides security for all citizens who may not be covered under the other two laws.

Others specific responsibility law those concerning drug system include:

1) Governmental Procurement and Inventory Management Act B.E. 2560^(43,44) standardizes operational boundary and procedures of procurement and inventory management to promote transparency and fair opportunity to all suppliers. In spite of said goals, The law has its preference on drugs manufactured by the Government Pharmaceutical Organization and Thai Red Cross and drugs . And promote or support

purchasing in Thai Innovative Drug List.

2) Office of the Prime Minister's Regulation on National Drug System Development Committee B.E. 2551⁽⁴⁵⁾ establishes national policy on drugs and strategic plan to ensure systematic and effective drug system development, develops maintenance and updating measures and processes for National List of Essential Medicines and corresponding reference prices, and specifies preventative and reactive measures to problems from drug use and drug resistance.

3) National Vaccines Security Act B.E. 2561⁽⁴⁶⁾ promotes and supports research and development, manufacturing, and distribution of quality vaccines in adequate quantity for building of immunity in people and animal vectors of human diseases.

Problems regarding laws on others specific responsibility

1. Governmental Procurement and Inventory Management Act dictates government departments to procure drugs manufacturable by the GPO only from the GPO, prevents suppliers in private sector from selling to the government, which is the major portion of the domestic market, even when they can offer a better price, in effect de-incentivize drug manufacturing in the private sector.

2. Growing and continual practice of collective bargaining of drug procurement among hospitals in every regions under the Ministry of Public Health has been driving down drugs' price from domestic manufacturers. This practice might have long-term influence on drug research and development of those manufacturers.

2. Analysis overall laws concerning drug

Table 1 presents the details the interconnectedness

of different categories of laws over drug system management from the perspective of governance, financing, research and development, manufacturing, selection, procurement, distribution, and utilization.

From the perspective of governance of drug system, Thailand passed 39 pieces of laws governing all related components of drug system. With 4 pieces on pharmaceutical products control, 11 on healthcare professions and services, 5 on consumer, 10 on trade and commerce (including international trade treaties), 3 on foundation of drug research and development and manufacturing organization, 3 on health security, and 3 on drug system, there requires an integration in application and enforcement of these laws to result in a drug system that can effectively protect the citizens.

On Drug Financing, international trade treaties have down-side effect on financing the drug system where they drive up drug expenses. Even with existing health security funds covering every citizen, citizens still go into bankruptcy from high healthcare expenses for there are still essential treatments that fall outside of the benefit coverage.

On Drug Research and Development and Manufacturing, pharmaceutical products control laws focus primarily on upholding products to international standard and not on promotion of domestic drug research and development. There exist tangible measures in promotion of research and development of herbal products as an alternative to modern medicines in recently passed Herbal Products Act, however they are still being implemented thus Thailand is still depending on foreign entity for imported drug and not self-reliance on the matter.

On Drug Selection, laws focuses on effectiveness, efficiency, and safety of controlled substances in

Table 1 Laws concerning drug analysis framework

Dimension of Drug System Management	1. Laws on Pharmaceutical Product Control	2. Laws on Health Care Professional and Services	3. Laws on Consumer Protection	4. Laws on Trade and Commerce	5. Laws on Others Specific Facilities
Governance	<ul style="list-style-type: none"> - Drugs Act, B.E. 2510 - Narcotic Act, B.E. 2522 - Psychotropic Substance Act, B.E. 2559 - Herbal Products Act, B.E. 2562 	-	<ul style="list-style-type: none"> - Liability for Damage from Unsafe Product Act, B.E. 2551 - Price of Goods and Services Act, B.E. 2542 	<ul style="list-style-type: none"> - International Trade Treaties (TRIP TRIP PLUS TPP CPTPP) - Patent Act, B.E. 2522 - Protection and Promotion of Knowledge on Thai Traditional Medicine Act, B.E. 2542 - Plant Variety Protection Act, B.E. 2542 - Criminal Liability of Legal Entity Representative Act, B.E. 2560 	<ul style="list-style-type: none"> - Thai Red Cross Act, B.E. 2461 - Government Pharmaceutical Organization Act, B.E. 2509 - Royal Decree for Organization Structure of the Office of the Minister and the Office of the Permanent Secretary for Defence, B.E. 2552 - Governmental Procurement and Inventory Management Act, B.E. 2560 - Office of the Prime Minister's Regulation on National Drug System Development Committee, B.E. 2551 - National Vaccines Security Act, B.E. 2561
Financing			<ul style="list-style-type: none"> - Price of Goods and Services Act, B.E. 2542 	<ul style="list-style-type: none"> - International Trade Treaties (TRIP TRIP PLUS TPP CPTPP) - Patent Act, B.E. 2522 	<ul style="list-style-type: none"> - Social Security Act, B.E. 2533 - Royal Decree for Medical Care Money Welfare, B.E. 2533

Table 1 Laws concerning drug analysis framework (cont.)

Dimension of Drug System Management	1. Laws on Pharmaceutical Product Control	2. Laws on Health Care Professional and Services	3. Laws on Consumer Protection	4. Laws on Trade and Commerce	5. Laws on Others Specific Facilities
				<ul style="list-style-type: none"> - Protection and Promotion of Knowledge on Thai Traditional Medicine Act, B.E. 2542 - Plant Variety Protection Act, B.E. 2542 	<ul style="list-style-type: none"> - National Health Security Act, B.E. 2545
R&D/Manufacturing	<ul style="list-style-type: none"> - Drugs Act, B.E. 2510 - Narcotic Act, B.E. 2522 - Psychotropic Substance Act, B.E. 2559 - Herbal Products Act, B.E. 2562 			<ul style="list-style-type: none"> - International Trade Treaties (TRIP TRIP PLUS TPP CPTPP) - Patent Act, B.E. 2522 - Protection and Promotion of Knowledge on Thai Traditional Medicine Act, B.E. 2542 - Plant Variety Protection Act, B.E. 2542 	<ul style="list-style-type: none"> - Thai Red Cross Act, B.E. 2461 - Government Pharmaceutical Organization Act, B.E. 2509 - Royal Decree for Organization Structure of the Office of the Minister and the Office of the Permanent Secretary for Defence, B.E. 2552
Selection	<ul style="list-style-type: none"> - Drugs Act, B.E. 2510 - Narcotic Act, B.E. 2522 - Psychotropic Substance Act, B.E. 2559 - Herbal Products Act, B.E. 2562 	<ul style="list-style-type: none"> - Health Facility Act, B.E. 2541 		<ul style="list-style-type: none"> - International Trade Treaties (TRIP TRIP PLUS TPP CPTPP) - Patent Act, B.E. 2522 - Protection and Promotion of Knowledge on Thai Traditional Medicine Act, B.E. 2542 - Plant Variety Protection Act, B.E. 2542 	<ul style="list-style-type: none"> - Social Security Act, B.E. 2533 - Royal Decree for Medical Care Money Welfare, B.E. 2533 - National Health Security Act, B.E. 2545 - Office of the Prime Minister's Regulation on National Drug System Development Committee, B.E. 2551

Table 1 Laws concerning drug analysis framework (cont.)

Dimension of Drug System Management	1. Laws on Pharmaceutical Product Control	2. Laws on Health Care Professional and Services	3. Laws on Consumer Protection	4. Laws on Trade and Commerce	5. Laws on Others Specific Facilities
Procurement	<ul style="list-style-type: none"> - Drugs Act, B.E. 2510 - Narcotic Act, B.E. 2522 - Psychotropic Substance Act, B.E. 2559 - Herbal Products Act, B.E. 2562 		<ul style="list-style-type: none"> - Liability for Damage from Unsafe Product Act, B.E. 2551 - Price of Goods and Services Act, B.E. 2542 	<ul style="list-style-type: none"> - Trade Competition Act, B.E. 2560 	<ul style="list-style-type: none"> - Social Security Act, B.E. 2533 - Royal Decree for Medical Care Money Welfare, B.E. 2533 - National Health Security Act, B.E. 2545 - Governmental Procurement and Inventory Management Act, B.E. 2560 - Office of the Prime Minister's Regulation on National Drug System Development Committee B.E. 2551
Distribution	<ul style="list-style-type: none"> - Drugs Act, B.E. 2510 - Narcotic Act, B.E. 2522 - Psychotropic Substance Act, B.E. 2559 - Herbal Products Act, B.E. 2562 	<ul style="list-style-type: none"> - Health Facilities Act, B.E. 2541 - Primary Health-care System Act, B.E. 2562 			<ul style="list-style-type: none"> - Social Security Act, B.E. 2533 - Royal Decree for Medical Care Money Welfare, B.E. 2533 - National Health Security Act, B.E. 2545 - National Vaccines Security Act, B.E. 2561

Table 1 Laws concerning drug analysis framework (cont.)

Dimension of Drug System Management	1. Laws on Pharmaceutical Product Control	2. Laws on Health Care Professional and Services	3. Laws on Consumer Protection	4. Laws on Trade and Commerce	5. Laws on Others Specific Facilities
Utilization	<ul style="list-style-type: none"> - Drugs Act, B.E. 2510 - Narcotic Act, B.E. 2522 - Psychotropic Substance Act, B.E. 2559 - Herbal Products Act, B.E. 2562 	<ul style="list-style-type: none"> - Health Professional Act (Medical, Nursing and Midwifery, Pharmacy, Dental, Medical Technology, Physical Therapy, Thai Traditional Medicine, Community Public Health) - Healing Arts Practices Act, B.E. 2542 - Health Facilities Act, B.E. 2541 - Primary Healthcare System Act, B.E. 2562 	<ul style="list-style-type: none"> - Consumer Protection Act, B.E. 2522 - Consumer Case Procedure Act, B.E. 2551 - Liability for Damage from Unsafe Product Act, B.E. 2551 - Manifesto of Patient Rights and Guidelines for Receiver of Healthcare Service, B.E. 2558 		<ul style="list-style-type: none"> - Social Security Act, B.E. 2533 - Royal Decree for Medical Care Money Welfare, B.E. 2533 - National Health Security Act, B.E. 2545 - Office of the Prime Minister's Regulation on National Drug System Development Committee, B.E. 2551

registration process but no requirement on cost and sale price. Drug selection process specified by National Drug System Development Committee for the National List of Essential Medicine and other collection used by government departments helps build confidence, to a degree, toward safety and value of drugs in the list to the public.

On Drug Procurement, government departments, especially those of the Ministry of Public Health, have been organizing joint drug procurement at district and provincial levels driving competition between suppliers to lower the price and resulting in lowered drug expenses. Private hospitals also adopt the practice among those in same chain/network. Health security

funds, in the same spirit, use collective bargaining power at national level to procure essential drugs at a reasonable price in support of hospitals to provide access to these drugs to the people.

On Drug Distribution, pharmaceutical products control and health facility laws allow drugs to be dispensed through drug stores, hospitals, and private clinics with exception for household remedies which can be sold at any shop. Thailand now have a policy encouraging patients to receive prescribed drugs at drug store with presence of prescription to reduce hospitals' workload. The policy could lead to common prescription system and clearer separation of responsibility between doctors and pharmacists in the future.

On Drug Utilization, the National Drug Committee prioritizes countermeasure drug resistance problem through continual support for RDU hospitals project promoting rational drug use with a goal to become an RDU country. People who suffer from improper healthcare services may, through Health Security Act, acquire preliminary recompense. Those suffering from unsafe products may, through Liability for Damage from Unsafe Products Act and Judicial Method for Consumer Cases Act, sue for reparation.

Discussion and Recommendations

To promote effective enforcement of aforementioned laws concerning drug for the result as intended by laws, the authors would like to present the following considerations.

1. Better enforcement of existing laws

1.1 The policy which allows prescription drugs to be dispensed at drug store with presence of the prescription does not have much utilization in practice as there is the only requirement for prescription on dispensing channel such as drug store but no requirement for the prescription to be issued by doctors when prescription drugs are to be applied to patients thus no actual prescription gets to the hand of pharmacist at drug store. Drug Act should cancel exception that hospitals and medical clinics must not request the drug sale license and give every health care facilities be under force of Drug Act.

1.2 Drug Store is health care services unit that stay closely to the people. Since legislate Drug Act in B.E. 2510 service of drug stores had been separated from state services. Thus Drug stores should be integrated into public service network and national public health system to alleviate the problem of

pharmacist shortage in public sector from government downsizing policy, and the overcrowdedness and long wait time in public health facilities.

1.3 Problem of transgression of responsibility scope between healthcare professions, for example, diagnosis, drug dispensing, blood sample collection, and blood pressure check should be rectified through provisions in healthcare profession acts establishing knowledge and skill assessment procedures and common standards to determine if an individual professional may perform those tasks in overlapping area.

1.4 Drugs be classified as dangerous waste. There should be separate to prevent the effects to the environment. Thus The Food and Drug Administration should set up a nation-wide system for drug waste management and disposal, detailing the specifics of collection, and disposal procedures.

2. Amendment to existing laws and enactment of new laws

2.1 Amendment or new law should be passed to promote innovation in domestic drug development through development fund which may be a joint venture between the government and private sector amount in proportion to the total market value of manufactured and imported drugs.

2.2 There should be a new law founding a fund for compensate and heal for patient suffered from receiving erroneous or non-standard healthcare services to lessen the amount of direct lawsuit against involving healthcare personnel.

2.3 To solve the problem that drug store is operating without a pharmacist. Office of Food and Drug Committees should be shifted requirement from fixing pharmacist to operate only at the store he/she was registered as operating pharmacist to letting any

pharmacist operates at any store with operating hours clearly declared, the pharmacist is compensated hourly and the store may sell drugs at anytime as long as there is an operating pharmacist on-site.

2.4 Drug Act should be established guidelines for drug sales through the internet and other emerging channels to protect public safety while allowing convenient enabled by new context.

2.5 There should be a standardized requirement for healthcare service providers to itemize the expenses collected from the consumer into cost of drug, professionals' service fee, administrative cost, etc. so that the consumer may gain insight into the expenses and more easily compare services by virtue of their quality and cost.

2.6 To alleviate negative impact of international trade agreements, amendments should be passed on various related legislation, especially the Patent Act, in compliance with TRIP but no more than required. There must be processes for the public to file objection to a patent both before and after the patent is granted. The power to exercise compulsory licensing, which complies with TRIP, must be preserved to protect the country's health security while allowing royalty fee to be negotiated between government department using compulsory licensing and the patent holder or its licensee.

3. Laws that hinder development of drug system

3.1 Article 75 of the Constitution of the Kingdom of Thailand states that the state must not operate business with competitive nature to private sector. So that the missions of the Government Pharmaceutical Organization should be realigned to cooperation with the private sector to advance domestic drug industry. Its

responsibility must be collaborate with private sector for pharmaceutical production and reserves and should be clearly defined in terms of amount and scope of drug types, and its privilege in government procurement should be revoked to enable free and fair competition while maintaining drug security.

3.2 The strict procedures implemented by government departments as prescribed by Governmental Procurement and Inventory Management Act to ensure correctness and transparency must be balanced with having enough flexibility to respond to changing situations, for instance, artificial drug shortage from delayed procurement as a result from excessive bureaucracy.

Recommendations for further research

- 1) Drug price structure and laws for standardized drug price.
- 2) Ideal laws for drugs from biological products, other new kind of drugs, and compounding pharmacies.
- 3) Trust building toward generic substitution.
- 4) Drug security and national self-reliance through research and development of drugs from herbal and biological products.
- 5) Guidelines for governance of drug sales and advertisement in electronic network.
- 6) Ramification of Governmental Procurement and Inventory Management Act on domestic drug manufacturing industry and drug system.
- 7) Method and process of periodic assessment of drug law enforcement effectiveness for amendment recommendation as prescribed in the constitution.

References

1. Katsomboon N, Manomayithikarn T, Limpananont K. Drug expenditure of Thailand, B.E. 2538–2556. In: Sirisinsuk Y, Pengsuparp T. Report for drug system situation, B.E. 2555–2559. 1st edition. Nonthaburi: Mata Printing; 2561. p. 64–9.
2. Wikibooks. Free textbook for free word [Internet]. [cited 2019 Sep 20]. Available from: <https://th.wikibooks.org/wiki/law>
3. Baanjomyut.com. Law [Internet]. [cited 2019 Sep 20]. Available from: https://www.baanjomyut.com/library_4/politics/05_2.html
4. Ourgreenfish. The way to lead technology AI to develop medical profession and medicines [Internet]. [cited 2019 Sep 20]. Available from: <https://blog.ourgreenfish.com/technology-ai-medical-profession-and-medicines>
5. Techsauce. Technology rocked the health world within 2020 [Internet]. [cited 2019 Sep 20]. Available from: <https://techsauce.co/tech-and-biz/top-5-technologies-disrupting-healthcare-by-2020/>
6. Drugs Act, B.E. 2510. Royal Thai Government Gazette Volume 84, Section 101 A, special (dated 20 October B.E. 2510).
7. Narcotic Act, B.E. 2522. Royal Thai Government Gazette Volume 96, Section 63 A (dated 27 April B.E. 2522).
8. Psychotropic Substance Act, B.E. 2559. Royal Thai Government Gazette Volume 133, Section 107 A (dated 20 December B.E. 2559).
9. Herbal Products Act, B.E. 2562. Royal Thai Government Gazette Volume 136, Section 56 A (dated 30 April B.E. 2562).
10. Nacotics Committee. Defining specification of Hemp B.E. 2562. Royal Thai Government Gazette Volume 136, Section 218 D, special (dated 30 August B.E.2562).
11. Medical Professional Act, B.E. 2525. Royal Thai Government Gazette Volume99, Section 111, special (dated 11 August B.E. 2525).
12. Nursing and Midwifery Professional Act, B.E. 2528. Royal Thai Government Gazette Volume 99, Section 111, special (dated 11 August B.E. 2525).
13. Pharmacy professional Act, B.E. 2537. Royal Thai Government Gazette Volume 111, Section 28 A (dated 30 June B.E. 2537).
14. Dental Professional Act, B.E. 2537. Royal Thai Government Gazette Volume 111, Section 40 A (dated 19 September B.E. 2537).
15. Medical Technology Professional Act, B.E. 2547. Royal Thai Government Gazette Volume 121, Section 65 A, Special (dated 20 October B.E. 2547).
16. Physical Therapy Professional Act, B.E. 2547. Royal Thai Government Gazette Volume 121, Section 65 A, Special (dated 20 October B.E. 2547).
17. Thai Traditional Medicine Professional Act, B.E. 2556. Royal Thai Government Gazette Volume 130, Section 10 A. (dated 1 February B.E. 2556).
18. Community Public Health Professional Act, B.E. 2556. Royal Thai Government Gazette Volume 130, Section 118 A (dated 16 December B.E. 2556).
19. Healing Arts Practices Act, B.E. 2542. Royal Thai Government Gazette Volume 116, Section 39 A (dated 18 B.E. 2542).
20. Medical Facilities Act, B.E. 2541. Royal Thai Government Gazette Volume 115, Section 15 A (dated 24 March B.E. 2541).
21. Primary Healthcare System Act, B.E. 2562. Royal Thai Government Gazette Volume 137, Section 56 A (dated 30 April B.E. 2562).
22. Consumer Protection Act, B.E. 2522. Royal Thai Government Gazette Volume 96, Section 72 a, special (dated 4 May B.E. 2522).
23. Consumer Case Procedure Act, B.E. 2551. Royal Thai Government Gazette Volume 125, Section 38 a (dated 25 February B.E. 2551).
24. Liability for Damage from Unsafe Product Act B.E. 2551. Royal Thai Government Gazette Volume 125, Section 36 A (dated 20 February B.E. 2551).
25. Price of Goods and Services Act, B.E. 2542. Royal Thai Government Gazette Volume 116, Section 22 A (dated 31 March B.E. 2542).

26. Announcement of the Central Committee deals with Price of goods and services No. 52 B.E. 2562. Price notification specifying criteria and conditions about selling medicines medical supplies, medical bills, medical fee and others health facility service charge. Royal Thai Government Gazette Volume 136, Section 142 D, special. (dated 4 June B.E. 2562).
27. Medical Technology Council. Manifesto of patient rights and guidelines for receiving healthcare service (B.E. 2558) [Internet]. [cited 2019 Sep 20]. Available from: http://www.mtc.or.th/file_ne_Thai-US_ws/file1_18.pdf
28. Pitaknitinun K. Impact on Thai-US free trade agreement: case study on drug. The 4th Public Economic Management for Chief Executive Program. Nonthaburi: King Prajadhipok's Insitution; 2549.
29. Akalephan C. Impact analysis of Trans Pacific Partnership (TPP) and Comprehensive and Progressive Trans Pacific Partnership (CTPP) on drug system of Thailand. Clinical Pharmacy Journal 2562;25(1):85-92.
30. Patent Act, B.E. 2522. Royal Thai Government Gazette Volume 96, Section 35, special (dated 16 March B.E. 2522).
31. Boondet P. Trade Secrets Act, B.E. 2545. Bangkok: Office of the Courts of Justice; 2549.
32. Trade Competition Act, B.E. 2560. Royal Thai Government Gazette Volume 134, Section 70 A (dated 7 July B.E. 2560).
33. Protection and Promotion of Knowledge on Thai Traditional Medicine Act, B.E. 2542. Royal Thai Government Gazette Volume 116, Section 120 A (dated 29 November B.E. 2542).
34. Plant Variety Protection Act, B.E. 2542. Royal Thai Government Gazette Volume 116, Section 118 A (dated 25 November B.E. 2542).
35. Criminal Liability of Legal Entity Representative Act B.E. 2560. Royal Thai Government Gazette Volume 134, Section 18 A (dated 11 February B.E. 2560).
36. Thai Red Cross Act B.E. 2461. Royal Thai Government Gazette Volume 35, Section 128 (dated 16 June B.E. 2461).
37. Government Pharmaceutical Organization Act, B.E. 2509. Royal Thai Government Gazette Volume 83, Section 69, special (dated 11 August B.E. 2509).
38. Royal Decree for Organization Structure of the Office of the Minister and the Office of the Permanent Secretary for Defence B.E. 2552. Royal Thai Government Gazette Volume 126, Section 19 A (dated 30 March B.E. 2552).
39. Social Security Act, B.E. 2533. Royal Thai Government Gazette Volume 107, Section 161 A, special (dated 1 September B.E. 2533).
40. Comptroller General's Department. Manual of medical welfare for government officials. Bangkok: Ministry of Finance; 2555 .
41. National Health Security Act, B.E. 2545. Royal Thai Government Gazette Volume 119, Section 116 A (dated 18 November B.E. 2545).
42. Governmental Procurement and Inventory Management Act B.E. 2560. Royal Thai Government Gazette Volume 134, Section 24 A (dated 24 February B.E. 2560).
43. Ministerial regulations specifying the inventory to promote or support and specify purchasing by selection and special identification methods, B.E. 2560. Royal Thai Government Gazette Volume 134, Section 86 A (dated 23 August B.E. 2560).
- Office of the Prime Minister's Regulation on National Drug System Development Committee B.E. 2551. Royal Thai Government Gazette Volume 125, Section 192 D, special (dated 24 December B.E. 2551).
44. National Vaccines Security Act B.E. 2561. Royal Thai Government Gazette Volume 135, Section 97 (dated 21 November B.E. 2561).

บทคัดย่อ: กฎหมายเกี่ยวกับยาในประเทศไทย

กิตติ พิทักษ์นิตินันท์ ภ.บ., น.บ., ศศ.บ., ส.ม. (บริหารโรงพยาบาล), ศ.ม. (ผู้นำทางสังคม ธุรกิจและการเมือง*;
 ยุพิน ลาวณิชย์ประเสริฐ ภ.บ., วท.ม. (อนามัยสิ่งแวดล้อม), ส.ด. (บริหารสาธารณสุข)**; ทรงศักดิ์ วิมลกิตติ-
 พงศ์ ภ.บ., น.บ.**

* ข้าราชการบำนาญ กระทรวงสาธารณสุข; ** คณะเภสัชศาสตร์ มหาวิทยาลัยรังสิต; *** สำนักยา สำนักงาน-
 คณะกรรมการอาหารและยา

วารสารวิชาการสาธารณสุข 2563;29(ฉบับพิเศษ):S15-30.

การศึกษานี้มีวัตถุประสงค์เพื่อทราบถึงสถานการณ์ของกฎหมายที่เกี่ยวข้องกับยา ความสัมพันธ์กับระบบยา และรวมถึง
 ปัญหาการบังคับใช้กฎหมายต่าง ๆ ที่เกี่ยวข้อง วิธีการศึกษาใช้วิธีการทบทวนสืบค้นจากเอกสาร และประชุมกลุ่มย่อยผู้เชี่ยวชาญ
 กรณีประเด็นปัญหา อุปสรรคของกฎหมายที่สำคัญและข้อเสนอแนะ ผลการศึกษา ประเทศไทยมีการออกกฎหมายในการ
 กำกับดูแลในทุกระดับประกอบที่เกี่ยวข้องกับระบบยา มีกฎหมาย ข้อตกลง ระเบียบ และประกาศที่เกี่ยวข้อง รวมทั้งสิ้น 39
 ฉบับ โดยแบ่งได้เป็น 5 กลุ่ม คือกฎหมายที่เกี่ยวข้องกับการควบคุมผลิตภัณฑ์ยา รวม 4 ฉบับ กฎหมายควบคุมการประกอบ
 วิชาชีพด้านสุขภาพและการจัดบริการ รวม 11 ฉบับ กฎหมายที่เกี่ยวกับผู้บริโภค รวม 5 ฉบับ กฎหมายที่เกี่ยวกับการค้า รวม
 10 ฉบับและกฎหมายที่เกี่ยวกับองค์กรที่สามและองค์กรอื่น ๆ ที่มีอำนาจหน้าที่เฉพาะ รวม 9 ฉบับ กฎหมายที่เกี่ยวกับการ
 เงินการคลังในระบบยาที่สำคัญ ก็คือกลุ่มกฎหมายเกี่ยวกับการค้าทำให้ประเทศไทยต้องเสียค่าใช้จ่ายด้านยาที่สูง กฎหมาย
 ด้านประกันสุขภาพยังไม่สามารถประกันไม่ให้ประชาชนล้มละลายจากการต้องเข้ารับการรักษาพยาบาลที่มีค่าใช้จ่ายสูงมากได้
 กฎหมายที่เกี่ยวกับการวิจัยพัฒนาและการผลิตยา กลุ่มกฎหมายเกี่ยวกับผลิตภัณฑ์ส่วนใหญ่ ยังไม่มีมาตรการการส่งเสริม
 สนับสนุนการผลิตและการวิจัยพัฒนายาในประเทศที่ชัดเจน ยกเว้นกฎหมายผลิตภัณฑ์สมุนไพรที่ออกใหม่ กฎหมายเกี่ยวกับ
 การคัดเลือกยา จะเน้นที่กระบวนการขึ้นทะเบียนยาในกลุ่มกฎหมายเกี่ยวกับผลิตภัณฑ์ซึ่งเน้นเรื่องประสิทธิผล ประสิทธิภาพ
 และความปลอดภัยเป็นหลัก มีกระบวนการคัดเลือกยาเพื่อเข้าสู่บัญชียาหลักแห่งชาติซึ่งทุกกองทุนประกันสุขภาพกำหนดใน
 ชุติลธิประโยชน์ กฎหมายที่เกี่ยวกับการจัดซื้อและจัดหายา ในส่วนภาครัฐโดยเฉพาะในกระทรวงสาธารณสุข ได้มีการจัดซื้อ
 ยาร่วมกันในระดับเขตหรือจังหวัด ซึ่งทำให้สามารถประหยัดงบประมาณค่ายาลงได้มาก และในกองทุนประกันสุขภาพต่าง ๆ
 ก็มีการใช้ระบบการต่อรองราคาภายในระดับประเทศเพื่อให้ได้ยาที่จำเป็นและมีราคาเหมาะสมทำให้ประชาชนเข้าถึงยาได้มาก
 ขึ้น กฎหมายที่เกี่ยวกับการกระจายยา กำหนดให้มีช่องทางการกระจายยา คือ ร้านขายยา โรงพยาบาลและคลินิกเอกชน ยกเว้น
 ยาสามัญประจำบ้านสามารถจัดซื้อได้ทั่วไป ปัจจุบันมีนโยบายให้ประชาชนนำไปสั่งยาไปรับยาที่ร้านยาได้ด้วยเพื่อลดความ
 แออัดในโรงพยาบาล ประชาชนจะมีทางเลือกมากขึ้นในการเข้ารับบริการด้านยา กฎหมายที่เกี่ยวกับการใช้ยา ปัจจุบันผู้ได้รับ
 ความเสียหายจากการรับบริการทางการแพทย์ สามารถอาศัยกฎหมายด้านการประกันสุขภาพในการขอรับความช่วยเหลือ
 เบื้องต้นเมื่อได้รับความเสียหายจากการรับบริการ และสามารถใช้กลุ่มกฎหมายเกี่ยวกับผู้บริโภคในการฟ้องเรียกร้องความ
 รับผิดชอบและเงินชดเชยความเสียหายได้สะดวกขึ้น ข้อเสนอแนะเพื่อให้กฎหมายเกี่ยวกับยาที่มีความสมบูรณ์ สามารถบังคับใช้ได้
 ตามเจตนารมณ์และมีประสิทธิภาพมากขึ้นจึงควรให้ความสำคัญในประเด็น การให้ความเข้มงวดในการบังคับใช้กฎหมายเดิม
 การปรับปรุงหรือออกกฎหมายใหม่ในบางประเด็น การแก้ไขรายละเอียดกฎหมายที่เป็นอุปสรรคต่อการพัฒนาระบบยาของ
 ประเทศ และรวมถึงการเตรียมการรับผลกระทบที่เกิดจากการออกกฎหมายทางการค้า

คำสำคัญ: ยา, ระบบยา, กฎหมาย, กฎหมายเกี่ยวกับยา