

**COMPULSORY LICENSING POLICY  
IMPLEMENTATION IN THAILAND**

**Tapanee Phueksuwan**

**A Dissertation Submitted in Partial  
Fulfillment of the Requirements for the Degree of  
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**Tapanee Phueksuwan  
School of Public Administration**

---

Professor.....*S. Thamrong*..... Major Advisor  
(Sombat Thamrongthanyawong, Ph.D.)

Professor.....*Anchana Na Ranong*..... Co-Advisor  
(Anchana Na Ranong, Ph.D.)

The Examining Committee Approved this Dissertation Submitted in Partial  
Fulfillment of the Requirements for the Degree of Doctor of Public Administration

Assistant Professor.....*Prayong Panichavala*..... Committee Chairperson  
(Prayong Panichavala, Ph.D.)

Professor .....*Anchana Na Ranong*..... Committee  
(Anchana Na Ranong, Ph.D.)

Professor.....*S. Thamrong*..... Committee  
(Sombat Thamrongthanyawong, Ph.D.)

Professor.....*Nisada Wedchayanon*..... Dean  
(Nisada Wedchayanon, Ph.D.)

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## ABSTRACT

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<b>Author</b>	Miss Tapanee Phueksuwan
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The objectives of this research were to investigate the following: 1) the reasons and needs for the compulsory licensing policy in Thailand, 2) the guidelines for implementing the policy in Thailand, 3) the factors that affect compliance with the policy in Thailand, and 4) patients' effective access to drugs as a result of the policy in Thailand. This research involved principals and concepts about public policy, as well as concepts about drug patents and compulsory licensing. The focus was on the reasons and needs for compulsory licensing, costs of production or importation of generic drugs for sale under the policy, guidelines and results of the policy implementation, as well as factors that have affected the policy implementation in Thailand. This research relied on mixed methods-qualitative methods and quantitative methods. Qualitative data were studied to explore answers to the research questions, based on secondary data and primary data by means of in-depth face-to-face and phone interviews. The interviewees included policy makers at the Ministry of Public Health (MOPH) and policy-implementing personnel-directors from government hospitals affiliated with the the Ministry of Public Health (MOPH) and universities. Out of 45 government hospitals, twenty hospital directors (representing 44.44%) gave their consent to the interviews. Quantitative data were used to confirm the study results of the evaluation of the policy implementation; such data included the number of new patients receiving the drugs and the savings in costs from 2008 to 2010.

The study results led to the conclusion that the compulsory licensing policy can definitely solve the problem of patients' inaccessibility to drugs. From 2008 to 2010, the amount of each drug administered to new patients increased continually, and the drug costs fell steadily by approximately two billion baht. As for the policy

implementation guidelines, the Ministry of Public Health (MOPH) formulated protocol guidelines as the MOPH's Notification for each drug. However, the performance of individual hospitals depended on their characteristics, which were different in many aspects-the roles of directors in the hospital, the roles of doctors in the hospital, and characteristics of the hospital.

Factors that affected the success in the policy implementation at the macro and micro levels covered the clarity of the policy, the consistency between the policy and the problem, budgets, and political changes. Factors that were related to the failure in the policy implementation included lack of communication of the policy, characteristics of respective hospitals, attitudes of practitioners, and political changes.

The study on these success and failure factors reflected the drawbacks of the policy implementation at both levels. They included: 1) lack of a strict, clear drug-pricing control mechanism that differentiates drugs from other commercial goods, 2) lack of knowledge about the evaluation of "innovative" drugs being applied for a patent before granting it to them, 3) the Ministry of Public Health's lack of campaigns for boosting knowledge and understanding about patients' rights in the public health system, the compulsory licensing policy, or generic and original drugs in terms of their efficiency, effectiveness, costs, quality and toxicology for the general public, patients, doctors and medical personnel; and its lack of surveys of government hospitals to determine how different they were with respect to preparedness, equipment, and equality in factors prior to the implementation of this policy, 4) the Ministry of Public Health's lack of clarification about legal mechanisms available to minimize the impacts from the allegations about intellectual property infringement by people who lost some benefits from this policy, 5) unequal medical care benefits among patients in different public health care schemes, 6) the Government Pharmaceutical Organization (GPO)'s need for building the faith and confidence that its production of generic drugs meets established standards, that the importation process of generic drugs is transparent, and that the quality and effectiveness of the imported generic drugs are equivalent to those of original drugs,

The Thai government and the Ministry of Public Health (MOPH) need to cope with the identified deficiencies and improve their performance in order to result in efficient policy implementation and solve the problem of patients' inaccessibility to drugs as a whole.

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## **ABBREVIATIONS**

### **Abbreviations**

### **Equivalence**

CL	Compulsory Licensing
DIP	Department of Intellectual Property
FDA	Food and Drug Administration
GPO	The Government Pharmaceutical Organization
GSP	Generalized System of Preferences
MOC	The Minister of the Ministry of Commerce
MOPH	The Ministry of Public Health
MOF	The Ministry of Finance
PWL	Priority Watch List
TRIPs	Trade-related Aspects of Intellectual Property Rights
USTR	United State Trade Representative
WHO	The World Health Organization
WL	Watch List
WTO	The World Trade Organization
NGO	Non-Government Organization

## **CHAPTER 1**

### **BACKGROUND AND SIGNIFICANCE OF THE PROBLEM**

Chapter 1 discusses the background and significance of the problem related to patients' inaccessibility to essential drugs that have led to this research. It presents the objectives, questions, and scope of this research, as well as its benefits in practitioner and policy terms. Additionally, it provides definitions of pharmaceutical terminology that is the key words in this research for clearer knowledge and understanding.

#### **1.1 Background and Significance of the Problem**

Appropriate, thorough and equal access to health services is a fundamental human right that all men shall have, and “drugs” are one of the key components of a health service system. Serving as one of the four requisites for life, drugs cure illness, reduce suffering, prolong life, enhance the quality of life of patients, and enable living a normal life among patients. It is a legitimate public health right for all patients to have equal access to drugs with dignity and human value. Accordingly, the right to health services is stated in the National Health Security Act, B.E. 2545 (2002); nonetheless, there are now patients in Thailand who cannot access drugs, accordingly. Some patients, especially those with chronic diseases, such as cardiovascular disease, acquired immunodeficiency syndrome (AIDS) and cancer, who need continual access to essential drugs are unable to do so. This has resulted in constantly and rapidly increasing mortality rates from these diseases, which have become major causes of death among the Thai population (MOPH, 2008b). The main reason for the inaccessibility to drugs is the fact that most drugs they need are “patented drugs,” which are, in other words, intellectual property that is legitimately protected by the Drug Patent Act. As official documents, these patents have been issued by the Department of Intellectual Property, Ministry of Commerce, to those who have invested in research and development of inventions having industrial value and commercial viability.

Innovations and product design have legal protection under the Drug Patent Act, B.E. 2522 (1979); the Drug Patent Act (Second Amended Version), B.E. 2535 (1992); and the Drug Patent Act (Third Amended Version), B.E. 2542 (1999). Under these acts, a monopoly is granted to people who have filed a request for registration to solely manufacture, import, sell or use their invention for a 20-year period in Thailand from the date when they file the request. In addition, details of an invention must be publicly disclosed. Accordingly, pricing of a patented drug relies on the patent owner or patentee, which results in non-competition under market mechanisms and then a monopoly in drugs. This is why patented drugs are costly. The Thai government has an insufficient subsidy for the entire Thai health system. As for patients, they are unable to bear drug costs on their own, so they discontinue treatment and fail to fully and continuously access essential drugs, thus resulting in death. Evidenced by steadily rising number of deaths due to these diseases, this incidence is grounds for a major public health problem in Thailand. Consequently, the Thai Government has decided to promulgate “The Compulsory Licensing Policy for Drugs.” This policy is applicable to seven drugs-two for AIDS (Efavirenz, Lopinavir/Ritonavir), one for cardiovascular disease (Clopidogrel), and four for cancer (Docetaxel 80 mg and Erlotinib, Letrozole and Imatinib 100 mg). The objective of this policy is to ensure all patients’ equal and thorough access to drugs that are essential to their treatment in order to reduce their suffering and promote their quality of life.

Thus, the formulation of the work plans and guidelines for implementing the policy to effectively achieve its objective is an important task of government agencies involved in the public health system. Aiming to enhance access to medicines among patients living with diseases that need drugs covered in the policy, this policy is implemented by different agencies. The first is the central agency directly in charge of this policy-the Ministry of Public Health (MOPH), whose task is to transform this policy into work plans and deliver them to operating agencies-government hospitals affiliated with the MOPH and universities. These hospitals implement this policy and work plans by distributing drugs to patients. Working at both levels, particularly policy implementation by the individual government hospitals, serves as an important mechanism that allows this policy to yield results. Equipped with public health personnel who develop tangible implementation guidelines under regulations set forth

by the central agency, the hospitals regularly encounter environmental factors that influence the effectiveness of the policy implementation. Therefore, operating personnel need to apply their knowledge, expertise, and judgment to properly make decisions about situations to achieve the objective of this policy. The policy promulgation has affected international relations, patent owners and the domestic pharmaceutical industry. Furthermore, it has led to arguments from operating personnel about medical personnel's and patients' lack of confidence in the equality of the quality of drugs that are imported from other manufacturers or locally manufactured to substitute for the patented original drugs. This is because to change the individuals' behavior, opinions, and attitudes involves several factors, not only the policy promulgation.

The realization that the results of the compulsory licensing policy and the policy implementation according to the Drug Patent Act and the degree of the results need be monitored had led to this research on the compulsory licensing policy and its implementation-case study of compulsory licensing policy in Thailand. This research aims to investigate the reasons and needs for the government to promulgate the compulsory licensing policy, to develop guidelines and procedures for the policy implementation to enhance all patients' equal and thorough access to essential drugs, and to examine factors of success and failure of this policy implementation.

## **1.2 Objectives of the Research**

1.2.1 To study the reasons and needs for the compulsory licensing policy in Thailand.

1.2.2 To study the guidelines for the implementation of the compulsory licensing policy in Thailand.

1.2.3 To study the factors that affect compliance with the compulsory licensing policy in Thailand.

1.2.4 To study patients' effective access to drugs under the compulsory licensing policy in Thailand.

### **1.3 Research Questions**

1.3.1 What are the reasons and needs for compulsory licensing in Thailand?

1.3.2 How different are the Government Pharmaceutical Organization (GPO)'s costs of production, development and research of drugs covered in the compulsory licensing policy and the costs of drugs that the GPO imports into Thailand?

1.3.3 What are the guidelines for the implementation of the compulsory licensing policy in Thailand? What are problems and obstacles with its implementation?

1.3.4 How effective is patients' access to drugs after the promulgation of the compulsory licensing policy?

1.3.5 What are the factors of success and failure with the implementation of the compulsory licensing policy in Thailand?

1.3.6 What should the guidelines be and what are some suggestions for how to achieve effective compliance with the compulsory licensing policy?

### **1.4 Scope of the Research**

As mentioned above, this research aimed to explore the reasons and needs for the Thai government to form the compulsory licensing policy and to study the manufacturing costs of drugs covered in the compulsory licensing policy, including the costs of locally-produced drugs as well as imported drugs. Also, it aimed to examine the guidelines for the compulsory licensing policy implementation to enhance patients' access to drugs in Thailand, taking into account policy implementation by the operating units-government hospitals affiliated with the MOPH and universities. This research was conducted under theoretical guidelines that were synthesized from concepts of drug patents, principles of compulsory licensing, policy formation, public policy implementation, process assessment, as well as models for studying policy implementation developed by academics. These were utilized as the framework to study the process of the compulsory licensing to increase patients' access to drugs in the Thai public health system, as well as studying the factors of success and failure of the compulsory licensing implementation.



## **1.5 Terminology**

1.5.1 Original drugs-Drugs that have passed research and are produced for the first time and patented for protection as intellectual property under laws of each country. They undergo commercial registration for sale and have a commercial name that is invented by the drug owner company.

1.5.2 Generic drugs-Drugs that are manufactured using the same active ingredients as original drugs. They may undergo a similar or different process and/or recipe.

1.5.3 Compulsory licensing-Exercise the right to manufacture or import generic drugs for sale and uses in the country, although the original drugs still have a protected right for public utilities business; preservation or acquisition of natural or environmental resources; prevention or mitigation of serious shortages of food, medicine or other commodities or other public uses; wars or emergencies; or national defense and national security. Fair remuneration will be provided for patentees and they must be immediately notified in writing.

## **1.6 Limitations of the Research**

### **1.6.1 Issues Concerning Data Collection**

1.6.1.1 Failure to collect complete data for the study of the formulation of the compulsory licensing policy by means of in-depth face-to-face and phone interviews with experts and qualified people involved in the formulation of the compulsory licensing policy in Thailand. These people came from the National Health Security Board, 2006, Subcommittee on the Selection of Essential Drugs and Medical Supplies with the Access Problem, the Committee on Negotiation on Prices of Patented Essential Drugs, and the Committee on the Promotion of the Government Use Compulsory Licenses for Patents on Drugs and Medical Supplies. The purpose of the interviews was to obtain important information about the formulation of the compulsory licensing policy as an appropriate public policy that can solve the problem about patients' inaccessibility to drugs. However, there was a limitation to the interviews. As most of the qualified people who are members of the committees

hold a high national position (Appendix A), they were too busy to meet or have an interview. Only five of them were available for the interviews, as follows:

- 1) One member of the National Health Security Board (2006)
- 2) One member of the Subcommittee on the Selection of Essential Drugs and Medical Supplies with the Access Problem
- 3) Two members of the Committee on the Negotiation on Prices of Patented Essential Drugs
- 4) One member of the Committee on the Promotion of the Government Use Compulsory Licenses for Patents on Drugs and Medical Supplies

1.6.1.2 Failure to collect complete data for the study of the implementation of the compulsory licensing policy by means of in-depth face-to-face and phone interviews with directors from 33 large-scale government hospitals, each having 300-500 beds, as well as 12 university-affiliated hospitals. The interviews provided feedback that highlight guidelines for, assessment of, as well as problems and obstacles to, the formulation of implementation plans by the central agency (MOPH) to deliver to the operating agencies (as mentioned, they are government hospitals and university-affiliated hospitals). The limitation to the data collection was that it could not be conducted in all the hospitals. A letter requesting permission for an interview with the hospital director was sent to 45 hospitals, but most of them did not give permission. Only twenty (44%) allowed the interview related to the compulsory licensing policy implementation. Assigned many responsibilities, whether they are management or attending domestic and overseas conferences in conjunction with medical care, most of them did not have enough time for the face-to-face or phone interviews.

1.6.1.3 Failure to collect complete data for the study of the evaluation of the implementation of the compulsory licensing policy-The collected data included information about respective patients' medication and medication costs of the MOPH and university- affiliated government hospitals. To assess the policy implementation, yearly data from 2006 to 2012 (before and after the promulgation of the compulsory licensing policy) were compared. The limitation to the data collection was that the data from 2006 to 2012 from each of the hospitals were not complete. Great variations in the data resulted from the inequality among the hospitals in terms of preparedness

of data collection systems and in terms of the efficiency of information technology that supports data collection, as well as shortages of a technology system that supports data collection systems in some hospitals. Therefore, the author needed to evaluate policy implementation as a whole from 2008 to 2010 because the data during these years are quite complete compared to those in other years.

## **1.7 Benefits of the Research**

1.7.1 Practitioner benefits: The research findings can be applied to solve problems and obstacles related to the implementation of the compulsory licensing policy in order to enhance its efficiency.

1.7.2 Policy benefits: Data and variables related to the policy implementation found in the research can be used to develop and optimize implementation guidelines, strategies and policies in line with practices for dealing with the problem of patients' inaccessibility to drugs according to the established objectives.

## **1.8 Organization of the Research**

This research deals with the compulsory licensing policy and its implementation in Thailand. Its significant details are presented and described in the way that shows the linkages among chapters in order to reflect a clear picture of this research. Chapters in the research include:

- Chapter 1: Background and Significance of the Problem
- Chapter 2: Drugs and Drug Distribution in the Public Health System
- Chapter 3: Concepts and Use of Drug Patents
- Chapter 4: Research Methodologies
- Chapter 5: Research Methodologies
- Chapter 6: Implementation of the Compulsory Licensing Policy in Thailand
- Chapter 7: Guidelines and Results of the Policy Implement;
- Chapter 8: Conclusion, Discussion, and Recommendations of the Research

## **CHAPTER 2**

### **DRUGS AND DRUG DISTRIBUTION IN THE PUBLIC HEALTH SYSTEM**

Chapter 2 presents details relating to drugs, which include the definitions and types of drugs, pharmaceutical product research and development, pharmaceutical product manufacturing and importation, as well as distribution of pharmaceutical products in a manner that makes them accessible to patients or those who have to put drugs into the public health system.

#### **2.1 Definition of Drugs**

“Drugs” refer to materials in the list of medicinal products announced by the MOPH Minister that will affect the health, the structure or any functions of humans’ body with the purposes of diagnosis, rehabilitation, relief, treatment, or prevention of diseases or illness. Drugs can be pharmaceutical chemical products or semi-pharmaceutical chemicals. They do not include materials intended for agricultural or industrial uses, according to the Minister’s Notification, or materials intended as food for humans, sport gear, health promotion devices, cosmetics, or instrument and their components for the practice of healing or medical practice. In addition, they do not refer to materials intended for use in scientific laboratories for research, analysis, or diagnosis that does not directly act upon human bodies (Patent Act, B.E. 2522 (1979)).

#### **2.2 Types of Drugs**

Drugs can be classified into three types according to the reasons and needs for their distribution to consumers. The types of drugs are promulgated in the Government Gazette, which are as follows (Patent Act, B.E. 2522 (1979))

2.2.1 Non-prescription drugs : Considered to be safe and pose minimal potential hazard to human health, non-prescription drugs are commonly available. The general population can buy them. Non-prescription drugs must be medicinal products which set for the proper properties, dosage, usage, warnings, storage method, and content specified by the Ministry of Public Health (MOPH).

2.2.2 Dangerous drugs : Dangerous drugs are available to the general population or sick people in modern pharmacies under control of the pharmacist on duty.

2.2.3 Special controlled drugs : These drugs must be prescribed to patients with a prescription from a doctor. Being highly toxic, they may be harmful to health, so their usage is strictly restricted.

## **2.3 Sources, Procurement and Distribution of Drugs in the Thai Public Health System**

Distribution of drugs into Thailand's public health system in a manner that makes them accessible to patients involves different processes. These processes range from the research and development of pharmaceutical products and manufacture of high-quality drugs with healing efficiency to the distribution of the high-quality drugs to all patients in the public health system. These processes entail the following details, criteria, and factors (Suwit Wibulpolprasert, et al, 2002)

### **2.3.1 Pharmaceutical Product Research and Development**

Pharmaceutical products from this process are new products arising from research on substances that can be developed to become precursors to pharmaceutical products. They are derived from the following two main sources:

#### **2.3.1.1 Natural substances**

1) Plants: In plants, there are many kinds of substances that can be extracted to help produce drugs. For example, quinine, which is from the chinchona plant, is used for treating malaria.

2) Animals: In animals, there are many kinds of substances that can be extracted to help produce drugs. For example, Vitamin A is extracted from cod liver, which is used for making drugs to prevent Vitamin A deficiency.

3) Minerals: In minerals, there are many kinds of substances that can be extracted to help produce drugs. For example, iodine is extracted from ore containing iodine. It is used for making tincture, which serves as an antiseptic.

2.3.1.2 Substances that are chemically synthesized from chemicals or an herbal extract in order to yield pharmaceutical products with healing properties and efficiency.

After a drug precursor is obtained from the synthesis of chemical or natural substances, the research and development of a medicinal product is started to produce a new pharmaceutical product. This involves clinical drug trials on animals and patient volunteers to ensure its therapeutic efficiency. Therefore, the effort, time, and processes dedicated to the study and invention of drugs entitle drug researchers and developers, whether they are persons or companies, to legal rights to protect their new or original pharmaceutical product. The drug is their intellectual property under intellectual property law through the issuance a patent, which is intended to protect innovations and serve as an incentive for people to study and create innovations for mankind in the future. Patents are classified into two categories: product patent and process patent. The characteristics and duration of the protection vary based upon patent law in each country. As a new or original pharmaceutical product is protected by its patent, the patent owner or patentee has legitimacy of being the sole agent to produce, use, sell, have for sale, offer for sale, or import the product according to the patent (Patent Act, B.E. 2522 (1979)). When the patent of a new or original pharmaceutical product expires, other drug manufacturers or other pharmaceutical companies that are not the patent owner or patentee are entitled to manufacture, use, sell, have for sale, offer for sale, or import this new or original pharmaceutical product in the form of a generic pharmaceutical product, whose properties and therapeutic efficiency are the same as those of the new or original pharmaceutical product.

### **2.3.2 Manufacturing or Importation of Pharmaceutical Products**

Before a pharmaceutical product is manufactured or imported for sale and use in a country, it must be registered in that country first. This law is applied to new, original, and generic pharmaceutical products in order to control their properties

before they are launched into the market. The objective is to have the Thai Food and Drug Administration (Thai FDA), a government agency, assess the quality, effectiveness and safety of the pharmaceutical products to see if they meet drug standards before approving their sale and use in the country. Mostly, approval of the registration of original and generic pharmaceutical products relies on the same criteria -they must be endorsed by documented evidence manifesting that they reach a standard and are effective and safe. In addition, as for generic pharmaceutical products, they must be endorsed by documented evidence showing their therapeutic equivalence to original pharmaceutical products so that patients, doctors and medical staff feel confident that they can substitute these in place of the original pharmaceutical products. Generic pharmaceutical products have the same active ingredients, strength, form, indications, and doses as the original pharmaceutical products. Because the effectiveness and safety of the original pharmaceutical products have been widely studied in clinical trials on patients and have been officially recognized, it is not academically or ethically necessary to conduct clinical trials for generic pharmaceutical products. However, manufacturers of generic pharmaceutical products must have documented evidence that proves their therapeutic equivalence to the original pharmaceutical products, through a bioequivalence study. A bioequivalence study is internationally recognized by the World Health Organization (WHO) as a method that proves the therapeutic equivalence of drugs. The study involves comparative bioavailability between a test product and a reference product. In general, reference products are typically original/innovator drugs that have been studied pharmacologically, toxicologically, and clinically, and their effectiveness and safety are recognized. They must include contraindications, precautions, side effects, dosage, dosage regimen, and frequency of doses based upon pre-clinical study on humans and phase I-III clinical trials. Original pharmaceutical products must be registered by the Thai FDA before serving as reference products to compare with test products, which are generic pharmaceutical products for which registration is requested. The following parameters are considered: the rate and extent of drug absorption into the bloodstream at different time intervals after both pharmaceutical products are provided for humans. These are determined by measuring drug levels in the blood and duration for which they go into the bloodstream among healthy volunteers. This method reveals bioavailability of a

generic pharmaceutical product compared with an original drug, which is a reference product. Therefore, to know if a generic pharmaceutical product can be substituted in place of an original pharmaceutical product, the bioequivalence study must find that the generic pharmaceutical product has bioequivalence to the original pharmaceutical product under the specified standard (Thai Food and Drug Administration, 2002).

Once an original or generic pharmaceutical product is registered and receives a drug registration number, it can be imported or manufactured for sale and use in the country. In addition, in the production of generic pharmaceutical products, drug manufacturers pass an assessment of standards for pharmaceutical manufacture in pharmaceutical production facilities according to good manufacturing practice (GMP) by the Thai FDA, as well as other standard requirements. This is to ensure that drug manufacturing will comply with standards and build trust and confidence among patients, doctors and medical staff in the quality of generic pharmaceutical products.

### **2.3.3 Distribution of Pharmaceutical Products into the Public Health System**

To distribute drugs into the public health system in a manner that will make them accessible to patients or people who have to use drugs in the public health system, there are many channels available. The main channels are hospitals and pharmacies. Approximately 90 percent of the value of pharmaceutical products consumed in Thailand comes from both channels, which use a different method and manner of procurement and sales to distribute pharmaceutical products.

2.3.3.1 Hospitals are divided into government hospitals and private hospitals. They procure and distribute pharmaceutical products for patients in the role of medical care; however, the way they procure and distribute pharmaceutical products for hospitals is different.

#### **1) Government hospitals**

(1) Procurement of pharmaceutical products by a government hospital is under the responsibility of the hospital's Pharmaceutical Section. The procurement of pharmaceutical products or non-drug medical supplies must meet certain requirements, including the MOPH's regulations and the Office of the Permanent Secretary of Public Health's Notification about the Regulations of the



Prime Minister's Office on Government Procurement, B.E. 2535 (1992) (concerning the procurement of drugs and medical supplies). Their details are set forth in Article 60 to Article 64, as follows:

Article 60: For government organizations, they shall procure generic drugs indicated in the national essential drug list prepared by the National Drug Committee. At least 60 percent of their budget monies shall be allocated for the drugs. For government organizations under the MOPH, at least 80 percent of their budget monies shall be spent on the drugs.

Article 61: As for drugs and non-drug medical supplies, such as gauze bandages, cotton, syringes, needles, splints, dental materials, x-ray films, and chemical pharmaceutical products that the Government Pharmaceutical Organization (GPO) produce for sale, government organizations shall procure them from the GPO. Government organizations affiliated with the Ministry of Defense shall procure them from the Defense Pharmaceutical Factory. The Police Department (the Royal Thai Police) shall procure them from the GPO or the Defense Pharmaceutical Factory by means of a special method. The drug prices offered by the GPO and the Defense Pharmaceutical Factory shall not exceed three percent of the median prices of drugs with the same generic names that are fixed by the MOPH.

Article 62: As for the procurement of generic drugs on the national list of essential medicines and non-drug medical supplies that the GPO does not produce but sells, government organizations are allowed to procure them from the GPO or any other sources or manufacturers under the following criteria:

(2) Procurement by requesting quotations or tendering : All government organizations shall always inform the GPO of the procurement processes. If the GPO bids at the same price of, or lower price than, other bidders, government organizations shall procure the products from the GPO.

(3) Procurement by a price agreement or a special method : The prices accepted shall not be higher than the median prices set by the MOPH.

Article 63: In the case where there is any law or cabinet resolution that supports the procurement of drugs and non-drug medical supplies from a particular agency, government organizations must procure them from that agency by means of a special method.

Article 64: The MOPH is responsible for circulating the national list of essential medicines prepared by the National Drug Committee and fixing median prices for the drugs and non-drug medical supplies to government organizations. The MOPH shall request the GPO to announce the list of drugs identified on the national list of essential medicines and non-drug medical supplies that the GPO produces or sells to other government organizations.

## 2) Private hospitals

Drug procurement by private hospitals can be classified into three types, which are single procurement, central procurement, and group procurement. No median prices are fixed for pharmaceutical products for private hospitals; they mainly vary based upon their decisions and market mechanisms.

2.3.3.2 Drug stores are drug distribution channels that are accessible and the most convenient. They are divided into three types-single drug stores, chain drug stores and franchise drug stores. These channels provide people or patients with their primary treatment so that they do not need to visit a doctor. Through these channels, people or patients have to pay for drugs themselves-no welfare is provided for them. No median prices are fixed for drugs in these channels; the prices vary based upon market mechanisms.

## **CHAPTER 3**

### **CONCEPTS AND USE OF DRUG PATENTS**

Chapter 3 presents relevant details from literature reviewed in this study. It aims to create a systematic understanding about concepts and principles relating to patents and the use of drug patents that has led to the failure to access drugs by the public, which breaches the principles of human rights and freedom. This chapter also describes concepts and principles relating to public access to medicines that has led to international solutions using compulsory licensing. Other topics presented here include compulsory licensing procedures, as well as phenomena and impacts of the compulsory licensing policy.

#### **3.1 Concepts and Principles About Patents**

The purpose of “a patent” is to protect the exclusive right to intellectual property; it is an important document issued by the government to protect an invention or a product design. According to intellectual property law, a patent may be granted only for an invention if the following conditions are satisfied (Department of Intellectual Property, 2010):

- 1) The invention is new, which is different from existing inventions and has never been widely used or sold within or outside a country.
- 2) It involves advanced technology and cannot be easily developed by those with average knowledge in a field, or a technical solution to existing inventions of the same kind.
- 3) It is capable of industrial application if it can be made or used in any kind of industry, including handicrafts, agriculture and commerce.

With this exclusive right, the inventors or product designers are entitled to make and sell their invention or product for a period of time as set forth in writing. The patent owners or patentees must publicly disclose details of their invention and

product design. In other words, “a patent” refers to an exclusive right that the law grants to the patent owners, which provides them with an absolute right to seek benefits from their patented inventions or product designs. It is their right to make and sell them until the patent expires (Nusaraporn Kessomboon, 2002: 1). Protecting the inventors’ natural rights, patents are utilized to compensate for introducing modern technology from abroad and serve as an incentive to create innovations for the benefits of mankind.

As for drugs, humans need to conduct research to develop new drugs to treat existing and new diseases in a more efficient and effective manner. Accordingly, new drugs are innovations, so they can have patent protection. Drug patents are typically divided into two categories depending on patent law in each country:

1) Product patent : The owner of a product patent has the right to the product and process by which the product is made (Jiraporn Limpananont, 2007). The patentee has the exclusive right to make, use, sell, have for sale, offer for sale, or import the product according to the patent regardless of processes through which it is made until the patent expires (Patent Act, B.E. 2522 (1979)). If a patent is granted to Drug X, the patentee has the absolute right to make and sell the product. If other people make, sell, or import it without the consent from the patentee, they are liable for the infringement of the patent regardless of processes through which it is made.

2) Process patent : This patent grants the exclusive right to the process by which a product is made. The patent owner has the exclusive right to make, use, have for sale, offer for sale, or import the product that is made through the process that is described in the patent (Patent Act, B.E. 2522 (1979)). If the patent is granted to Drug X, the patentee has the absolute right to sell the product only when it is made under the patented process. People, in general, are allowed to make Drug X provided that it is made under a different process.

When the patent protection expires, other people are entitled to make and sell the product, but if the patent protection is still valid, other people are not allowed to make or sell it, except for the case when compulsory licensing is imposed as prescribed by law.

## **3.2 Problems About Application of Drug Patents in Thailand**

### **3.2.1 Drug Patents and Patients' Inaccessibility to Drugs**

Promulgated in 1979, the first version of the Thai Patent Act included only process patents. In terms of drugs, the process patents protected only processes and technology through which drugs are made, but did not protect the drugs themselves, with a protection term of 15 years after the application for the patent. In 1985, the U.S.A. commenced the implementation of a harsh trade barrier measure with Thailand. From 1991 to 1992, U.S. authorities cut the generalized system of preferences (GSP) for many Thai products, which resulted in Thailand losing revenue worth 165 million dollars, or approximately 4.125 billion baht (MOPH, 2007).

To pressure and force Thailand to effectively solve copyright infringement issues by amending laws on copyrights, trademarks, and patents, especially drug patents, the U.S.A. requested that the protection be extended to product patents and that the patent protection period be extended from 15 years to 20 years. On 30 September 1992, the Thai government, under the administration of Prime Minister Chuan Leekpai, formulated the second version of the Patent Act, B.E. 2535 (1992) to reduce the country's trade loss. This amended Act increased the potential for a patent monopoly in new drugs, which deprived the marketplace of competition. The Thai government's failure to seriously manage the system for monitoring the prices of new drugs resulted in the soaring prices of drugs as a result of price mechanisms depending on the drug patent owners (Jiraporn Limpananont, 2007). Unfortunately, the Thai pharmaceutical industry had inadequate capacity of capital and technology for the research and development of new drugs, and it lacked strong marketing strategies to compete with other international pharmaceutical companies that owned the drug patents (Nusaraporn Kessomboon, 2002). These issues had an impact on patients who needed to take patented drugs, especially those who suffered from chronic and serious diseases, such as AIDS, cardiovascular disease, and cancer. People living with these diseases require continuous and lifelong use of drugs to relieve their suffering to achieve a good quality of life. Particularly, patients suffering from these diseases in developing countries and underdeveloped countries in Asia, Latin America, and the Caribbean did not have thorough and equal access to

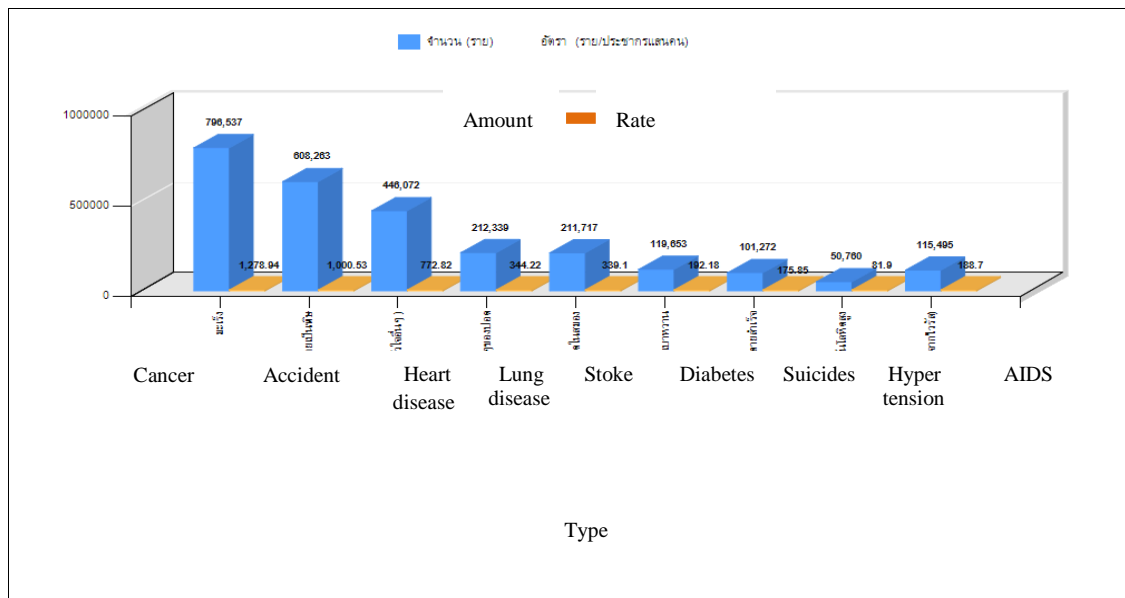
necessary medication as a result of their low-middle incomes (Robert, 2008). In addition, funding and budgets in these countries are insufficient for treatment of the diseases. Thus, public accessibility to essential drugs became low and increasingly lower, which resulted in a sharp rise of the morbidity and mortality rates of these diseases (Shanti, 2007). These diseases were the cause of sixty percent of the deaths worldwide (WHO, 2004). This was also true for Thailand, as shown in Table 3.1 and Figure 3.1 and 3.2, respectively.

**Table 3.1** Mortality Rate per 100,000 People by Major Causes, from 2000 to 2011

Year	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
<b>Cancer</b>	<b>39,480</b>	<b>42,497</b>	<b>45,834</b>	<b>49,682</b>	<b>50,818</b>	<b>50,622</b>	<b>52,062</b>	<b>53,434</b>	<b>55,403</b>	<b>56,058</b>	<b>58,076</b>	<b>61,082</b>
Accidents	32,401	31,579	34,568	35,804	36,855	35,818	37,433	35,661	34,851	35,304	32,861	33,868
<b>Cardiovascular disease</b>	<b>19,708</b>	<b>18,807</b>	<b>15,361</b>	<b>17,462</b>	<b>16,766</b>	<b>17,539</b>	<b>17,775</b>	<b>18,452</b>	<b>18,820</b>	<b>18,375</b>	<b>18,399</b>	<b>20,130</b>
Lung diseases	9,286	11,163	13,185	15,074	16,462	13,946	13,766	14,179	14,542	14,542	16,369	16,884
<b>Stroke</b>	<b>8,260</b>	<b>11,309</b>	<b>13,427</b>	<b>18,332</b>	<b>19,265</b>	<b>15,719</b>	<b>12,921</b>	<b>12,995</b>	<b>13,133</b>	<b>13,353</b>	<b>17,540</b>	<b>19,283</b>
Diabetes	7,558	8,173	7,383	6,663	7,665	7,371	7,486	7,686	7,725	7,019	6,855	7,625
<b>Suicide</b>	<b>6,703</b>	<b>5,498</b>	<b>4,905</b>	<b>4,486</b>	<b>4,296</b>	<b>3,941</b>	<b>3,612</b>	<b>3,756</b>	<b>3,778</b>	<b>3,787</b>	<b>3,761</b>	<b>3,776</b>
<b>Hyper tension</b>	<b>3,403</b>	<b>3,912</b>	<b>3,213</b>	<b>3,402</b>	<b>2,491</b>	<b>2,452</b>	<b>2,363</b>	<b>2,291</b>	<b>2,463</b>	<b>2,295</b>	<b>2,478</b>	<b>3,664</b>
<b>AIDS</b>	<b>8,695</b>	<b>10,113</b>	<b>15,597</b>	<b>16,892</b>	<b>11,473</b>	<b>7,949</b>	<b>6,551</b>	<b>5,522</b>	<b>4,685</b>	<b>4,046</b>	<b>3,638</b>	<b>3,758</b>
<b>Total deaths</b>	<b>365,741</b>	<b>369,493</b>	<b>380,364</b>	<b>384,131</b>	<b>393,592</b>	<b>395,374</b>	<b>391,126</b>	<b>393,255</b>	<b>397,327</b>	<b>393,916</b>	<b>411,331</b>	<b>414,670</b>

**Source:** Bureau of Policy and Strategy, MOPH, 2011.

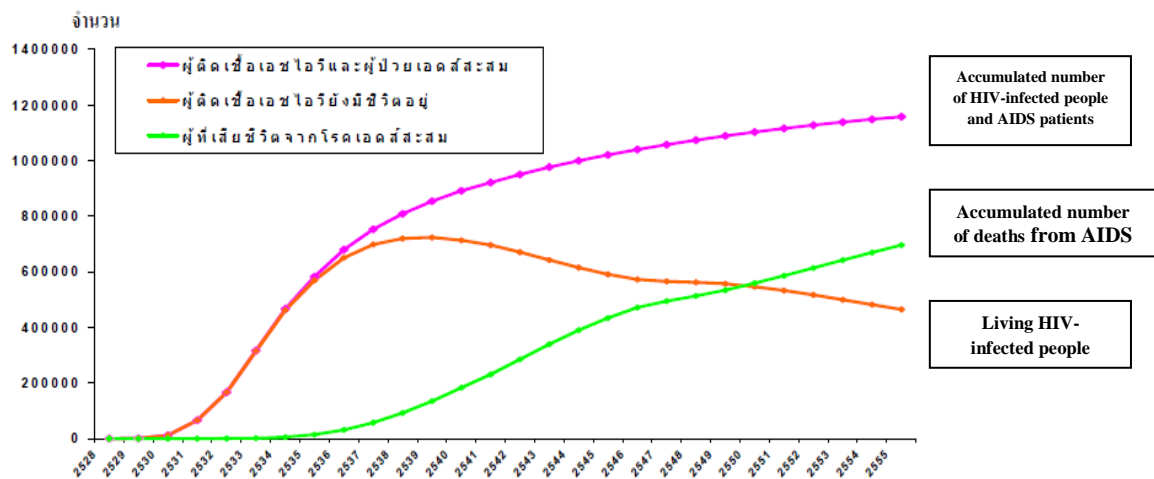
**Note:** Major Diseases Refer to Preventable Diseases, but their Death Toll Rises Every Year.



**Figure 3.1** Mortality Rate per 100,000 People by Major Causes, from 2000 to 2011

**Source:** Bureau of Policy and Strategy, MOPH, 2011.

**Note:** Major Diseases Refers to Preventable Diseases, but their Death Toll Rises Every Year.



**Figure 3.2** Accumulated Number of HIV-infected People and AIDS Patients, Accumulated Number of Deaths from AIDS, and Number of Living HIV-Infected People, from 1985 to 2012.

**Source:** Department of Disease Control, 2012.

Table 3.1 and Figure 3.1 illustrate that the death rates from 2000 to 2011 as a result of cancer and cardiovascular disease steadily increased. In the case of AIDS, Figure 3.2 reveals that the accumulated number of deaths from AIDS and the number of HIV-infected people steadily increased from 1995 to 2012 and the number of AIDS patients who were still alive significantly decreased.

In 2001, the Thai government promulgated the Universal Access to Essential Healthcare Policy, with the rationale to reduce public health costs for poor and low-income people and to allow the public to have equal and thorough access to public health services. In the following year, the National Health Security Act, B.E. 2545 (2002) was launched with the purpose to provide public health care schemes for the entire Thai population. The schemes included the Universal Healthcare Coverage Scheme (30 baht Healthcare Scheme), Social Security Scheme, as well as the Medical Benefit Scheme for Civil Servants and State Enterprise Employees. Under this Act, more drugs for more diseases were added to the National Essential Drug List, and the public's right to access drugs on the National Essential Drug List was enhanced. Nonetheless, the incidences of these diseases signaled that they were uncontrollable, especially AIDS, and the morbidity and mortality rates gradually rose. In 2006, the Ministry of Public Health (MOPH), in collaboration with the World Health Organization (WHO), World Bank, and NGOs, studied public health policies on AIDS. They found that the AIDS situation in Thailand was serious, and this would lead to major public health issues and greatly affect the quality of life of the Thai population in the future (MOPH, 2007). Despite various comprehensive public health care schemes, they could not function effectively because of the inaccessibility to "drugs." This was because drugs are a key factor that drives the public health care schemes to provide thorough and equal treatment for all people. In general, patients' inaccessibility to drugs can be divided in four levels: 1) Lack of drugs or medical service centers, 2) Excessively expensive drugs, 3) Unsustainable budget for drug procurement, and 4) Wrong use of drugs. The levels of inaccessibility to drugs vary from country to country. Most developing countries are facing level 1 and 2. In Thailand, level 1 and 2 are the most common; however, the prevalence of level 3 and 4 is increasingly evident. Problems at the respective levels have linkages-essential drugs in hospitals are costly as a result of patent protection and excessive drug use.



The Thai government had inadequate funding for drug procurement to respond to public health problems in a sustainable manner (Bureau of Drug Control, 2007). Some essential drugs cost 6-10 times as much as those available in international markets because of monopolies in drug markets by patented drugs, which were exclusively priced by the patent owners. Foreign drugs that patients bought from government health institutions and private health institutions cost 6.28 times and 9.01 times as much as international markets, respectively. As for foreign drugs procured by the government sector and private sector, they cost 4.67 times and 7.79 times as much as international markets, respectively. Thai drugs procured by the government sector and private sector cost 1.15 times and 1.48 times as much as international markets, respectively (Online Manager, 2009).

Currently, the Thai government is responsible for 5.1 million civil servants and state-enterprise employees in terms of healthcare benefits (disbursement from each agency), as well as 46.6 million people under the National Health Security Policy (a lump sum of approximately 1,899.69 baht per person per year). In total, government healthcare support must be provided for a population of at least 50 million. The budget monies for public health increased every year, from 89,163.7 million baht in fiscal year 2005 to 101,040.5 million baht and 148,739.6 million baht in fiscal years 2006 and 2007, respectively (MOPH, 2007). Nonetheless, they were inadequate for patented drugs for the foregoing diseases. Alternatively, generic drugs that can be substituted in place of patented original drugs are many times cheaper than the patented original drugs. With generic drugs, the Thai government is able to allocate more budget monies to allow patients to have better access to necessary drugs. Details of prices of patented original drugs and generic drugs are presented below in Table 3.2.

**Table 3.2** Drug Price per Tablet/Injection and Monthly Drug Cost per Patient:  
Patented Drugs and Generic Drugs

Diseases	Names of patented original drugs	Prices of patented original drugs	Cost of treatment by original drugs	Prices of generic drugs	Cost of treatment by generic drugs
<b>AIDS</b>	Stocrin 600 mg (Effavirenz 600 mg) Merck Sharp & Dohme Co., Ltd.	1,400 baht per bottle (30 tablets/bottle)	1,400 baht per month	650 baht per bottle	650 baht per month
	Kaletra (Lopinavir/Ritonavir) Abbott Co., Ltd.	72,000 baht per bottle	72,000 baht per month	25,000 baht per bottle	25,000 baht per month
<b>Cardio vascular disease</b>	Plavix (Clopidogrel) Sanofi-Aventis Co., Ltd.	73 baht per tablet	2,190 baht per month	5-6 baht per tablet	150-180 baht per month
<b>Cancer</b>	Glivec TM 100 mg table (Imatinib 100 mg) Novartis Co., Ltd.	917 baht per tablet	27,510 baht per month	50-70 baht per tablet	1,500-2,100 baht per month
	Texotere TM 80 mg injection (Docetaxel 80 mg) Sanofi-Aventis Co., Ltd.	250,000 baht per injection	250,000 baht per month	4,000 baht per injection	4,000 baht per month
	Tarceva TM 150 mg tablet (Erlotinib 150 mg) Novartis Co., Ltd.	2,750 baht per tablet	82,500 baht per month	735 baht per tablet	22,050 baht per month
	Femara TM 2.5 mg tablet (Letrozole 2.5 mg) Roche Co., Ltd.	230 baht per tablet	6,900 baht per month	6-7 baht per tablet	180-210 baht per tablet

**Source:** The Ministry of Public Health, 2007.

Table 3.2 shows that the costs of patented original drugs are 10-100 times higher than generic drugs, thus resulting in 10-100 times higher monthly drug expenditures for patients with chronic diseases, i.e. AIDS, cardiovascular disease, and cancer. The costs are too high for patients to access continuous treatment, even if lifelong treatment is needed. Patent protection makes original drugs costly, thus leading to inaccessibility to the drugs among the Thai population with the chronic diseases.

### **3.3 Concepts and Principles About Public Access to Drugs**

It is a legitimate public health right for all people to have equal and thorough access to medicines, whether it is the right to standard treatment from medical staff or access to drugs and medical supplies without any discrimination. More importantly, “drugs” are merit goods that are vital for life when people encounter ailments. The following discussion is dedicated to the principles and concepts that support patient’s rights to access drugs.

#### **3.3.1 Rights and Freedom to Public Health According to the WHO**

The WHO demonstrated the linkage between human rights and good health and decent quality of life on the basis of promotion of public access to public health services in order to prevent harm from diseases. Accordingly, national policies have to take into account human rights (WHO, 2011).

#### **3.3.2 Rights and Freedom of Thai People Under the Constitution of the Kingdom of Thailand, B.E. 2550 (2007)**

Thailand’s constitution has been the country’s supreme law since the end of absolute monarchy in 1932. The country’s first constitution came into force on 27 June 1932. After 18 versions of the constitutional law in Thailand, the rights and freedom of Thai citizens were first provided in the Constitution of the Kingdom of Thailand, B.E. 2540 (1997)-the 16<sup>th</sup> Constitution of the Kingdom of Thailand. On 19 September 2006, the Council for Democratic Reform under Constitutional Monarchy waived the 16<sup>th</sup> Constitution and promulgated the 17<sup>th</sup> Constitution of the Kingdom of Thailand (temporary version). After that, the Constituent Assembly was established to draft the 18<sup>th</sup> Constitution of the Kingdom of Thailand in 2007 (Kanin Boonsuwan, 2008: 1). This constitution is the first Thai constitution that was approved by a public referendum and contains legal provisions of the rights and freedom of Thai citizens. It states that human dignity, rights, and freedom for all Thai people shall be equally protected without discrimination, regardless of sex, religion, age, or physical or health conditions; and the rights and freedom are bound to the parliament, cabinet, court, organizations under the constitution, as well as government agencies that enact,

enforce and interpret Thai law. Also, it dictates that Thai citizens' rights shall be equally protected, one of which is the right to receive public health services and state welfare, whether it is treatment by medical personnel or access to drugs and other necessary medical supplies used in the public healthcare system. This right is described in the following articles.

Section 51: A person shall enjoy an equal right to receive appropriate and standard public health service, and the indigent shall have the right to receive free medical treatment from public health centers of the State. A person shall have the right to receive public health services provided by the State, universally and efficiently. A person shall have the right to be protected from and eradicated from harmful contagious diseases by the State appropriately, without charge, and in timely manner. (Constitution of the Kingdom of Thailand, B.E. 2550 (2007)).

Health professions from the Medical Council of Thailand, Pharmacy Council, Nursing Council, Dental Council, and Board of Arts of Healing promoted patients' rights to public health services by jointly issuing an announcement to endorse patients' legitimate rights. This announcement was based on the fundamental rights set forth in Section 51 of the Constitution of the Kingdom of Thailand, B.E. 2550, which deals with the right to receive public health services and state welfare. This announcement aimed to build a good relationship and a mutual understanding and trust between health professionals and patients. Its content that is consistent with the Constitution is: All patients have basic rights to receive healthcare services as provided in the Constitution, and they shall enjoy equal rights to services from healthcare professionals without discrimination on the grounds of differences in social status, race, nationality, religion, society, political doctrine, sex, age and nature of illness (Medical Council of Thailand Council, 2008).

### **3.3.3 Equality**

Equality is a basic legal principle which takes into account human dignity. Under the principle of equality, all men shall be equally guaranteed protection under

the law, regardless of their personal characteristics, such as race, religion, language, or origin. It can be said that all men shall be equally guaranteed legitimate rights and shall be equally protected under the law, which refers to the principle “equality before the law.” This principle recognizes the rights and freedom that are innate to all humans; equality has a close connection with freedom because it leads to equal freedom in all men. However, if freedom is exclusive to some people and excludes other people, it can be said that freedom does not take place. Accordingly, equality is a key foundation of freedom and a guarantee of freedom (Kriengkrai Charoenthanavat, 2004).

The equality principle under provisions of law is a principle that creates non-discrimination towards individuals. Equal treatment must be treatment towards things that are the same in essence in an equal manner and treatment towards things that are different in essence in a different manner. This will result in justice under the equality principle.

The evolution of the equality principle is a long process. Currently, legal concepts about equality are being better recognized. Thailand gradually adjusted the equality principle to be in line with the country’s situations until the Constitution of the Kingdom of Thailand, B.E. 2550. In the draft constitution, the equality principle was adopted as a provision in Section 30 of the Constitution, which prescribes that all persons are legally equal and are equally protected by law; men and women have equal rights; and discrimination shall be prohibited on the grounds of the differences in origin, nationality, race, language, disability, age, health or physical condition, socio-economic status, and political views that do not conflict with provisions of the Constitution.

### **3.3.4 Concepts for Utilitarianism**

Utilitarianism is a concept developed by Jeremy Bentham, a scholar in political philosophy; the concept is based on hedonism, which believes that “All men are born to seek pleasure and avoid pain.” Bentham (1832) believed that politicians with a legislative function are responsible for making laws to enhance the pleasure of the majority of people in society and minimize their grief and pain. It can be considered to be “the best action for the greatest number of people.” This is why

utilitarianism is generally known as “the greatest happiness theory.” Under this concept, if all people in a society are happy, the overall society and the state will be happy, too. So, it is necessary for a State to minimize limitations in the pursuit of happiness of its people. This concept is supported by many scholars, most of whom consider it to have a connection with human rights. Section 25 of the American Declaration on Human Rights adopted in 1960 holds that everyone has the right to a standard of living adequate for the health and well-being of himself and of his family. Accordingly, equal rights of people as a whole must be taken into account in replace of rights for particular groups of people. This concept involves four principles: 1) Equality of thorough access to health services, 2) Equality in terms of needs of the majority of people in society, 3) Mechanisms to distribute equality of thorough access to health services; and 4) Equality in terms of listening to opinions of different groups of people in society (Susser, 1993). In addition, utilitarianism is related to ethical concepts. Herley (2001) noted that financial support for public health services needs to take into account ethics and the majority of people, which consist of four basic components: 1) Maintaining and sustaining human life, 2) Thorough distribution of public health services in society, 3) Access to public health services at a level that meets the majority’s needs for solving public health problems in a thorough and equal manner, and 4) Financial support that takes into account ethics in the distribution of public health services and the equal rights to access good health and quality of life of the majority of people in society, which cannot be exclusive to particular groups of people (Tauber, 2002).

From the concepts of health rights and equality to receive public health services, as well as the concept of utilitarianism that focuses on creating benefits that result in happiness and minimize what most people are suffering from, it can be said that the majority of people’s equal access to drugs without discrimination is a key factor that drives public health services to function effectively, lessens people’s suffering from different diseases, and promotes their happiness and quality of life. Drugs are products that always rely on new research and inventions to keep pace with current diseases. The development of new drugs involves the “known-how” of inventors and is said to be an innovation. As such, new drugs are granted protection via a patent, a document that shows the ownership according to Intellectual Property

Law. However, “drugs” are merit goods that everyone is entitled to access thoroughly and equally, which is a basic human right. Drugs are one of four basic necessities for people; people need drugs for treatment to maintain their well-being. This is why codes relating to drug patents and agreements on intellectual property are in agreement for the sake of justice of mankind. An exclusion to patent laws is called “compulsory licensing,” which can be imposed during an emergency, such as epidemics, shortages of food, medicine, and consumer goods, or during war. Under such circumstances, countries that are not patentees of the invention or product design are allowed to make, import for sale, or sell it, even though the patent protection is still valid.

### **3.4 Concepts and Principles About Compulsory Licensing**

#### **3.4.1 Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs Agreement)**

The TRIPs Agreement allows exercising rights without authorization by the patentees in Article 31, which states that the World Trade Organization (WTO) member states are entitled to impose compulsory licensing on drugs to make or import them for sale without authorization. The details are set forth in Article 31 (b) and 31 (h), which hold that compulsory licensing can be imposed under several conditions. For example, persons or companies can apply for compulsory licensing after they have attempted to get a voluntary license from the patentee. If the application is successful and the compulsory license is granted, the patentee is entitled to receive an appropriate royalty. The right granted by the compulsory license cannot be transferred to others. In the case of national emergency or other circumstances of extreme urgency, public non-commercial use or government use, or anti-competitive practices, compulsory licensing can be imposed without the authorization by the patentees.

#### **3.4.2 Multilateral Trade Negotiations: The Doha Round**

Multilateral trade negotiations have served as a forum for countries to conduct negotiations on trade with the purpose of maximizing trade liberalization. In the

beginning, the multilateral trade negotiations were under the General Agreement on Tariffs and Trade. Today, they are under the WTO, and they cover the trading of goods and services and issues related to intellectual property rights. The results of the multilateral trade negotiations will become international economic regulations, which WTO member states are bound to comply with. The negotiations have been conducted several times. On 14 November 2001, the ninth ministerial-level negotiations took place in Doha, Qatar, which were called “Multilateral Trade Negotiations: The Doha Round,” where the Declaration on the TRIPs Agreement and Public Health was presented. It was concluded that attaching great importance to intellectual property protection was the key to the creation and development of new pharmaceutical products; however, developing and underdeveloped countries’ public health issues were also important. These countries have failed to control the pandemic of AIDS/HIV, leprosy, malaria and other diseases, so it was necessary to consider the TRIPs Agreement and the impacts of patents on product prices. The meeting participants agreed to announce the Doha Declaration to endorse the TRIPs Agreement relating to the right to protect public health circumstances in each country, especially “public access to drugs.” As a result, the agreement on intellectual property rights relating to trade and public health in Doha dictated that all WTO member states are entitled to impose compulsory licensing (WTO, 2001) in order to control serious and urgent problems. The failure to control the spread of AIDS/HIV, leprosy, malaria and other diseases was an example of a serious and urgent problem for which compulsory licensing can be imposed (WHO, 2005).

### **3.4.3 Thai Patent Act**

The Thai Patent Act included exclusions for compulsory licensing, as set forth in Section 51 and Section 52 (Patent Act, 1979).

Section 51: In order to conduct any business that deals with public utilities or is of vital importance to the defense of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service, any ministry, bureau or department of the government may, by themselves or through others, exercise any right under Section 36 by paying a royalty to the patentee or his



exclusive licensee under paragraph 2 of Section 48 and shall notify the patentee in writing without delay. In the circumstances listed in the above paragraph, the ministry or bureau or department shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General. The royalty rate shall be as agreed upon by the ministry or bureau or department and the patentee or his licensee.

Section 52: During a state of war or emergency, the Prime Minister, with the approval of the Cabinet, shall have the power to issue an order to exercise any right held under any patent which is necessary for the defense and security of the country by paying a fair remuneration to the patentee and shall notify the patentee in writing without delay. The patentee may appeal the order or the amount of remuneration to the court within sixty days from the receipt of the order.

The international intellectual property law and Thai drug patents prescribe flexibilities for the State or others to exercise the right on behalf of the patentee in the following two ways:

#### 3.4.3.1 Right Exercising by Persons

It is identified in Section 46-50 of the Patent Act, B.E. 1979 that if ones see that an invention, such as a drug, is not imported, made, and sold in their country by the patentee or is sold in their country with inadequate quantities or excessive cost and they wish to make it or import it for sale, they can negotiate with the patentee to exercise the right and pay the patentee royalty as agreed upon. If an agreement is reached, it means the patentee grants them voluntary licensing, but if it is not, they can apply to the Department of Intellectual Property (DIP) for compulsory licensing with a reasonable royalty.

#### 3.4.3.2 Right Exercising by Government Agencies

1) In order to conduct any business that deals with public utilities or is of vital importance to the defense of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumer items or for any other public services, any ministry, bureau or department of the government may promulgate compulsory licensing without a need to make negotiations with the patentee, but they shall notify the patentee in writing without delay and shall pay for remuneration for the

exploitation to the patentee and shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General of the Department of Intellectual Property (DIP).

2) During a state of war or an emergency, the Prime Minister, with the approval of the Cabinet, shall have the power to issue an order to exercise any right held under any patent that is necessary for the defense and security of the country by paying a fair remuneration to the patentee and shall notify the patentee in writing without delay.

### 3.5 Compulsory Licensing in Foreign Countries

Concepts and principles of compulsory licensing and significant public health problems in different countries have forced such countries to grant compulsory licenses on different drugs to protect their citizens' rights during an emergency or urgent situations, to alleviate a severe shortage of food, medicines, and other consumer items, or to protect other public interests, as presented in Table 3.3 below.

**Table 3.3** Examples of Countries that Promulgated Compulsory Licensing, from 2001-2005

Year	Country	Compulsory Licensing Policy	Results of the Implementation of Compulsory Licensing Policy
2001	U.S.A.	After the event 9/11, the United States Department of Health and Human Services (DHHS) imposed a compulsory licensing policy, under 28 USC 1498, to import ciprofloxacin, a generic drug patented by	This policy reduced the shortage of ciprofloxacin and its cost. It decreased its selling price, improved public access to it, and alleviated the pandemic and its mortality rate (Harmon & Pear, 2001).

**Table 3.3** (Continued)

<b>Year</b>	<b>Country</b>	<b>Compulsory Licensing Policy</b>	<b>Results of the Implementation of Compulsory Licensing Policy</b>
		Mayer, a German company. The drug was used for preventing the spread of Anthrax (WHO, 2004).	
2001	Canada	On 18 October 2001, Canada's Ministry of Public Health promulgated the compulsory licensing policy to manufacture ciprofloxacin, a generic drug patented by Mayer, a German company. The drug was used for preventing the spread of Anthrax (WHO, 2004).	This policy reduced the shortage of ciprofloxacin and its cost, which decreased its selling price, improved public access to it, and alleviated the pandemic and its mortality rate (Harmon & Pear, 2001).
2004	Malaysia	On 1 November 2003, the Malaysian government promulgated the compulsory licensing policy to produce Didanosine and Zidovudine, antiretroviral generic drugs, for a two-year time period from the date of the policy promulgation (WHO, 2004).	This policy reduced the average drug cost per AIDS patient, from 3,800 U.S. dollars to 700 U.S. dollars. This increased AIDS patients' access to the drugs by three times (Ling, 2006).

**Table 3.3** (Continued)

<b>Year</b>	<b>Country</b>	<b>Compulsory Licensing Policy</b>	<b>Results of the Implementation of Compulsory Licensing Policy</b>
2004	Brazil	On 26 April 2004, the Brazilian government promulgated the compulsory licensing policy for d4T, an antiretroviral drug (WHO, 2004).	This policy resulted in a decrease in the mortality rate of AIDS patients by over 50 percent (Okie, 2006) and resulted in a savings in treatment and hospital fees for HIV-infected people by over 2.2 billion U.S. dollars.
2005	Italy	On 21 March 2005, the Italian government approved the implementation of the compulsory licensing policy for antibiotics patented by Imipenem/Cilastatin. Two years later, on 21 March 2007, it imposed the compulsory licensing policy on Finasteride and an associated generic drug with the trade name “Proscar.” The drugs were used for treating benign prostatic hyperplasia and prostate cancer in males. In this case, the drugs were allowed to be exported to Europe (WHO, 2004).	This policy reduced the drug costs, improved public access to the drugs, reduced mortality rates, and eliminated a monopoly in drug markets (Autorita, 2006).

### **3.6 Compulsory Licensing in Thailand**

The Thai government, under the administration of Police Lieutenant Colonel Thaksin Shinawatra (also the Prime Minister), and Dr. Mongkol Na Songkhla, the MOPH Minister, manifested the political will to seriously tackle the problem of inaccessibility to drugs for the Thai population. The aim was to meet the objectives of the Universal Healthcare Coverage Policy and the Universal Healthcare Coverage Act, B.E.2545 (2002) and to adhere to policy views and the WHO's drug strategies, 2004-2007. Under the WHO's drug strategies, public access to essential medicines is a basic human right, and drugs are a basic necessity that are not general consumer goods. Accordingly, drug patents should be managed without bias and measures to enhance public access to essential drugs should be advocated. At the same time, fair protection should be granted to the patentees' interest and public health interest of the country (WHO, 2004b). The Thai government's measures were as follows:

#### **3.6.1 First Step**

Analyze and assess situations of necessary drugs for the aforementioned chronic diseases-As these necessary drugs had patent protection and were costly, treatment costs were a great burden on patients. The Thai government's limited budget monies contributed to the inaccessibility to drugs among the Thai population, and this resulted in a significant public health impact upon the country. Consequently, the National Health Security Board (MOPH's Order, 4 April 2004) issued an order to establish the Subcommittee on the Selection of Essential Drugs and Medical Supplies with the Access Problem. The appointed Subcommittee was chaired by the Secretary of the National Health Security Office, and its functions were to study the need for medication use, select essential drugs, and propose a list of drugs to the MOPH Minister for consideration in order to cope with the problem of drug access.

##### **3.6.1.1 Criteria for Drug Selection:**

Drugs and medical supplies: The drugs that appeared on the National Essential Drug List included essential drugs for solving public health problems during an emergency, essential drugs for use during epidemics, or essential drugs for saving

life. The medical supplies must be those that solve public health problems or those used during an emergency or epidemic.

#### 3.6.1.2 Steps of Consideration:

- 1) Survey experts on different diseases, patients, service units, and others about problems and needs.
- 2) Set priorities and make decisions on the following issues:
  - (1) Burden of diseases-The degree of the impacts of diseases that were the major causes of death for the Thai population.
  - (2) Prices
  - (3) Cost effective analysis of modern treatment, which took into account prices of generic drugs in the country and outside the country to serve as reference prices.
- 3) Proposing a list of drugs to the MOPH Minister in order that suitable criteria for solving the problem of drug access were identified.

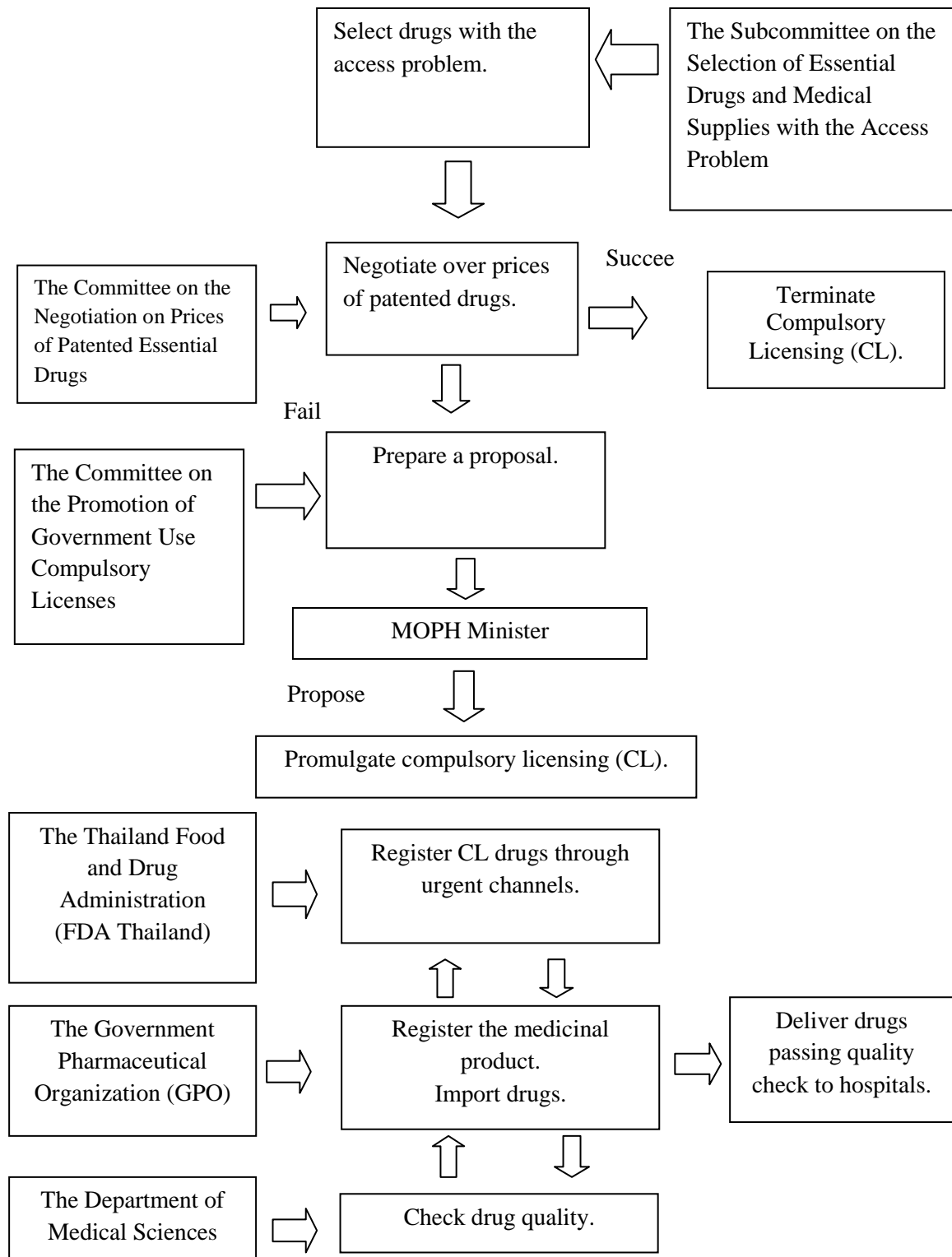
### 3.6.2 Second Step

Bargaining for lower prices for the patented drugs with the access problem – The MOPH bargained for lower prices for the drugs with the representatives from the drug patentees, and set up the Committee on the Negotiation on Prices of Patented Essential Drugs, which was chaired by the Secretary of the Thai FDA and was composed of representatives from the Ministry of Commerce. On behalf of the government, the Committee entered into negotiations over prices with pharmaceutical companies, studied and formulated conditions and measures to reach an agreement, and reported the negotiation results to the MOPH for further action (MOPH's Official Letter, 16 November 2004). When the negotiation was successful, compulsory licensing was not imposed.

### 3.6.3 Third Step

Once the negotiations over lowering the prices for the essential drugs failed, the National Health Security Board issued Order, no. 4/2006 (dated 17 April 2006), to appoint the Committee on the Promotion of the Government Use Compulsory Licenses for Patents on Drugs and Medical Supplies, which was chaired by Dr.

Mongkol Chokwiwat. The Committee's function was to collect supporting information and prepare a proposal to the MOPH Minister. The promulgation of compulsory licensing depended on the MOPH Minister's final decision. If it was imposed, the MOPH authorized the GPO to import the drugs and register them before delivering them to the Office of the National Health Security. Exercising this right conformed with Sections 51 and 52 of the Patent Act, B.E. 2522 (1979), Section 31 (b) in the TRIPs Agreement, and the Doha Declaration. They stated that government ministries and departments were entitled to grant compulsory licenses for the public interest without negotiating with the patent-owner companies (Jakkrit Kuanpoth, 2007). Also, the MOPH assigned the GPO to clarify the purpose of exercising this right and all details to the patent-owner companies in order to prevent a conflict between both parties that could affect long-term trade and investment. The compulsory licensing policy directly affected the rights and revenues of the patent-owner companies, and it was subject to objection by the companies. Fairness for both pharmaceutical companies and patients could reduce the conflict between the Thai government and pharmaceutical companies. Accordingly, the MOPH started the compulsory licensing policy for the first time, by assigning the GPO (on behalf of the government) to make, sell, or import the drugs for sale while granting the patentees remuneration, which was 0.5-2 percent of the sale value of each generic drug. Figure 3.3 below illustrates the steps of compulsory licensing in Thailand:



**Figure 3.3** Steps of Compulsory Licensing in Thailand

**Source:** The Standing Committee on Public Health, 2011.



The MOPH first issued compulsory licenses for three drugs, including two antiretroviral drugs-Stocrin 600 mg (Efavirenz 600 mg) made by Merck Sharp & Dohme Co., Ltd. and Kaletra (Lopinavir/Ritronavir) made by Abbott Laboratories Co., Ltd.; and one cardiovascular drug-Plavix<sup>®</sup> made by Sanofi-aventis Co., Ltd. (MOPH's Official Letter, 16 November 2006), as presented in Table 3.4 below.

**Table 3.4** List of Drugs with Compulsory Licenses and Patentee Companies: Two Antiretroviral Drugs and One Cardiovascular Drug.

<b>Date of Compulsory License Promulgation</b>	<b>Original Drugs with Compulsory Licenses</b>	<b>Patent-Owner Companies</b>	<b>Generic Drugs</b>	<b>Expiration Dates</b>
29 November 2006	Stocrin 600 mg <sup>®</sup>	Merck Sharp & Dohme Co., Ltd.	Efavirenz 600 mg	31 December 2011
24 January 2007	Kaletra <sup>®</sup>	Abbott Laboratories Co., Ltd.	Lopinavir/Ritronavir	31 December 2011
25 January 2007	Plavix <sup>®</sup>	Sanofi-Aventis Co., Ltd.	Clopidogrel	The patent expires or is no longer needed.

**Source:** The Ministry of Public Health, 2007.

The Subcommittee on Compulsory Licensing for Drugs and Medical Supplies by the State considered that the drugs should have compulsory licenses for the following reasons:

3.6.3.1 Efavirenz under the Trade Name Stocrin 600 mg: It was the first line drug for AIDS patients and was proven to be one of the most effective

antiretroviral drugs producing less harm and complications than Navirapine. Navirapine was put in GPO VIR, which was an antiretroviral drug made by the GPO. Despite being highly effective, GPO VIR's side effects were four times greater than Efavirenz. Twenty percent of people who were allergic to it or did not tolerate its toxicity needed Efavirenz, which was on the drug list under the National Security Scheme for Access to AIDS Drugs. However, with its patent protection, the GPO or other pharmaceutical companies were not allowed to make or import equivalent generic drugs for sale in the market. The government's limited budget monies could support only about 25 percent of patients for the patented drug; the rest needed to use other drugs that had no patent protection because of their cheaper prices. These alternative drugs were far less effective and were more likely to pose complications.

3.6.3.2 Lopinavir and Ritonavir under the Trade Name Kaletra: These drugs were prescribed to patients who have resistance to GPO VIR or Efavirenz (a basic drug formula) soon after the start of the treatment. The drug resistance depended on the regularity of drug taking and characteristics of the virus of each patient. There was a 10 percent increase in the number of cases with resistance to the basic drug formula. The Lopinavir with Ritonavir combination was proven to be one of the most effective antiretroviral drugs for patients with resistance to the basic drug formula. This combination was provided under the National Security Scheme for Access to AIDS Drugs. However, due to its patent protection, the GPO or other pharmaceutical companies were not allowed to make or import equivalent generic drugs for sale in the market. The drug combination was a lot more expensive than the generic drugs in some countries, so many patients with resistance to the basic drug formula failed to access the drug combination and had to suffer from complications from fatal infections.

3.6.3.3 Clopidogrel under the Trade Name Plavix: This was used to treat myocardial ischemia and cerebrovascular accidents, Thailand's major public health problems that resulted in high rates of disabilities and death. Although the diseases were preventable by having proper lifestyles, especially good eating and exercise, their incidences increased steadily. Therefore, this drug was needed to reduce their morbidity and mortality rates. Clopidogrel was empirically effective in preventing the intensity of these diseases, and coronary stent implantation by inhibiting platelet

congregation took a short time. However, this drug was costly, which made it difficult to access. Only 20 percent of patients suffering from the diseases could be treated with this drug under the Universal Healthcare Coverage Scheme (MOPH, 2007). If competition in the market was allowed by importing or producing equivalent generic drugs in the country, the price of the drug would dramatically drop and patients' access to the drug would increase by 6-12 times, which would fulfill the goals of the policy on creating universal healthcare coverage.

### **3.7 Consequences of Compulsory Licensing in Thailand**

After the compulsory licensing was imposed under the Patent Act for three drugs-Plavix<sup>®</sup> (generic name: Clopidogrel), a patented drug for myocardial ischemia and cerebrovascular accidents made by Sanofi-Synthélabo Co., Ltd., France; and two patented antiretroviral drugs, the GPO was authorized to make or import generic drugs from non-patent owner countries. One drug was a highly effective antiretroviral drug used for patients with resistance to the basic drug formula. Its trade name was Kaletra<sup>®</sup> (generic name: Lopinavir/Ritonavir), which was made by an American company, Abbott Laboratories Co., Ltd. Another one was an antiretroviral drug under the trade name Stocrin<sup>®</sup> (generic name: Efavirenz), which was made by Merck Sharp & Dohme Co., Ltd., also an American company. This aimed to resolve public health problems in order to increase the public's thorough and equal access to medicines according to the human rights principle. Generic drugs with compulsory licenses that were imported or locally made had to be registered with the MOPH. For most of the generic drugs, some original drugs were registered in Thailand, for example, Lopinavir and Ritonavir tablets. For the registration of original drugs and generic drugs, the Thai Food and Drug Administration (Thai FDA) applied the same criteria. That is, the drugs must be pharmaceutical products with documented evidence that they are of good quality, effective, and safe. More importantly, for generic drugs, they must have documented evidence showing that they have therapeutic equivalence to the original drugs to allow public health personnel involved with the drugs, including patients, doctors and medical staff to feel confident that the generic drugs can be substituted for their original drugs as they have the same active ingredients, strength,

form, indications, and doses. Because the effectiveness and safety of the original drugs have been widely studied on patients in clinical trials and have been internationally recognized (WHO, 2004a), it is not academically or ethically necessary to conduct clinical trials for generic drugs. However, generic drug manufacturers must have documented evidence that proves their therapeutic equivalence to the original drugs through a bioequivalence study. These are determined by measuring drug levels in the blood and duration for which they go into the bloodstream among healthy volunteers, which will reveal bioavailability of a generic drug compared with the original drug. The bioequivalence study must manifest that the generic drug has bioequivalence to the original drug. The results of the bioequivalence study are important evidence for the approval of generic drugs; it is recognized internationally, for example, by the WHO.

Despite following legal and international principles for compulsory licensing, there were many groups within and outside Thailand who were adversely affected by compulsory licensing. As discussed more fully below, these groups applied measures to respond to Thailand after the MOPH promulgated compulsory licensing.

- 1) Abbot Laboratory Co., Ltd., the owner of the patented antiretroviral drug Kaletra<sup>®</sup> (generic name: Lopinavir/Ritonavir), decided not to apply for the registration of 10 new drugs and withdrew the application for the registration for more effective drugs that they had filed with the Thai FDA to export to Thailand. The drugs included Zemplar for chronic kidney disease, Simdax for heart failure, Humira for autoimmune disease, and the Aluvia tablet. Abbot stated it would not change its decision until the Thai government changed their position related to compulsory licensing. Furthermore, it would also halt the process to register new drugs until the MOPH paid attention to the protection of intellectual property and canceled the compulsory licensing for Kaletra<sup>®</sup>, its patented drug. As for its 12 drugs that were available in the market, it continued selling them (The Nation, 15 March 2007).

- 2) Merck Sharp & Dohme Co., Ltd., the owner of the patented antiretroviral drug Stocrin 600 mg<sup>®</sup> (generic name: Efavirenz) announced the discount for Stocrin 600 mg<sup>®</sup> for developing countries worldwide and countries with severe HIV pandemics, including Thailand. Before the compulsory licensing, a patient had to pay 1,500 baht per month for the drug. Later, the cost went down to 700 baht per

month. The discount was aimed to response to commercial competition with generic drugs that Thailand was manufacturing (by the GPO) and importing from India, whose retail price was 650 baht per month (Prachachat Turakij, 2007).

3) The U.S.A.-The U.S.A. was the owner of the patents of Kaletra<sup>®</sup> and Stocrin<sup>®</sup>, which were made by Abbott Laboratories Co., Ltd. and Merck Sharp & Dohme Co., Ltd., respectively. Both companies submitted a letter to the Pharmaceutical Research and Manufacturers of America (PhRMA) with regard to the compulsory licensing imposed by Thailand. The two companies responded to Thailand's action by requesting the United State Trade Representative (USTR) to consider re-ranking Thailand's intellectual property infringement degree, from the Watch List (WL) to the Priority Watch List (PWL)-countries with high levels of intellectual property infringement. They claimed that Thailand had not provided adequate protection for American intellectual property (Matichon Online, 2007) and Thailand's violation of intellectual property remained high from 2005 to 2006. They also referred to Thailand's CD Production Act, B.E. 2005, which was not strong enough to suppress piracy of CD products; violation of property rights of books; sale of goods with trademark infringement, such as apparel and footwear; stealing television signals and cables; and piracy of entertainment and businesses software. Other claims included inappropriate penalties for intellectual property violation, which has allowed violations to continue, as well as the Thai government's issuance of compulsory licenses on many drugs from late 2006 to early 2007. They also stated that even though the issuance of compulsory licensing was allowed under the obligations of the WTO, the compulsory licensing imposed by the Thai government lacked transparency and proper implementation, and Thailand's protection of drug registration data was not strong. In Thailand, to register drugs under patent law, all information about the drugs must be disclosed, which may result in information leaks about a company and unfair commercial exploitation (Department of Intellectual Property, 2007). All of these pushed the U.S.A. to take measures to re-rank Thailand's violation of intellectual property from the WL to the PWL under Special 301. Later, the U.S.A. decided to cut the Generalized System of Preferences (GSP) with Thailand. Under the GSP, some Thai industries are entitled to export products to the U.S.A. without tax. On 1 July 2007, the USTR promulgated the cancellation of the GSP for three products from

Thailand, which included gold jewelry, polyethylene terephthalate pellets, and flat screen color TVs (Intira Yamabhai et al, 2006b: 40). This event brought about great “anxiety and stress” for the Thai business sector. The Thai Chamber of Commerce’s assessment revealed that Thailand’s top four export products under the GSP of the U.S.A. included the following: gems and accessories, worth 303.27 million U.S. dollars; jewelry, worth 255.47 million U.S. dollars; radial tires, worth 173.47 million U.S. dollars; and ignition wires and other kinds of wires used in vehicles, worth 124.14 million U.S. dollars. If the GSP for these exports was canceled, their selling prices would be cut by approximately 10 percent, which would affect export revenues and profits worth an estimated 80 million U.S. dollars-2.5 billion baht (based upon 32 baht per U.S. dollar) (BangkokBiz News, 2008).

Although there were many groups of people losing profits who protested against Thailand’s compulsory licensing program, there were groups of people within and outside Thailand that supported the action to improve public access to drugs, in order to meet the objective of compulsory licensing. The groups who supported the compulsory licensing program included the following:

- 1) Civil society and NGOs-Thaiplus, the AIDS Access Foundation, the Advocacy Center for AIDS, the Thai NGO Coalition of AIDS (TNCA), and the Foundation for Consumers jointly advocated for the policy of the MOPH and the Thai government, which were committed to solve public health problems in Thailand and improve the access to medicines and treatment of patients with chronic diseases, such as cardiovascular disease, cancer, and AIDS. They encouraged the Thai population to boycott goods from Abbott Co., Ltd., i.e., the antibiotic erythromycin-Ery-ta<sup>b®</sup>; painkiller ibuprofen-Brufe<sup>n®</sup>; antibiotic clarithromycin-Klaci<sup>d®</sup>; food supplements-Ensure, Similac, Isomil, and Pedialyte; and the anti-obesity drug-Reductil. They urged Thai people to take generic drugs and other alternative products and support the domestic pharmaceutical industry. In addition, the Médecins Sans Frontières (MSF) announced their standpoint of endorsing each country’s right to apply the WTO’s TRIPS Flexibilities to enhance public access to essential drugs (Consumer Protection Foundation, 2007).

- 2) International organizations-The WHO, United Nations Development Program (UNDP), and UNAIDS jointly issued a policy brief under the

title “Using TRIPS Flexibilities to Improve Access to HIV Treatment,” which was published on 15 March 2007. Urging countries to improve the access to HIV treatment by incorporating TRIPS Flexibilities (e.g., compulsory licensing, as imposed by Thailand and Brazil), they supported the clarity of granting drug patents as set forth in the Indian Patent Act. This aimed to eliminate the extension of the product patents that did not lead to new inventions or products, or in other words “ever-greening patents” in order to reduce drug prices and improve public access to drugs. Developing countries were heavily pressured by most developed countries that were patent owners to waive this right, particularly in newly emerging pharmaceutical markets, such as Thailand and Brazil. However, the UN believed that compulsory licensing is based on human rights declared in the UN’s Human Right Declaration. The policy brief expressed concern over the bilateral trade agreements that forced countries to protect intellectual property over TRIPs Agreements, which would significantly affect countries’ public health systems.

3) Support by U.S.A. Congress members: Twenty-two U.S. congressmen provided written explanation about their advocacy for intellectual property protection to achieve innovations. However, they suggested that this protection should create a balance between being an incentive to create innovation and a need to comply with flexibilities during an emergency and other circumstances of a country, as noted in the TRIPS Agreement and the Doha Round of Multilateral Trade Negotiations (MOPH, 2008). They notified the USTR that the allegation that Thailand had taken inappropriate action was wrong since it was justified, and most importantly, it complied with humanitarian principles and law. They proposed that organizations should stop pressuring the Thai government (Ellen, 2009).

On Tuesday 19 September 2006, the Council for Democratic Reform under the Constitutional Monarchy, consisting of military officers, police officers and civilians, led by Gen. Sonthi Boonyaratglin, seized the power from Police Lieutenant Colonel Thaksin Shinawatra, the Prime Minister. It occurred at the army headquarters on Ratchadamnoen Nok Road, Phra Nakhon, Bangkok. On 1 October 2006, a new government was set up, in which Gen. Surayud Julianont served as the Prime Minister and Dr. Mongkol Na Songkhla served as the Acting Secretary to the MOPH. Carrying on the previous government’s policies, the new government had a clear policy about

the universal healthcare coverage scheme. During that time, all drugs with compulsory licenses were under the National Essential Drug List, which all Thai citizens were entitled to receive no matter which health security scheme they were covered by. One of the MOPH's main policies was compulsory licensing. The previous government imposed compulsory licensing for the three drugs, which both positively and negatively affected many groups of stakeholders. The new government under Gen. Surayud requested that all concerned agencies have a formal dialogue with the U.S.A. to avoid the escalation of the problem and to move Thailand down from the PWL to the WL. To develop health security schemes in Thailand, the MOPH allocated funding for research to assess the impacts of compulsory licensing and the practices of compulsory licensing in Thailand from 2006 to 2008. Based on different documents, this research assessed health impacts, economic impacts associated with health, impacts on exports and investment, and social and psychological impacts. In terms of economic impacts associated with health, it was found that compulsory licensing exposed patients to better access to medicines and longer life as a result of lower drug prices. Concerning exports and investment, cutting the GSP had no statistically significant impacts on gold jewelry or flat screen TVs, but it did impact polyethylene terephthalate pellets. As a result of the GSP cutting, the export value of polyethylene terephthalate pellets dramatically dropped and investment from foreign countries was slightly affected. Lastly, with respect to social and psychological impacts, Thais and foreigners agreed with compulsory licensing for enhancing public access to medicines (Intira Yamabhai et al., 2006b). Considering the impacts identified, the Thai government decided to resume the compulsory licensing program to provide the public with thorough and equal access to essential drugs.

The Thai government and the National Health Security Board considered issuing compulsory licenses for four more drugs, all of which were cancer drugs since cancer was a major cause of death for the Thai population. Each year, at least 40,000-50,000 people died from cancer, and each year 100,000 more people suffered from the disease. Its incidence steadily increased, and was not less important than AIDS or cardiovascular disease. Lung cancer and breast cancer were the most frequent types of cancer despite chemotherapy and drugs for targeted therapy, which proved to be highly effective if cancer was detected during its early stage. Cancer drugs were



costly as a result of their patent protection, thus resulting in a monopoly in the market of cancer drugs. For low-medium income people, they could not access the drugs, and public health care schemes in the country-the Universal Healthcare Coverage Scheme (30 baht Healthcare Scheme), Social Security Scheme, as well as the Medical Benefit Scheme for Civil Servants and State Enterprise Employees, failed to achieve the goals and objective of the universal healthcare coverage under the National Health Security Act, B.E. 2545 (2002). This stemmed from the country's limited public health budget monies, even though they steadily increased each year. This was the reason why many drugs were not on the National Essential Drug List, so the possibility of a cancer patient to access the drugs was very low. Some patients were able to afford the drugs for a limited time and then stopped taking the drugs and died. Therefore, the Subcommittee on the Selection of Essential Drugs and Medical Supplies with the Access Problem in the health security systems proposed that the MOPH Minister, according to Letter, no. So Po So Cho. 05/013521 (dated 25 September 2007), should take action to allow the public to get better access to cancer drugs. Later, the MOPH Minister directed the Committee on the Promotion of the Government Use Compulsory Licenses for Patents on Drugs and Medical Supplies to provide ideas about this issue. The resolution adopted from Meeting, no. 7/2007 (dated 2 October 2007) proposed that the MOPH Minister issue compulsory licensing for the following four cancer drugs:

1) Imatinib (trade name or original drug: Glivec™), which was used for treating leukemia and GIST and patented by Novartis Co., Ltd., Switzerland.

2) Docetaxel (trade name or original drug: Taxotere™), which was used for treating lung cancer and breast cancer and patented by Sanofi-Avantis Co., Ltd., France.

3) Erlotinib (trade name or original drug: Tarceva™), which was used for treating lung cancer and patented by Novartis Co., Ltd., Switzerland.

4) Letrozole (trade name or original drug: Femara™), which was used for treating breast cancer and patented by Roche Co., Ltd., Switzerland.

Before promulgating this policy for the four cancer drugs, the MOPH assigned the Committee on Price Negotiations for Patented Drugs to negotiate with

these drug companies (MOPH's Official Letter, 28 December 2007). The Committee conducted negotiations with Novartis Co., Ltd., Sanofi-Avantis Co., Ltd., and Roche Co., Ltd. 12 times within three months. The results of the negotiations that came out on 28 December 2007 are as follows (MOPH's Official Letter, 28 December 2007):

1) Imatinib 100 mg (trade name or original drug: Glivec™) – The patentee, Novartis Co., Ltd., did not offer a discount for the drug but provided the drug for free to patients in the 30 baht Healthcare Scheme according to the conditions of the Glivec® International Patient Assistance Program (GIPAP) under the MAX Foundation. These conditions for qualifying patients are:

(1) The patients without any health security scheme to pay for drugs.

(2) The patients whose yearly household income does not exceed three times Thailand's GDP per capita-not over 300,000 baht.

Considering the proposal of Novartis Co., Ltd., the Committee on Price Negotiations for Patented Drugs agreed that the proposal did not offer anything different from the current situation. During that time, the National List of Essential Drugs Committee was considering including Imatinib on the National Essential Drug List, under which patients in any of three healthcare schemes were entitled to receive. As for Section 1.1, the Committee on Price Negotiations for Patented Drugs claimed that there were many patients whose conditions did not fit under Section, and the price of Imatinib 100 mg produced by Dabur Co., Ltd from India was 170 baht per tablet, while that of the patented original drug was 3,427 baht per tablet.

Thus, the Committee on Price Negotiations for Patented Drugs realized a need to issue government use compulsory licensing for Imatinib 100 mg, pursuant to the original proposal of the Committee on the Promotion of the Government Use Compulsory Licenses for Patents on Drugs and Medical Supplies.

2) Docetaxel 80 mg (trade name or original drug: Taxotere™)- The patentee, Sanofi-Avantis Co., Ltd., proposed reducing the price from 25,000 baht to 3,750 baht per tablet, but with a lot of conditions-There must be at least 1,500 patients per year; the drug must be included on the National Essential Drug List; and the proposal must be signed on a yearly basis.

Considering the proposal and conditions, especially the yearly basis contract, the Committee on Price Negotiations for Patented Drugs agreed that the contract was conducive to a monopoly and prohibited the MOPH from purchasing another drug that was over 50 percent cheaper. Furthermore, the Committee was afraid that Sanofi-Avantis might alter conditions in the contract in the following years. Also, the Committee was aware that the generic drug from India did not exceed 2,500 baht per tablet, and this price could be lowered without conditions.

The Committee agreed upon the issuance of government use compulsory licensing for Doxetacel 80 mg, following the original proposal from the Committee on the Promotion of the Government Use Compulsory Licenses for Patents on Drugs and Medical Supplies.

3) Erlotinib 150 mg (trade name or original drug: Tarceva<sup>TM</sup>)-The patentee, Novartis Co., Ltd., offered a discount for the drug, from 230 baht to 150 baht per tablet under the condition that at least 60,000 boxes of the drugs must be purchased per year.

After considering the proposal and conditions by Novartis Co., Ltd. about the quantities of drugs that Thailand must purchase and the fact that the generic drug could be made by India's Dabur Co., Ltd, which was 21 baht per tablet (seven times cheaper), the Committee realized the need to impose government use compulsory licensing for Erlotinib 150 mg, according to the original proposal issued by the Committee on the Promotion of the Government Use Compulsory Licenses for Patents on Drugs and Medical Supplies.

4) Letrozole 2.5 mg (trade name or original drug: Femara<sup>TM</sup>)-The patentee, Roche Co., Ltd., offered a discount for the drug, from 2,750 baht to 1,925 baht per tablet.

After considering the proposal and conditions presented by Roche Co., Ltd. about the discount and the fact that the generic drug could be produced by India's Dabur Co., Ltd, which was 700 baht per tablet (three times cheaper), the Committee on Price Negotiations for Patented Drugs concluded that government use compulsory licensing needed to be imposed on Letrozole 2.5 mg, according to the original proposal by the Committee on the Promotion of the Government Use Compulsory Licenses for Patents on Drugs and Medical Supplies.

The Committee submitted details about their negotiations over drug prices and prepared a draft announcement to the MOPH Minister to sign. On 4 January 2008, the MOPH Minister, Dr. Mongkol Na Songkhla, signed the announcement of the compulsory licensing for the four cancer drugs, as presented below in Table 3.5. Later, “the GPO” was authorized by the government to make, sell, or import for sale the drug at a fair price and provide remuneration of three percent of the sale value of each generic drug to the patentee.

**Table 3.5** List of Drugs with Compulsory Licenses and their Patent Owners

<b>Date of Promulgation</b>	<b>Original Drugs with Compulsory Licenses</b>	<b>Patent Owner Companies</b>	<b>Generic Drugs</b>	<b>Expiration</b>
4 January 2008	Glivec TM 100 mg tablet	Novartis Co., Ltd.	Imatinib 100 mg	Expiration date or until the drug is no longer needed.
4 January 2008	TexotereTM 80 mg injection	Sanofi- Synthélabo Co., Ltd.	Docetaxel 80 mg	Expiration date or until the drug is no longer needed.
4 January 2008	Tarceva TM150 mg tablet	Novartis Co., Ltd.	Erlotinib 150 mg	Expiration date or until the drug is no longer needed.
4 January 2008	Femara TM 2.5 mg tablet	Roche Co., Ltd.	Letrozole 2.5 mg	Expiration date or until the drug is no longer needed.

**Source:** The Ministry of Public Health, 2007.

The National Health Security Board proposed imposing compulsory licensing for the four cancer drugs; however, the MOPH Minister suggested delaying it and requested the Committee on Price Negotiations for Patented Drugs to negotiate with these companies one last time prior to imposing the compulsory licensing. This aimed to reduce impacts as they had experienced from compulsory licensing for the

first three drugs. The results of the last negotiations with the drug companies are as follows:

1) Novartis Co., Ltd. sent a letter of intent dated 18 January 2008 to promote the access to Imatinib 100 mg (Glivec TM 100 mg tablet) and a confirmation letter. The letter by Novartis Asia Pacific dated 23 January 2008 offered Imatinib 100 mg (Glivec TM 100 mg tablet) without charge to patients under the Universal Healthcare Coverage Scheme. For patients who had to take 400 mg of the drug per day, they were eligible to access the drug if their household income did not exceed 1.7 million baht per year (this is greater than the aforementioned amount, which was not over 300,000 baht per year). For patients who had to take 600 mg, their household income must not exceed 2.2 million baht per year. These patients received Imatinib under the GIPAP. The proposal allowed all patients under the Universal Healthcare Coverage Scheme (30 baht Healthcare Scheme) who had trouble paying for 100 mg Glivec TM tablet to receive the drug without charge. Therefore, it was unnecessary to issue government use compulsory licensing for Imatinib 100 mg (100 mg Glivec TM tablet).

2) Other patent owner companies confirmed the old proposal. Dabur Co., Ltd, in India, proposed a discount for the following generic drugs:

(1) Imatinib 100 mg-The old proposed price was 170 baht and the new price was 135 baht (140 mg), valued at 3.9 percent of the original drug.

(2) Docetaxel 80 mg-The old proposed price was 2,500 baht and the new price was 1,875 baht, valued at 50 percent of the original drug.

(3) Letrozole 2.5 mg-The old proposed price was 21 baht and the new price was 15 baht, valued at 10 percent of the original drug.

(4) Erlotinip-No price change.

The Committee on the Promotion of Government Use Compulsory Licenses proposed that the MOPH Minister approve implementation of the three signed announcements (except for Imatinib) from 4 January 2008 (MOPH's Official Letter, 25 January 2008). The MOPH Minister approved the implementation (except for Imatinib) and waived the old government use compulsory licensing for Imatinib, but imposed conditional government use compulsory licensing. This was to ensure

that patients would regularly receive Imatinib 100 mg under the GIPAP. The details (MOPH's Announcement, 25 January 2008) are follows:

1) Issuing government use compulsory licensing when the GIPAP was completed or when the GIPAP implementation did not comply with the Company's letter or failed to provide all patients under the Universal Healthcare Coverage Scheme (30 baht Healthcare Scheme) with the access to the drug.

2) Implementing the Compulsory Licensing Announcement if any events fit in Section 1) until the end of the patent term or when the drugs were no longer needed.

3) Providing a sufficient quantity of the generic drugs for patients, especially those who were eligible under the Universal Healthcare Coverage Scheme (30 baht Healthcare Scheme)-The number of patients who were allowed to receive the drugs was not limited. However, this was under the discretion of the attending physician.

4) The remuneration for the patentee shall be five percent of the sale value of the generic drug sold by the GPO.

The MOPH shall immediately notify the GPO, the patent owner, and the DIP of the details.

After the promulgation of the compulsory licensing policy on the four cancer drugs, cancer patients' access to the drugs improved, but there were people who were directly and indirectly negatively affected by the policy, as in the previous policy for the three drugs.

1) U.S.A. -Although the U.S.A. did not own the patents of the four cancer drugs with the compulsory licenses, the PhRMA proposed that the USTR should review the trade measures under Special 301 provisions of the Trade Act of 1974 in order to shift Thailand onto the Priority Foreign Country (PFC) list. In 2008, Thailand was moved from the WL to the PWL after the Thai government issued compulsory licenses for antiretroviral and cardiovascular drugs. The PhRMA justified its shifting of Thailand to the PFC because Thailand lacked clarity about the compulsory licensing policy and would continually issue more compulsory licenses without consultation with the private sector or meeting with the Joint Committee between the government and private sector, to deal with drug access issues. The

PhRMA believed that Thailand's action resulted in poor-quality counterfeited drugs that were widely available in the markets, without investigations to arrest offenders, and that the Thai government had inappropriate and ineffective penalties, patent linkages, or protection of data exclusivity (Prachachat Turkij, 2009).

2) Thai Pharmaceutical Manufacturers Association (TPMA), together with some groups of medical professionals, academics, and lawyers urged the Thai government to review and amend Section 13 of the Drug Act, B.E. 2510 (1967), as well as Sections 61 and 62 of the Office of the Prime Minister on Procurement Regulations, B.E. 2535 (1992). They felt that all these provisions were highly conducive to a monopoly of drug markets by the government sector as they did not allow private manufacturers to improve their capacity to make and sell drugs, thus affecting public access to high-quality drugs. Section 13 of the Drug Act, B.E. 2510 (1967) grants exclusive rights to the GPO to make and sell drugs without authorization by responsible agencies. Sections 61 and 62 in the Office of the Prime Minister on Procurement Regulations, B.E. 2535 (1992) hold that government hospitals shall purchase drugs from the GPO first. They considered this to be unfair competition in pharmaceutical markets during the free trade era, as some pharmaceutical companies in Thailand had the capacity to produce good quality drugs at cheaper prices than those made by the GPO, which might be 20-30 percent cheaper. They claimed that private pharmaceutical companies were able to produce drugs similar to those with compulsory license that the GPO imported according to the government's order, and that many Thai pharmaceutical entrepreneurs had sufficient potential to compete with foreign companies (Manager 360 Degrees, 2010).

In the meantime, politics in Thailand became volatile after the military coup seizing the power of Police Lieutenant Colonel Thaksin Shinawatra, Prime Minister, on Tuesday 19 September 2006. The new government had Gen. Surayud Chulanont as the Prime Minister and Dr. Mongkol Na Songkhla as the Acting MOPH Minister. After the Constitution B.E. 2007 (2007), the newly designated government came to the end. The new election took place on 23 December 2007; it was the first general election under the Constitution of the Kingdom of Thailand, B.E 2007 (2007). Under the Constitution, the House of Representatives shall consist of 480 members-400 from the constituency basis and 80 from the proportional representation basis. On

29 January 2008, the new government was formed. The House of Representatives approved Mr. Samak Sundaravej as the Prime Minister and Mr. Chaiya Sasomsap as the MOPH Minister. Due to changes in the government and ministers in each ministry, policies from the previous government were delayed in order to be in line with the direction of the new government.

At the beginning of his term, Mr. Chaiya Sasomsap, the MOPH Minister, clearly announced that he would review the drug access policy and imposed government use of compulsory licensing. He received two documents from Dr. Prat Boonyawongvirote, the Permanent Secretary to the MOPH. The first was Letter, no. Pho No 07003/FTA/5 (dated 30 January 2008) from the Ministry of Commerce, which was about ranking Thailand under Special 301 of the U.S. trade law. The other one was the Compulsory Licensing Announcement signed by Mr. Krirk-krai Jirapaet, a former Minister of the Ministry of Commerce (MOC). In the meantime, the PhRMA proposed that USTR should move Thailand from the PWL to the PFC. The Ministry of Commerce also indicated that the government's use of compulsory licensing had to be delayed to wait for the new government to implement it, as it would affect the country's ranking in the WL and exports. Finally, he decided that the government's use of compulsory licensing for the three drugs-Strocin, Kaletra, and Plavix would continue as they served a large number of people, but the government's use of compulsory licensing for the four new cancer drugs had to be reviewed again to explore its advantages and disadvantages. Although the government's use of compulsory licensing in the past saved a lot of government budget monies, it greatly affected the Ministry of Commerce and exports, so different aspects had to be prudently considered on the legal basis in term of patients' access to drugs and peril on the country's economy.

The delay and review of compulsory licensing for the four cancer drugs was followed by the movement by various groups that advocated compulsory licensing for the drugs, especially the civil society sector. The details are as follows

- 1) The public networks-Over 50 representatives from Thaiplus, the Thai Kidney Club, cancer patients, the Thai NGO Coalition of AIDS (TNCA), the Consumer Protection Foundation, and AIDS Foundation would like to listen to the explanations about the review of the compulsory licensing for the four cancer drugs



and submitted a proposal about compulsory licensing to the new MOPH Minister at the Office of Permanent Secretary for Ministry of Public Health.

2) After that, over 100 representatives from the foregoing groups traveled to the Government House and the MOPH to submit a letter to the Cabinet requesting clarity about the review of the compulsory licensing for the four cancer drugs.

3) Civil servants from the MOPH collected a petition of 20,000 people to submit to the House of Representatives requesting that Mr. Chaiya Sasomsap be removed from the position of the MOPH Minister.

From the movement, Mr. Samak Sundaravej, the prime minister, ordered the Ministry of Foreign Affairs, Ministry of Commerce, and the MOPH to have a meeting before reviewing or issuing the compulsory licenses for the cancer drugs. The meeting took place at the MOPH on 15 February 2008, in which the participants were 10 representatives from the National Health Security Office (NHSO), the Thai Food and Drug Administration (Thai FDA), the National Cancer Institute, the AIDS Patient Network, the Consumer Network, and the Cancer Patient Network. The meeting aimed to develop a conclusion to prepare for a meeting among the MOPH, Ministry of Commerce, and Ministry of Foreign Affairs for decision-making at the policy level. The meeting participants agreed that all patients in all the healthcare security schemes should equally access high-quality cancer drugs. Therefore, three working groups were set up, comprising the National Health Security Office, which was responsible for processing data about treatment costs for patients in the public health system; the National Cancer Institute, which took care of treatment measures; and the Cancer Patient Network, which dealt with adjusting information primarily adhering to public benefits. It was proposed that the review had to be completed within two weeks before being presented to the government for further consideration; and if the MOPH did not issue any compulsory licensing within two weeks, the Consumers Foundation and NGO networks would file proceedings against the MOPH to the Administrative Court for failing to perform a duty. This was because all parties recognized that compulsory licensing was a right thing to impose and had no errors that were subject to review or cancellation (Thai Post, 2008).

Later, a working group composed of representatives from the Office of the National Health Security, the National Cancer Institute, Ramathibodi Hospital, the Patient Network, Consumers Foundation, and Doctors without Borders-Belgium (Thailand), jointly conducted a study on the number of cancer patients who needed the four cancer drugs, and presented the results to the MOPH. Based on an estimate of drugs used by lung cancer and breast cancer patients, if Thailand issued compulsory licenses for cancer patents, within a period of five years Thailand could save a minimum of 3.2 to 8 billion baht. After considering details about cancer treatment and the number of cancer patients who needed the medication, the Thai government decided to implement the compulsory licensing policy for the four cancer drugs (Daily News, 16 June 2008). As for policy implementation, it was assigned to micro-macro government agencies which included the following:

- 1) The MOPH, which shall formulate the policy, allocate budget monies, and implement the policy to thoroughly distribute drugs with compulsory licenses to all government hospitals to support patients in the three healthcare systems – the Universal Healthcare Coverage Scheme (30 baht Healthcare Scheme), Social Security Scheme, as well as the Medical Benefit Scheme for Civil Servants and State Enterprise Employees. This aimed to sufficiently improve public access to medicines.

- 2) The GPO, which shall procure drugs with compulsory licenses to feed into the public health welfare system to enhance the public to access the drugs equally and thoroughly. Their functions were as follows:

- (1) Studying, experimenting and producing generic drugs with compulsory licenses with equivalent efficiency and effectiveness to the original drugs, for sale and use across the country.

- (2) Acting as the intermediary for bidding for drugs to import for sale while waiting for the GPO conducting studies and experiments to produce sufficient quantities of drugs with compulsory licenses in the Thai public health system.

- 3) Government hospitals, which shall be directly responsible for management of the distribution of drugs with compulsory licenses to ensure they reach all target groups, according to the objective of the policy – to improve public access to medicines.

## **CHAPTER 4**

### **PUBLIC POLICY CONCEPTS**

Chapter 4 describes concepts and theories relating to public policy, which include the definitions of a public policy and the public policy process-policy formation, searching and designing policy alternatives, decision-making about policy alternatives, policy implementation, and policy evaluation. In addition to explaining the concepts of the policy system and policy evaluation in detail, this chapter discusses reviewed literature on the use of the compulsory licensing policy in Thailand and other countries, as well as factors that have influenced the policy implementation that have led to the framework of this research.

Public policy is formulated by the government, which justifies formulating it and identifies the differences that a policy will make, if adopted (Dye, 1976: 1). In addition, the government has to state what it has chosen to do or not to do, as well as its routine or irregular activities (Dye, 1984: 1). Composed of a set of proposals that connect to the public's aspects of life, a public policy has the ultimate goal to resolve a problem or to improve the public's prosperity. A public policy has to comprise key concepts-goals, objectives, values, and guidelines for implementation of government programs and work plans under the policy. Government programs and work plans should be consistent with the public's problems, needs, and values to achieve their goals (Lasswell and Kaplan, 1970: 7, quoted in Sombat Thamrongthanyawong, 2006: 19). It can be said that a public policy is relevant to people from all social classes, ranging from people having issues that call for action taken by political authorities directly responsible for formulating public policies, to civil servants responsible for implementing the policies to cope with problems of the general public.

A public policy can be developed via diverse channels, e.g. government agencies, civil servants, political parties, and private organizations that may influence the development of government policies. A policy has to contain a course of action with clear goals (Anderson, 1994: 5-6). Thus, a public policy is characterized by: 1)

Linkage between the public policy and the course of action that can fulfill specific goals, or action that yields clear outcomes, 2) Courses or patterns of action taken seriously and continually by government agencies without discrimination or judgment for only particular cases. Accordingly, a public policy covers formulating law and regulations and decision-making that aim to impose or implement the policy, 3) Respond to the need to have the policy of the public or people who have identified what the government must or must not do; or respond to issues raised by different groups, e.g. the private sector, representatives of interest groups, or civil servants to result in action as demanded; 4) Something that the government needs to implement, not something it intends to do or has said it will do; 5) Positive or negative aspects with the aim to solve problems experienced by people or society as a whole to maximize their benefits (Anderson, 1994).

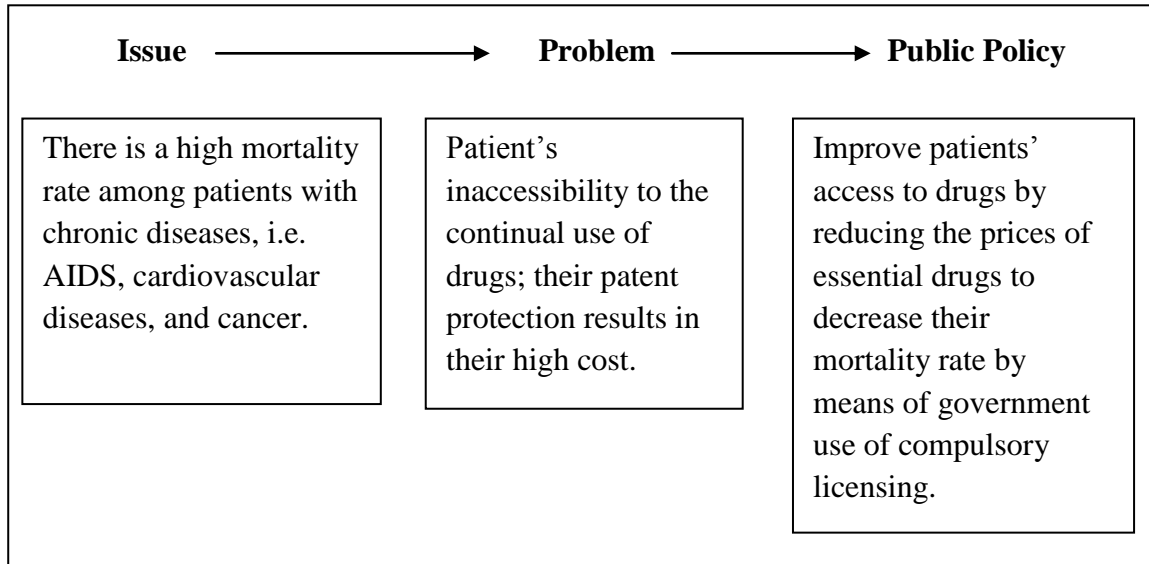
#### **4.1 Public Policy Process**

A public policy is developed based upon the environment, need or situation during a particular period of time. Policy makers make decisions on a policy by considering it to be a process. A policy process is a political activity covering: 1) Identifying issues, 2) Presenting proposals or alternatives for policy formation, 3) Selecting proposals or alternatives to formulate a policy to implement, 4) Implementing the policy (by identifying agencies to implement it), 5) Evaluating the policy, which deals with studying programs implemented, reporting the outputs, assessing the impacts on the target and non-target groups, and proposing changes as necessary to efficiently achieve the policy's goals (Dye, 1984: 23-24). As for the theoretical public policy process, it consists of the following major stages.

##### **4.1.1 Policy Formation**

Being the first stage of the policy process, policy formation starts with identifying a problem and its cause. Generally, it starts with individuals' problems. If the problem experienced by individuals is the same as that experienced by the majority of people or is a national problem, that problem will become a public problem that the government needs to focus upon and seek ways to tackle it. The

government does this by setting it as a public policy. An example is the study of the inaccessibility to drugs of the Thai population, which is illustrated in Figure 4.1 below.



**Figure 4.1** Policy Formation

#### **4.1.2 Searching and Designing Alternatives**

After policy formation is completed, alternatives to policy implementation need to be examined by collecting information, considering the policy's goals, and forecasting the outcomes, impacts, and side effects that the alternatives may pose. The aim is to consider the advantages, disadvantages, and value of the alternatives before a draft policy is presented.

#### **4.1.3 Decision-Making About Alternatives**

Policy makers are responsible for selecting, or making decisions about, the alternatives to formulate the optimum policy to solve the identified problem and yield benefits to the nation as a whole. The benefits must be thoroughly and fairly distributed to all people. The policy must be promulgated to all concerned agencies or personnel.

#### **4.1.4 Policy Implementation**

When a policy is clearly formulated and widely notified, in order to achieve the policy's objectives and goals related to solving the country's problem, government agencies at both macro and micro levels have to perform their roles and duties properly. Operating units must serve as a liaison with relevant agencies, the private sector, and stakeholders in order to ensure that there is a correct understanding about the policy that is being implemented. The aim is to solve the problem and bring benefits to all parties involved; this will provide a benefit to society and the country as a whole.

#### **4.1.5 Policy Evaluation**

When a policy is implemented, there must be evaluation and analysis of its outcomes, impacts, side effects, and unexpected results in order to reveal problems, obstacles, and defects arising during the policy implementation. This information will be studied to assess the achievement or failure of the policy. Policy evaluation is intended for providing feedback, and this feedback has to be studied to examine, analyze, and review the policy to see if it achieves its goals. If it does not, it will be adjusted to be in line with current social circumstances and contexts or canceled to formulate a new policy.

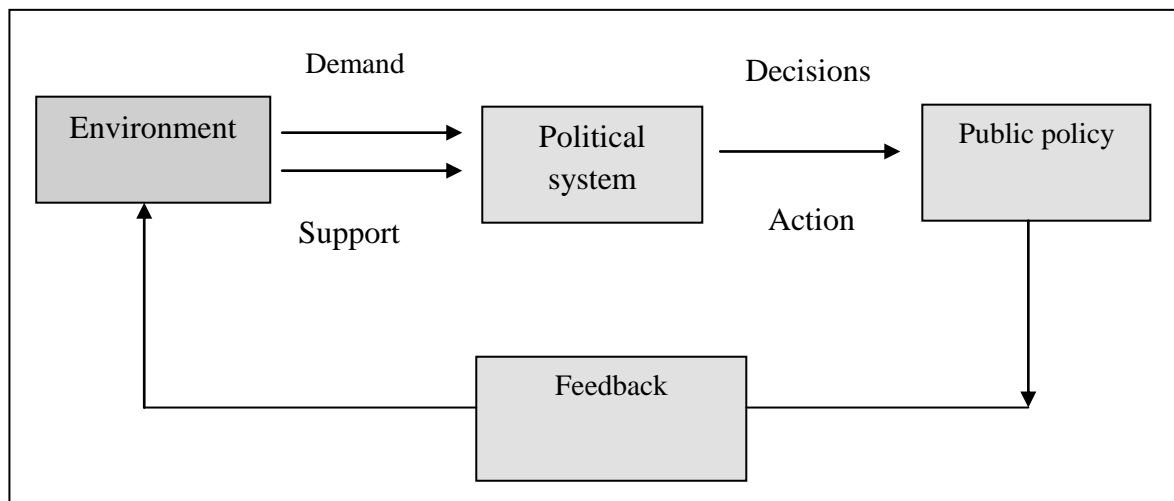
As mentioned above, the public policy process has linkages as a repeated cycle. It consists of several steps, starting with clarifying the problem – identifying what the problem is and which groups of people it affects. Typically, it starts with a personal problem, and if it is shared by the majority of the public, it will become a public problem that the government must focus upon and seek ways to fix. Thus, it is necessary to clarify the problem to serve as the cornerstone for determining the objectives of the policy. Furthermore, the process involves searching and designing potential alternatives to solve the problem in line with the objectives. In this step, information about different alternatives needs to be collected and analyzed for comparison, by building and testing models of these alternatives to determine the degree of their practicality and consistency in achieving a solution. The alternatives' models have to be investigated to find the ones that are appropriate and are consistent with the public's values. When suitable alternatives are identified, their costs and

effectiveness will be evaluated. The results of the evaluation will then be translated to help the policy makers with making the optimum choice. When the selected alternative is implemented, it must be evaluated to review the questioning assumption to see if its outcomes meet the objectives. If not, this will trigger new alternatives (Quade, 1982). Dunn (1994), expressed a similar view about the policy process, suggesting that the process comprises two parts: the policy methodology and policy information system. The policy methodology consists of five steps: 1) Problem structuring, which is done by gathering information about the problem and its solutions, 2) Forecasting the environment and outcomes of each alternative, 3) Recommendations, which consists of selecting alternatives to solve the problem in line with the environment, 4) Monitoring to check if the causes and results of the policy are in line with the objectives, 5) Evaluation to investigate how effective the implemented alternative is in solving the problem. As for the policy information system, it deals with five sets of information: 1) Policy problem, which is a problem that can be resolved through policy implementation, 2) Policy future, which is a course of action that can solve the problem according to social values, 3) Policy implementation, which is a policy's action taken to achieve the objectives, 4) Policy outcomes, which are the results of policy implementation, and 5) Policy performance, which deals with policy evaluation to reveal if the policy's performance reaches the desired levels. Both parts have connections and they center around the policy problem in order to find the optimal solution.

## **4.2 Policy System**

The concept of the public policy process of Dye (1976) can be studied to analyze and formulate the conceptual framework of the policy. Easton (1965: 9-16, quoted in Sombat Thamrongthanyawong, 2009: 107) indicated that politics exists as a system as a political life. His idea is based on the assumption that a political system has different components, both internal and external. The internal components are political institutions, and the external component is the environment, which influences the functioning of the political system. There are interactions between political activities and the environment. A political system is a dynamic system, in which the

interactions between political activities and the environmental result in an important output-a public policy. His assumption can clearly explain the relationship between the political system and the environmental setting-the environment (external factor) will be brought into the political system in the form of a demand to resolve a problem and gain support. When the demand and support from the environment are brought into the political system, the political system will transform them via the conversion process, and decisions will be made to meet the demand and support. The result of decisions by the political system is a public policy. When a public policy is implemented, it will provide feedback to the environment and will be brought back into the political system as a cycle. Thus, the relationship among the environment, political system, and a public policy can be described as a dynamic system. A public policy is regarded to be the dependent variable and the environment and political system to be the independent variables, as shown in Figure 4.2 below.



**Figure 4.2** Policy System

**Source:** Easton, 1965: 9-16.

Compulsory licensing is an output of the social environment, which is Thailand's public health problem-a continuous rise in the number of deaths of patients with chronic diseases, especially AIDS, cardiovascular disease, and cancer. It resulted from the fact that essential drugs for the diseases had patent protection, thus making them costly. Despite providing patients' rights as part of the public health care



schemes (the Universal Healthcare Coverage Scheme, Social Security Scheme, as well as the Medical Benefit Scheme for Civil Servants and State Enterprise Employees), the Thai government had insufficient budget for the entire drug costs. The vast majority of the Thai population, who had low-moderate incomes, could not afford essential drugs on their own or through government welfare. Preventing the population from having equal and thorough access to these drugs, despite their basic human rights, the unaffordability to the drugs caused discontinuity in treatment with these drugs, thereby resulting in premature death. The rates of new patients from the diseases, especially AIDS patients, increased dramatically. Thus, the Thai population's failure to access essential drugs became a national public problem. A lot of civil society organizations, such as the Thai National AIDS Foundation, the Médecins Sans Frontières (MSF), NGOs, the ThaiPlus, and other groups raised the issue to reflect the significance of the problem that the political system has to consider, and make decisions on alternatives to establish a course of action to solve the problem. The Thai government assigned the Ministry of Public Health (MOPH) to formulate the government use compulsory licensing policy. The MOPH authorized the GPO to manufacture or import these drugs for sale to government hospitals, which were operating units that implemented the compulsory licensing policy. Addressing the problem of patients' inaccessibility to drugs that became a national public problem was the demand of the majority of the Thai population, who were stakeholders in this policy. This policy received support from civil society groups that agreed with the government's use of compulsory licensing as a public policy. In addition to groups that benefited from the policy, there were groups that lost benefits from it, such as drug companies that patented the drugs, the Pharmaceutical Research and Manufacturers of America (PhRMA), the Office of the U.S. Trade Representative (USTR), the Thai Pharmaceutical Manufacturers Association (TPMA), and others. Opposing this policy, these organizations took different measures to respond to the policy. For example, they did not apply for the registration of new drugs in Thailand and put economic pressure on Thailand by cutting the Generalized System of Preferences (GSP). Beneficiaries in Thailand and people who lost benefits inside and outside Thailand, worthiness of the policy, outcomes and impacts of the policy, political changes in the country, and others might or might not affect the policy system and the policy process (from the policy formation to policy implementation).

The study on the public policy formation and the results of this policy alone could not reveal the root causes of the problem, as well as obstacles and failures experienced during the policy process. For this reason, academics shifted their focus to policy implementation since it is comparable to an airplane's black box, which is the center linking the precedence-a public policy with clear objectives or goals, to something that follows-policy implementation. Policy implementation is concerned with activities for the entire government sector; it will achieve successful and complete outcomes and fulfill the goals of the policy. It is regarded to be a process whereby the goals interplay with the action taken to achieve the goals. For this reason, the success or failure of a public policy does not depend only on policy formation on the basis of concepts, theories, and principles. If it fails to effectively respond to the public's problems due to circumstances that are not conducive to the implementation, the goals of the policy cannot be achieved. This is why it cannot be ensured that activities or processes related to policy implementation will be always successful. Policy implementation is a complex process, as it involves various factors inside and outside the organizations or countries. They have to be evaluated by a lot of people and agencies that affect policy implementation. Many academics presented different concepts that support the study of policy implementation. For example, Carl, Van Horn and Van Meter (1975: 103) focused on organizations' relationships that influence policy implementation. They suggested that policy implementation is an action taken by individuals or groups of individuals, both in the government or private sector. It is intended to achieve objectives set forth during the decision-making about the policy implementation. Furthermore, policy implementation is an output of the political process, through collaboration under a law approved by the three branches-the legislature, the executive, and the judiciary, based on the Supreme Court's verdict. The verdict includes social problems to address, objectives, structures, and expected outcomes, and impacts, which will lead to activities that will achieve the policy's goals. The process involves passing a law that is the key to the policy, decisions made by agencies that implement the policy, and willingness to implement the policy that affects the target groups (Mazmanian and Sabatier, 1983: 538-560). Many Thai academics presented concepts and models that support the linkages among these factors to visualize the research on policy implementation. Sombat Thamrongthanyawong (2006: 432-446) compiled studies and opinions from scholars in the field of public

policy, which led to the conclusion that success and failure factors of policy implementation are the source of the policy, clarity of the policy, support for the policy, complexity of management, incentives of practitioners, and resource allocation. Similarly, Supachai Yavaprabhas (2009: 101-118) analyzed factors that influence the success or failure of policy implementation and he found similar factors. The factors include the nature of the policy, objectives of the policy, political feasibility, technological feasibility, adequacy of resources, nature of agencies that implement the policy, attitudes of personnel who implement the policy, as well as mechanisms within the agencies or between agencies that implement the policy.

It can be said that policy implementation is a crucial step in the process. Despite academically proper policy formation, if a policy has no practical achievement, it does not achieve the goals. Policy implementation is a complex process as it is related to various factors, such as personnel, resources, as well as internal and external agencies that influence policy implementation.

Furthermore, the implementation of a public policy aims to tackle public problems via processes or programs run by operating units. To fulfill the policy's goals, policy evaluation must be conducted along with policy implementation. The aim is to monitor if the performance of policy implementation meets the goals and what problems or obstacles arise during the implementation process. Policy evaluation will help to analyze the problem and seek ways to improve the efficiency and effectiveness of policy implementation. More importantly, it will identify the success or failure levels of policy implementation, as well as resources used in different processes run by responsible agencies, outputs, outcomes, and impacts associated with the policy. It is an important tool that allows policy makers to decide to continue or improve the policy, or discontinue it.

### **4.3 Results and Indicators of Public Policy Implementation**

The assessment of the policy implementation demonstrates the degree of the policy's success or failure in resolving public issues after it has been implemented; it reveals the results of activities carried out during policy implementation. Criteria or indicators are a tool utilized for evaluating the activities. For any policy, the criteria or indicators must indicate if policy implementation meets the needs of the target groups

and their demands. If these are met, it can be said that the policy implementation is successful (Guerci and Vinante, 2010). Other indicators in the evaluation of a public policy vary according to the policy's objectives and types of activities undertaken under the policy. As for public health policies, indicators can be equality in the distribution of public health services (Gruffud, 2007), childbirth services (Avortri et al., 2009), and primary public health services (Alhashem et al., 2009). Being tangibly measurable, the target groups' satisfaction is an indicator that represents the level of success and failure of policy implementation. In addition, the number of patients and the degree of acceptance of the drugs among patients and medical personnel, especially doctors, who directly distribute drugs to patients, are some indicators for policy implementation assessment. Creating the target groups' awareness of, understanding of, efficient compliance with, and willingness to participate in, the policy will efficiently achieve the policy's objectives (Narang, 2010). However, evaluation of the policy's outcomes needs to be conducted over the long term to document outcomes and potential impacts (Nasser and Doumit, 2009). In terms of the access to public health services, it is found that service units, treatment, and access to medicines will identify the outcomes and potential impacts on people after they receive public health services under the policy (Thrasher et al., 2010). Compulsory licensing is a public health policy that is formulated to solve the problem of inaccessibility to drugs among patients living with chronic diseases, especially AIDS, cardiovascular disease, and cancer. Its objectives are to enhance patients' thorough and equal access to essential drugs and enhance their quality of life. Therefore, the patients and doctors who treat them are the target groups in the assessment of the policy.

The assessment addresses the following questions: Do patients suffering from the diseases have a more thorough and equal access to their essential drugs? Do they accept or are they satisfied with the drugs provided through compulsory licenses? Do doctors who prescribe the drugs for treating AIDS, cardiovascular disease, and cancer comply with the policy by using drugs with compulsory licenses? What are their practices? How do they provide information to build the patients' awareness, understanding, and acceptance of the drugs with compulsory licenses? How much is

the patients' quality of life improved, as compared with the time when they were not able to access essential drugs thoroughly?

## **4.4 Approaches for Policy Evaluation**

There are different approaches to evaluate policies or programs, each of which has its own principles, methodologies, concepts, strengths, and weaknesses. What an assessor needs to consider when conducting policy evaluation are the features, problems, objectives, and factors of the programs or policies, as well as the objectives of the evaluation. Policy evaluation involves different methods; they are typically divided into five types (Rossi, 2004)

### **4.4.1 Needs Assessment**

Being the first step in policy evaluation, a needs assessment is intended to reveal if a policy or program needs to be implemented and what social situations or needs force the policy or program to be born. The assessment deals with the nature and seriousness of a problem, target groups, and the policy and program that are developed to address the problem.

### **4.4.2 Assessment of the Theory of a Policy or Program**

The assessment deals with development of a conceptual framework based on logical assumptions that will lead to solutions during the assessment. Here, four key elements of the policy or program are assessed.

4.4.2.1 Inputs, which refer to management-related resources that are put into the processes of the program or activity implementation, such as personnel, budget, equipment, time, and venues.

4.4.2.2 Activities, which refer to steps of action, from the start until the output or outcome is received.

4.4.2.3 Outputs, which come from implementation of a program or activity under the policy. They are compared with work plans.

4.4.2.4 Outcomes, which are the result of implementation of a programs or activity under the policy. They can be divided according to three time periods:

1) Initial outcomes of a project or policy, which are directly assessed after activities under the program or policy, are completed.

2) Intermediate outcomes of a project or policy, which are assessed based on the impacts on matters related to the initial outcomes, as a result of the continuity of activities under the program or policy.

3) Long-term outcomes of the program or policy, which are assessed based on the outcomes according to the goals of the program.

#### **4.4.3 Assessment of the Process of a Program or Policy**

An aim of this assessment is to diagnose if approaches or activities carried out have complied with the plans to solve a social problem, and if they can solve the problem according to the established objectives. Another aim is to find weaknesses or defects in activities under the policy. The information can be studied to optimize the implementation. The assessment is conducted on the implementation of a policy, work plan, or program in all aspects, such as the consistency of management, objectives of services, performance in each part of the program, target groups' response to the program, access to services of the program, use of resources for implementation, target groups' and operating units' satisfaction with the implementation, and impacts of the policy. These can serve as feedback that traces the causes of the impacts or failure of policy implementation.

#### **4.4.4 Impact Assessment**

Which is to determine how much the program or policy implementation can solve the problem and if it poses any unexpected impacts. It considers if the outcomes can achieve the objectives and goals of the program or policy.

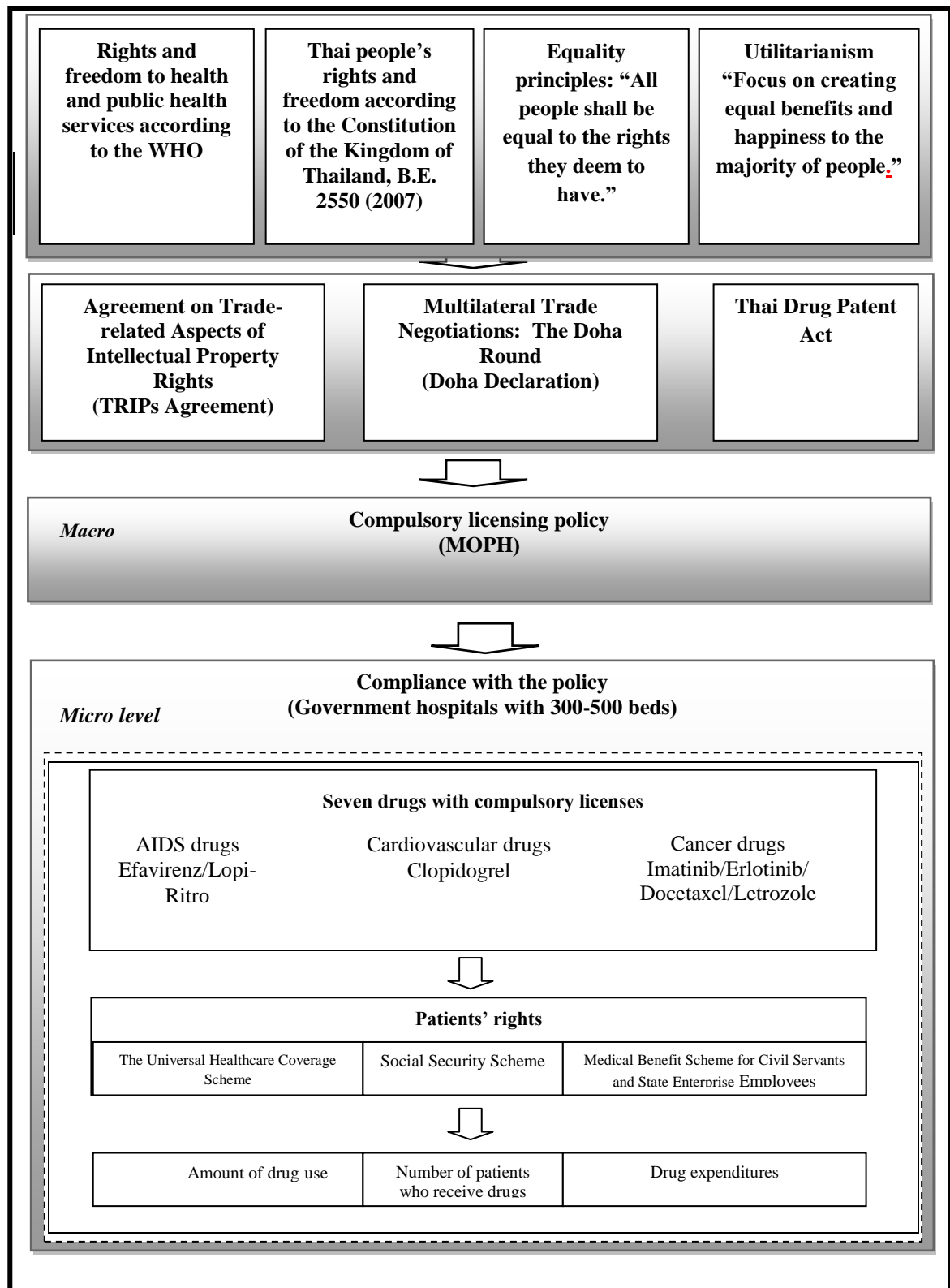
#### **4.4.5 Efficiency Assessment**

Which is focused on the worthiness of limited resources, in addition to program achievement. This assessment helps the policy or program run in accordance with social circumstances.

From the above, it is noted that steps of policy or program evaluation are crucial and have connections, ranging from the need to have a policy that resolves

public problems, to the problems or obstacles during the implementation. The aims are to identify shortcomings of policy implementation and to assess the outcomes and worthiness of policy implementation to detect its efficient achievement. This will help to form the picture of the policy and serve as information to improve the policy. It will also help to decide how to implement the policy to be in line with public's needs and social condition or if the policy should be cancelled.

From the aforementioned concepts and principles related to the formulation of the compulsory licensing policy, policy implementation, and policy evaluation, Figure 4.3 below provides a diagram to shape an understanding about the reasons, process, and approaches of this research.



**Figure 4.3** Approaches to the Research



## **4.5 Literature about Compulsory Licensing in Thailand and Other Countries**

A focus of most research conducted by academics on the compulsory licensing phenomena is the respective stages of the policy process, e.g. policy formation, legal consistency, and forecast of potential impacts of the formation of the compulsory licensing policy. Another focus is factors in policy implementation and forecasting of outcomes for improving the public's access to drugs among operating units. There are not many research works that focus on phases from policy formation to policy implementation due to limitations of the access to the sources for the information. Related to treatment of patients, especially for AIDS patients, the information is confidential. Moreover, some operating units (most of which are government hospitals that use drugs with compulsory licenses) have no data collection system; some do but their system is not modern. Therefore, the information is not complete for conducting research on the topic. The study on the outcomes of the policy entails only forecasting and relies on information provided by hospitals that are consent to provide the information. To study the processes, from policy formation to policy implementation, or from the origin until the end, medical personnel in government hospitals, e.g. doctors or pharmacists or agencies authorized by the MOPH to conduct research, are more likely to have more potential to access the information than outsiders. However, the research conducted by these medical personnel is usually concerned with duties and responsibilities of individuals with the major aim to produce academic work for their key performance indicators (KPI) evaluation.

The research works on the formation of the compulsory licensing policy in Thailand and other countries mainly focus on the legitimacy of the policy promulgation. Typically, they present disputes from stakeholders in this policy, who feel that the policy implementation is not the right action, as it violates the intellectual property protection law. The works suggest that improvement of public access to medicines by means of compulsory licensing complies with compulsory licensing law and fundamental human rights to access drugs, as endorsed by the WHO, the TRIPs, and the Doha Declaration. The works conclude that compulsory licensing is acceptable and legitimate, especially in the case when the countries are in urgent,

severe, and emergent circumstances or incidences which affects national security. They include wars, epidemics, and a shortage of consumer goods, e.g. drugs and food not for commercial use (McFetridge, 1997). It is also found that compulsory licensing is consistent with law and the right to use compulsory licensing to improve public access in necessary cases (Bartelt and Sandra, 2003). In the case of Thailand, there are studies about the consistency between compulsory licensing law and the TRIPs Agreement and the Doha Declaration. They show that there is consistency between them, and that compulsory licensing has been internationally recognized (Pearunya Potisathian, 2009).

Studies on the implementation of the drug licensing policy identify both successes and failures in the improvement of public access to medicines. For the success cases, compulsory licensing is the government's important tool that has been recognized for its effectiveness in improving the equal and thorough access to medicines among patients who need a continual use of drugs to save their lives and reduce suffering. When drugs are protected by their patents, they are costly, particularly for developing countries and underdeveloped countries. In these countries, the access to drugs is very low, as they have insufficient budgets. It has been proven that compulsory licensing is a significant method to improve patients' access to essential medicines and efficiently reduce mortality rates among patients with chronic diseases (Robert and Bird, 2008). As for some developed countries, for example, Canada, it has imposed compulsory licensing as efficiently as underdeveloped countries. It has succeeded in imposing compulsory licensing on Ciprofloxacin to reduce the spread of Anthrax and on other drugs to increase the public's thorough access to essential medicines. Despite an obstacle-no local industry producing raw materials for drug manufacturing-Canada's key to success was cooperation given by the domestic pharmaceutical industry in supporting materials and technology, as well as the willingness and strong support by the Canadian people who trusted generic drugs that were made in their home country under the policy (Sumana Chatterjee, 2005). In Thailand, there are studies about the effects of compulsory licensing on a generic drug (efavirenz 600 mg) under the Access to Care Program. When compulsory licensing was imposed on this drug by the MOPH, which imported the generic drug from India, it was found that the rate of access to the imported drug,

compared with the access rate under the Access to Care Program, increased by 79 percent. Medical personnel in hospitals also agreed that the compulsory licensing enhanced patients' access to essential drugs (Raksaworn Jaisa-ard, 2006). Despite the success in increasing public access to drugs in many countries, e.g. Canada, the compulsory licensing policy failed in some countries, especially in developing and underdeveloped countries, because of different factors influencing the compulsory licensing. For instance, in India, despite flexibilities in the compulsory licensing policy to improve public access to drugs, many factors prevented the policy from being implemented effectively. These factors included finances and resources for the local pharmaceutical industry, political support, domestic legal structure to support this implementation, and lack of good management for the policy implementation (Bassheer, 2000). The research by Shanker (2002) focused on South Korea's implementation of the compulsory licensing policy for Glevac, which was made by Novartis Co., Ltd. The policy was aimed at solving the problem of inaccessibility to the drug among leukemia patients. The policy allowed the Korean government sector or bodies authorized by the Korean government to produce the generic drug. The research showed that this case was a failure, which stemmed from the objection or non-support from the local pharmaceutical industry, including manufacturers of drugs and raw materials, which was a major factor influencing the discontinuity of the policy. In the case of Rwanda, an African country that encountered severe and uncontrollable AIDS pandemics, government support led to the failure of the use of TRIPS Flexibilities. Imposing compulsory licensing, the Rwandan government imported a generic drug for AIDS from Canada, but it did not comply with an item in the TRIPS Agreement-notifying the patent-owner company and paying remuneration. This resulted in a halt and delay in the policy implementation due to disputes between both countries. As for China, compulsory licensing was not impacted by internal factors, but external factors. A major internal factor was the economic factor. It was found that the WTO, whose member states were drug patent-owner companies, might take action to pressure China not to impose compulsory licensing by utilizing trade barriers, which would have great impacts on China's economy. As a result, compulsory licensing in China was halted and failed (Pang, 2003).

From the aforementioned studies, there are cases of both success and failure with respect to the implementation of the compulsory licensing policy. The policy implementation has been influenced by both internal and external factors; therefore, the success and failure factors must be taken into account during the research in the field. Having both direct and indirect impacts upon the policy implementation, these factors have linkages from the policy formation phase to the policy implementation phase. Implementation of the compulsory licensing policy involves many factors, and a question that needs to be asked is whether the policy's objectives are clear and appropriate. Apart from converting the policy into work plans for operating units to achieve the policy's goals, the government sector has to provide them with supporting resources or other factors and formulate supporting laws for operations and to respond to external factors that may affect the policy implementation, including political, economic and social factors. The factors include:

First: Clarity of the policy-clarity is a standard for a policy. It allows policy-implementing personnel to know what they are expected to do, including how and how much is expected of them. To achieve the policy's goals, the policy must be clear from the formulation stage, and issues related to the policy must be correctly interpreted. It must be ensured that the public policy has consistency with the needs or problem that is the focus or interest of the public. Basically, a policy deals with a particular problem that has an impact on the majority of the population. This problem must large, be something that is close to a population, and have a great impact on the public's life, emotions, or feelings. With these features, the problem attracts the majority of people, and the people would like the government to take action to deal with it by setting it as a public policy (Page and Shapiro, 1983). Information related to the needs and interests of most people, especially grass root people in developing or underdeveloped countries, is crucial in formulating a policy. If policy-formulating authorities pay attention to dealing with people's needs but do not understand their actual needs, the policy they have developed will be irrelevant, and this will be followed by problems and obstacles during policy implementation. If a policy fails to meet the public's need, it will fail to solve their problem (Sanger and Levin, 1999). Also, to implement a policy efficiently and successfully according to its goals, policy-implementing personnel in all operating units need to comprehend the problem

framework that leads to the policy formation, as well as the objectives of the policy formation (Coburn, 2006). The study by Foster (2011) on China's compulsory licensing policy aiming to solve economic problems revealed that China's lack of careful examination of existing problems and impacts of different factors in different provinces, e.g. socio-cultural factors, caused this policy to fail and face unexpected problems and obstacles during its implementation.

A policy issue must be defined and interpreted correctly to be in line with the public's needs, and a clear policy must contain clear details of its objectives and goals to ensure that they can be communicated to operating units and practitioners to understand easily. If this is achieved, it will allow government agencies to establish the objectives and goals of their work consistent with the government policy, as well as to link to the performance evaluation system using appropriate indicators (Schraven et al., 2011). Another important factor for a policy is the analysis of the objectives of the policy towards the communication network for the access to health services. In South Korea, it has been found that policy-implementing agencies' understanding of the policy's clearly-defined and practical objectives and goals will result in efficient operations in the same direction among the government sector, private sector, and other stakeholders. If this is achieved, it will lead to the terms of reference (TOR) that identify systematic implementation plans for executing agencies. Similarly, the Netherlands has provided established a law for the communication network for public health services, including medical services and access to drugs. The country has also determined the levels of the private sector's participation in holding partnerships with the government sector in this network (Menon, 2010).

Second : Political changes-A factor that has impacts on the compulsory licensing policy is political changes. Being related to the government or political authorities, e.g. political parties, this factor affects a public policy from the first policy process until the policy implementation because politics drives a public policy to solve problems in line with the public's demand. A public policy is formulated to address peoples' concern in accordance with their needs. This is consistent with the model presented by Easton (1957: 383-400), who presented a concept that a public policy stems from a response to politics. Under the concept, the government has to exist as a system, which entails the relationships between the political system and its

surrounding environment. Influencing the political system, the environment serves as a means of input in terms of demand or support. The environment within the political system can be culture, economy, and social structure; the environment outside the political system is other political and social systems. The political system is compared to an airplane's black box that allocates shared social values or makes decisions on policies, which will yield outputs for the political system. Outputs of the political system are returned to the environment in the form of impacts. The relationship in the model is a dynamic relationship, and adaptation is needed to create balance in the political system to ensure its sustainability. Therefore, it can be said that politics has a significant influence on public policy, especially with regard to resource allocation for implementation consistent with the needs of different groups of people in society (Cook, 2010). Political factors, i.e. political changes, support from political parties, budget allocations, and legislation, play a significant role in supporting and slowing the implementation of public policies, especially public health policies (Beck-Lewis and Michael, 1997). The research by Hauge and Scott, (2009) revealed that all political factors, including political parties, laws, budget allocations, and compensation can result in efficient policy formation and the achievement of the policy's goals. Apart from policy formation, political changes affect the success and failure of policy implementation, both directly and indirectly. This is also consistent with the findings of a study on the implementation of the decentralization policy for the management of the access to public health services in public health agencies in Ghana. The study showed a lack of resources, including personnel and budget monies, to support the policy implementation. In addition, political interference when political polarization occurred was another significant factor that froze activities under the policy, thus failing to achieve the goal (Sakyi et al., 2011). Likewise, the study on the social process, especially in organizations in southeast Mexico, showed that political changes and economic factors had significantly positive impacts on changes in the social process. On the positive side, public health policies resulted in improved living conditions and health. On the negative side, corruption could freeze the policy and the policy could not be fully exploited (Wilshusen, 2008).

Third: Policy resources-They are additional important factors that nurture and smooth operations by policy-implementing units, and they are, for example,

personnel, budget, and incentives. For operating units, the effective and efficient achievement of the policy's objectives and goals relies on these resources provided by policy makers. A resources-related policy significantly affects socio-economic conditions of operating units and practitioners, which is evidenced by the relationship between the allocated budget and policy implementation. Adequate and systematic funding support in policy implementation will lead to a significant achievement of the goals of policy implementation (Gloria and Carole, 2002). Furthermore, the gaps in the policy with respect to human resource management and policy implementation have direct negative effects on policy implementation. The factors that contribute to these gaps are labor unions, inadequate funding for management, unclear delivery of management power, uncertain timeframe for implementation, and political interference (Meyer, 2011). The study on the implementation of the budget allocation policy for public health services in Denmark and France by Anthon et al. (2010) revealed that this policy needed negotiations between government authorities and public health service units to equip them with an understanding about the policy's objective and goals. More importantly, it suggested that a negotiation had to be conducted on compensation in a written contract, which served as a guarantee and incentive for policy implementation. It was also an important factor that allowed government officers and public health services to work in the same direction, and it could prevent political interference, influence by groups, and corruption.

Fourth: Communication-The communication of messages between the policy makers and policy-implementing bodies is an important factor that links details of the policy's goals and objectives developed by policy makers and transforms the policy into activities and programs for policy-implementing bodies. Communication can shape a better understanding about the policy implementation among concerned practitioners at all levels through various communication methods. Accordingly, it plays a significant role in determining the success or the failure in fulfilling the policy's objectives. A factor that has a direct impact on communication is the vagueness of the policy's objectives. For example, during the implementation of the policy towards the comprehensive distribution of public health services in Brazil, operating units received distorted information, and their misunderstanding resulted in a complete failure of policy implementation (Gloria and Carole, 2002). In addition,

the failure in communication and relationships between organizations and between organizations and individuals, misunderstanding, or lack of attention to communication came from distorted information. Distorted information brings about distorted and incomplete concepts, attitudes, understanding, and perception; it is the root cause of conflicts and negative attitudes between agencies or between personnel within the same agency or between different agencies. Also, it can cause activities to fail to meet the desired goals (Sakyi et al., 2011). As a matter of fact, clear, precise and regular communication during the implementation process leads to activities that are in line with the policy's goals. Other than affecting activities during the policy implementation, miscommunication affects supporting factors of the policy. For example, there was a failure to enact laws and regulations to be enable efficient implementation of activities under the public health policy in South Africa because of a lack of communication regarding data storage management. The lack of a modern data storage system caused incomplete data and a failure to understand the public's issues and demands. The system was the cornerstone of the communication between policy makers and policy-implementing bodies (Ben-Ali, 2011). Involving different agencies, policy implementation requires communication on the basis of correct and clear information during the early stages of the process. If the objectives of a policy are clearly set, policy makers can convert the policy into work plans. Communication about the work plans can be conducted by explaining their details to operating units to implement. Likewise, operating units need to communicate the work plans to practitioners to ensure correct and efficient implementation.

Fifth: Characteristics of policy-implementing agencies-They include the structure of respective agencies, which consist of the line of command, formality in working, as well as qualifications of personnel in operating units. There have been numerous studies completed on the relationship between the characteristics of agencies and policy implementation, and they suggest that Ripley et al., the agency characteristics had direct and indirect impacts on policy implementation (1973). For instance, the Timor government formulated a public health policy with the purpose to promote its population's well-being and the quality of life. To accomplish this, both original and generic drugs were provided for patients in hospitals or public health facilities in replace of original drugs alone. This policy was not satisfactorily



successful as a result of the characteristics of the operating units. The units were found to be too informal, have unclear structure, and lack strict regulations. Because the practitioners' culture, concepts, and attitudes could not be adjusted immediately according to the policy, essential activities ran slowly and the policy was difficult to comply with. Qualifications of personnel in the operating units also played a significant role in policy implementation. To run activities to achieve the policy's goals, the personnel should have ample expertise and understanding about what tasks they would perform. If they were deficient in expertise, the policy implementation failed to achieve the goals. This notion is supported by many studies (Reynold, 2010). Many studies on the implementation of the policy for public health management revealed that a significant factor for the success in policy implementation was personnel with expertise and understanding about the implementation of activities of their operating units (Gkeredakis et al., 2011).

Sixth: Practitioners' attitudes-The attitudes of the policy-implementing personnel substantially contribute to policy implementation in terms of response to, willingness to accept, and dedication to do, activities undertaken under the policy. If they have positive attitudes towards the policy, they will be willing to accept and fully respond to activities, which will fulfill the policy's desired goals. On the other hand, if they are equipped with bad attitudes towards it, they will not agree with the implementation, thus resulting in conflict with, and resistance to, the policy and then failure in the policy implementation. This is confirmed through research on the attitudes towards the use of generic drugs in replace of original drugs produced by the drug-patent owners. The samples in this research were doctors, pharmacists, and patients from five hospitals where generic drugs were substituted in replace of original drugs. The research showed that they rejected generic drugs because their distrust in their effectiveness and safety, as well as their perception of, and familiarity with, the therapeutic effectiveness of original drugs. They agreed with the use of generic drugs in a few cases-where no original drugs are available and saving treatment costs (Reeta et al., 2007). There are studies about the assessment of the use of generic drugs for patients in Finland. The assessment was conducted on their attitudes and experiences after the use of generic drugs instead of the original drugs for a period of three years. The study revealed that one-third of them had negative

attitudes towards, and negative experiences with, generic drugs, which partly resulted from their perception that generic drugs did not have therapeutic equivalence to the original drugs. One study was about the policy for introducing generic drugs to replace more expensive original drugs in the public health system. It suggested that medical personnel had negative attitudes towards generic drugs, so they neglected studying the details of these drugs. This was followed by a lack of clear knowledge and understanding about generic drugs, and this caused them to have problems explaining and communicating with their patients about the effectiveness of generic drugs compared with original drugs (Inge, Morten and Anne, 2006). In addition to attitudes, there are studies about pharmacists' knowledge of the properties of drugs that would be registered as generic drugs, ingredients of generic drugs, and factors related to generic drugs and their ingredients. This knowledge was necessary for providing advice on treatments with cost-benefit considerations. It was found that because of their confidence that original drugs from foreign companies were more effective than generic drugs, many of them did not pay attention to the information received about generic drugs, even if the information was essential for indicating their effectiveness, e.g. bioequivalence (Mohamed et al., 2007).

As stated, crucial factors for the success in the policy implementation include communication, adequate resources, and incentives that urge practitioners to fully understand the policy and be ready to implement it with their full capacity. The study of Bhakoo Vikram and Chan Caroline focused on the introduction of the E-business policy for procurement in the public health system. This study showed that to achieve efficient policy implementation, apart from personnel's expertise in collecting basic data and high-level data for procuring drugs into the E-business system, the personnel's motivation to work and their supporting resources are important. Most academics have focused upon individuals' interactions, which were another crucial factor for fully effective and efficient working. Sussmann and Vecchio (quoted in Steer and Porter, 1991: 208-220) identified that motivation consists of two parts: 1) Motivation process, which is the belief that all humans have their own desires, and 2) Desire, which drives them to seek what they lack in order to respond to their desire. Rewards are used to motivate individuals to accomplish their responsibilities, which will help them achieve the objectives of their work. Sussmann and Vecchio (quoted in Steer

and Porter, 1991: 208-220) suggested that individuals' motivation stemmed from their being part of the organization, which exposed them to change according to various circumstances. A study conducted in West Midland was about pharmacists' satisfaction with their profession, current work, and future. It revealed that factors contributing to the pharmacists' satisfaction with their work were the environment of their workplace, importance of the role of the profession, and more importantly, and resources for conducting their work. All these were top factors that influenced elderly pharmacists to continue working beyond the age of 65 (Helen and Keith, 2001).

#### **4.6 Research Framework**

The compulsory licensing policy played an important role in public health in changing patients' access to medicines from 2006-2008, when AIDS pandemics were uncontrollable. During this serious circumstance and emergency, patients' inaccessibility to drugs for AIDS and other chronic diseases, which were costly, forced the Thai government to promulgate the compulsory licensing policy for seven drugs used for treating AIDS, cardiovascular disease, and cancer. This policy was formulated to endorse the National Health Act, B.E. 2550 under the Strategies for Universal Drug Coverage for the Thai Population. The purpose of this research was to investigate the background and needs for promulgating this policy and its implementation. The MOPH served as the host agency to oversee government hospitals, which were the central units dealing with processes related to compulsory licensing to achieve the policy's goals. The policy implementation in Thailand has taken into account the establishment of principles and processes related to compulsory licensing consistent with legitimacy and fairness in the patent-related principles. These patent-related principles are basic principles that link the concepts of protecting inventions and intellectual property, human rights, and flexibilities together with the rules, regulations, and agreements, for example, by the WHO, WTO, and the Doha Declaration. It is universally recognized that compulsory licensing is a legitimate and fair practice. One focus of this research was to study the implementation of the compulsory licensing policy by operating units to identify the levels of their acceptance of, and compliance with, the implementation of this policy, as well as

work plans or programs developed by the central agency. This research also examined the process of modifying the policy, work plans, or programs, as well as government hospital staff's confidence and willingness to comply with the policy in their work routine. It focused upon the working process of doctors who used drugs with compulsory licenses in government hospitals to improve patients' access to medicines, the goal of the compulsory licensing policy, as well as the linkage between the central agency and operational agencies. Also, this research dealt with the analysis and evaluation of the structure and functions in the policy implementation to improve access to drugs, as well as the consistency between the policy implementation and work plans and other applicable standards.

The author focused on the characteristics and attitudes of the target groups, who were patients who received access to essential drugs for the aforementioned diseases and doctors who prescribed these drugs with compulsory licenses, as they were affected by the policy implementation. Concepts, viewpoints, and practices of the target groups could be a real reflection of the outcomes of this policy.

The author analyzed the results of the research and assessed the relationship between the factors influencing the success and failure of operations for improving the drug access under the compulsory licensing policy, in terms of the characteristics of the policy, policy-implementing agencies, communication mechanisms, coordination within or between the policy-implementing agencies, and other environmental conditions that affect the access to drugs under this policy according to the research framework (Figure 4.1) and conceptual framework (Figure 4.2). This served as the analysis guideline that provides an insight into the improvement of drug access under the compulsory licensing policy among operating units, impacts of the implementation on the target groups, and factors that influenced the success or failure of the policy implementation. The results of this research will lead to guidelines for implementation to improve patients' access to drugs under the policy.

#### **4.6.1 Research Framework**

This research utilized both qualitative and quantitative methods to ensure the accuracy and reliability of the compulsory licensing policy. The qualitative method involved the study of the background and need for compulsory licensing in Thailand,

as well as the guidelines for the policy implementation, which can be linked to problems, obstacles, or factors that had impacts on the policy implementation. The reviewed literature on exercising the right of compulsory licensing, formulation of the policy, and the policy implementation indicated that there are many factors that influenced policy implementation. The conceptual framework for the qualitative research is as follows:

First step: This author studied the first set of the factors as a result of the formulation of the compulsory licensing policy. The factors included the clarity of the policy, the consistency between the policy and the problem, and political changes. They were studied to identify if they had direct or indirect effects on the policy implementation and to how they were related to one another.

Second step: This author investigated message communication, as this was an important factor for delivering details, clarity, and changes of this policy due to the three aforementioned factors. This will improve knowledge and understanding of operating units and practitioners, as well as build good relationships between operating units that need to cooperate with each other in implementing this policy.

Third step: This author investigated communication-related factors that had direct impacts on the policy implementation, including characteristics of the operating units, attitudes of practitioners in operating units, political changes, and budget for the policy implementation through programs or activities.

From the three steps of the qualitative research framework, this author described what factors influenced the policy, how much influence they had, and how they did in each step, if the factors were related to one another in each step (if yes, how much). This author also analyzed the relationship of respective factors as a whole again to develop conclusions and answer the research questions. The information allowed this author to propose the guidelines and suggestions for effective policy implementation.

As for the quantitative research, this author gathered information about the effects of the policy implementation to improve the patients' access to drugs and decreased drug costs during the years before and after the policy promulgation in order to evaluate the policy's achievement.

## **CHAPTER 5**

### **RESEARCH METHODOLOGIES**

This chapter mainly focuses on research methodologies, starting with research design. This research relied on mixed methods-qualitative methods and quantitative methods. Also, this chapter provides details about the specific objectives, concepts and methodologies of the qualitative research, which includes sampling techniques, interviewees for policy formulation, informants for policy implementation, fields of study, data collection, data validity, data analysis, and research ethics. With regard to quantitative research methodologies, data used in the study and analysis is presented.

#### **5.1 Research Design**

In this research, the design of research methodologies was an important step that continued from the information provided in the previous chapters. The previous chapters outline the significance of the research problem, review of phenomena of the compulsory licensing policy and the policy implementation, and related literature. Relevant theories, concepts, principles, and research about factors influencing the policy implementation led to the conceptual framework, questions and objectives of this research. This chapter explains research methods and other details that helped to answer the research questions and to meet the research objectives.

In research works, research methodologies are key guidelines for exploring the answers to research questions. That is to say, they determine appropriate alternatives for research so research questions are answered accurately in line with the objectives of the research (Jonker and Pennink, 2009). Research methodologies reflect researchers' set of ideas used for defining the research process systematically, precisely, and pertinently (Marshall and Rossman, 1999). In this research, mixed methods were utilized-the qualitative methods were the main methods, which were supported by quantitative methods. The mixed methods were intended to achieve preciseness and

reliability of the study on compulsory licensing. Qualitative research was conducted to answer the research questions, while quantitative data were utilized to confirm the results of the study of the policy evaluation. The procedures for this research are as follows.

## **5.2 Qualitative Research**

### **5.2.1 Specific Objectives**

The major objective of this research was to evaluate the implementation of the compulsory licensing policy in Thailand using four research questions:

5.2.1.1 What are the reasons and needs for compulsory licensing in Thailand?

5.2.1.2 What are the guidelines for the implementation of the compulsory licensing policy in Thailand? What are problems with, and obstacles to, its implementation?

5.2.1.3 What are the factors influencing the implementation of the compulsory licensing policy in Thailand?

5.2.1.4 What should the guidelines be and what are some suggestions for how to achieve effective compliance with the compulsory licensing policy?

In terms of the qualitative research, an analysis was conducted to define and design research methodologies. Topics that were considered were the philosophy of qualitative research, goals of qualitative research, and research design, which were based on the principles of Sauaders, Lewis, and Thornhill (2009).

### **5.2.2 Concepts about Qualitative Research**

Research paradigms reflect natural thinking and belief systems (Guba and Lincoln, 1994). They can be clearly seen in components of knowledge that are available at a particular time. Therefore, to define forms, processes, directions, and methods of research, researchers need to comprehend the philosophies of qualitative research in order to apply it as a basis for accurate and efficient research (Thomas, 2004). Philosophies applied in research methods are positivism and phenomenology. The positivist paradigm is derived from methods of finding realities in physical

science, which focus on casual realities. That is, it relies on empirical evidence from observations or experiments and mathematics as the language for analysis. The theme of research is establishing a causal relationship and exploring an explanation for this relationship. On the contrary, “phenomenology” is derived from the humanities, which focus on holistic views and surrounding contexts and rely on qualitative data and interpretation to develop an understanding. The differences between “positivist” and “phenomenological” paradigms are clearly recognizable, which are summarized in Table 5.1.

**Table 5.1** Differences between the Positivistic and Phenomenological Paradigms

	<b>Positivist paradigm</b>	<b>Phenomenological paradigm</b>
Basic beliefs	<ul style="list-style-type: none"> <li>- The world is external and objective.</li> <li>- The researcher is independent.</li> <li>- Science is value-free.</li> </ul>	<ul style="list-style-type: none"> <li>- The world is socially constructed and subjective.</li> <li>- The researcher is part of what is being observed.</li> <li>- Science is driven by beliefs and interests of humans.</li> </ul>
Researcher should:	<ul style="list-style-type: none"> <li>- Focus on facts.</li> <li>- Look for causality.</li> <li>- Reduce phenomenological simplest elements.</li> <li>- Formulate hypotheses and then test them.</li> <li>- Use quantitative methods.</li> </ul>	<ul style="list-style-type: none"> <li>- Focus on meanings of phenomena.</li> <li>- Try to understand what is happening.</li> <li>- Look at the totality of each situation.</li> <li>- Develop ideas through induction from concrete data.</li> <li>- Use qualitative methods.</li> </ul>
Preferred methods include:	<ul style="list-style-type: none"> <li>- Operationalizing concepts so that they can be measured.</li> </ul>	<ul style="list-style-type: none"> <li>- Using multiple methods to develop concepts about phenomena.</li> </ul>



**Table 5.1** (Continued)

<b>Positivist paradigm</b>	<b>Phenomenological paradigm</b>
- Use of theoretical frameworks to lead the study.	- No use of theoretical frameworks to lead the study on natural phenomena.
- Taking large samples.	- Small samples investigated in depth.
- Use a laboratory as the research field.	- Use a natural setting as the research field.

The main purpose of the analysis of reasons for formulating and implementing a policy is to reveal information that indicates if the policy has been implemented in line with its established objectives and guidelines; what factors have affected the policy implementation; and what issues in program implementation should be addressed. The guidelines for this research were developed based on “phenomenology.” This philosophy suggests that the world is socially constructed and subjective and the researcher is part of what is being researched. In addition, it focuses on the totality of a situation and tries to understand and define the phenomenon, using qualitative research methods, which involves small samples which are investigated in depth.

The implementation of the compulsory licensing policy in Thailand is always a dynamic phenomenon as a result of both internal and external factors. To explain and evaluate the policy implementation, the author studied it based upon attitudes and behaviors of the research population, in order to obtain information that reflects the actual phenomenon in issues studied. The compulsory licensing policy in Thailand has involved two parts. The first is the Ministry of Public Health (MOPH), the central agency responsible for formulating the policy and overseeing its implementation. The second part is government hospitals, which conduct activities relating to the use of drugs for patients under the policy, which is formulated by the MOPH. The author had to study and evaluate the policy implementation of executives and operational staff of both parts to determine the reasons and needs for the policy formulation and evaluate guidelines for the policy implementation in Thailand. Furthermore, the

author studied attitudes towards the policy amongst executives and operational staff at the MOPH and studied their practice guidelines that contributed to the policy implementation.

### **5.2.3 Qualitative Research Methodology**

The qualitative methodologies of this research dealt with sampling, choosing fields of study, data collection, data validity, duration of data collection, and data analysis.

#### **5.2.3.1 Sampling**

The purposive sampling technique was employed for key informants (sources) in government hospitals, which are the context of using drugs for which compulsory licensing has been issued. The snowball sampling technique was used for non-key informants in the research fields. The key informants were divided into two groups, as follows:

1) Key informants for policy formulation-The key informants were MOPH personnel who took charge of formulating the compulsory licensing policy. Interviewing them was intended to explore the reasons and needs for the use of compulsory licensing. They were members from the National Health Security Board (2006) the Subcommittee on the Selection of Essential Drugs and Medical Supplies with the Access Problem, the Committee on the Negotiation on Prices of Patented Essential Drugs, and the Committee on the Promotion of the Government Use Compulsory Licenses for Patents on Drugs and Medical Supplies.

2) Informants for policy implementation-Executives of government hospitals or government institutions that administer drugs under the compulsory licensing policy, including AIDS, cancer and cardiovascular drugs. They were divided into three groups, as follows:

(1) Directors of 12 university hospitals, as outlined in Table 5.2.

(2) Directors of 33 large-scale government hospitals, each having 300-500 beds. Despite having fewer beds, data from cancer hospitals were collected because patients at cancer hospitals were the target group that used cancer drugs with compulsory licenses, as presented in Table 5.3.

(3) Directors of the Government Pharmaceutical Organization (GPO), which is the central agency designated to produce, import, and sell drugs with compulsory licenses.

**Table 5.2** Number of Beds, Affiliation, and Types of 12 University Hospitals

No.	Hospital	Affiliation	Type	Number of beds
1.	Siriraj Hospital	Ministry of Education	University hospital	2,600
2.	Maharaj Nakorn Chiang Mai Hospital	Ministry of Education	University hospital	2,267
3.	<u>King Chulalongkorn Memorial Hospital</u>	Ministry of Education	University hospital	1,439
4.	<u>Phramongkutklao Hospital</u>	Ministry of Education	University hospital	1,600
5.	Ramathibodi Hospital	Ministry of Education	University hospital	959
6.	Rajavithi Hospital	Ministry of Education	University hospital	1,182
7.	Vajira Hospital	Ministry of Education	University hospital	875
8.	Srinagarind Hospital	Ministry of Education	University hospital	1,200
9.	Songklanagarind Hospital	Ministry of Education	University hospital	853
10.	Thammasat Chalermprakiet Hospital	Ministry of Education	University hospital	600
11.	HRH Princess Maha Chakri Sirindhorn Medical Center	Ministry of Education	University hospital	500
12.	Naresuan University Hospital	Ministry of Education	University hospital	200

**Table 5.3** Number of Beds, Affiliation, and Types of Large 300-500 Bed Government Hospitals and Cancer Hospitals

No.	Hospital	Affiliation	Type	Number of Beds
1.	Rajavithi Hospital	Ministry of Public Health	Central hospital	1,182
2.	Lerdsin Hospital	Ministry of Public Health	Central hospital	528
3.	Buddhachinnaraj Hospital, Phitsanulok	Ministry of Public Health	Provincial hospital	904

**Table 5.3** (Continued)

<b>No.</b>	<b>Hospital</b>	<b>Affiliation</b>	<b>Type</b>	<b>Number of Beds</b>
4.	Lampang Hospital, Lampang	Ministry of Public Health	Provincial hospital	862
5.	Sawanpracharak Hospital, Nakhon Sawan	Ministry of Public Health	Provincial hospital	653
6.	Chiangrai Prachanukroh Hospital, Chiang Rai	Ministry of Public Health	Provincial hospital	790
7.	Uttaradit Hospital, Uttaradit	Ministry of Public Health	Provincial hospital	647
8.	Nakhon Ratchsima Hospital, Nakhon Ratchsima	Ministry of Public Health	Provincial hospital	1,134
9.	Sapphasitthiprasong Hospital, Ubon Ratchathani	Ministry of Public Health	Provincial hospital	1,227
10.	Khon Kaen Hospital, Khon Kaen	Ministry of Public Health	Provincial hospital	867
11.	Udon Thani Hospital, Udon Thani	Ministry of Public Health	Provincial hospital	806
12.	Si Sa Ket Hospital, Si Sa Ket	Ministry of Public Health	Provincial hospital	700
13.	Surin Hospital, Surin	Ministry of Public Health	Provincial hospital	688
14.	Buriram Hospital, Buriram	Ministry of Public Health	Provincial hospital	590
15.	Chon Buri Hospital, Chon Buri	Ministry of Public Health	Provincial hospital	825
16.	Rayong Hospital, Rayong	Ministry of Public Health	Provincial hospital	555
17.	Prapokklao Hospital, Chanthaburi	Ministry of Public Health	Provincial hospital	733
18.	Chao Phya Abhaibhubejhr Hospital, Prachin Buri	Ministry of Public Health	Provincial hospital	622
19.	Ratchaburi Hospital, Ratchaburi	Ministry of Public Health	Provincial hospital	855

**Table 5.3** (Continued)

<b>No.</b>	<b>Hospital</b>	<b>Affiliation</b>	<b>Type</b>	<b>Number of Beds</b>
20.	Chaoprayayomraj Hospital, Suphan Buri	Ministry of Public Health	Provincial hospital	634
21.	Saraburi Hospital, Saraburi	Ministry of Public Health	Provincial hospital	700
22.	Nakhon Pathom Hospital, Nakhon Pathom	Ministry of Public Health	Provincial hospital	552
23.	Phra Nakhon Si Ayutthaya Hospital, Phra Nakhon Si Ayutthaya	Ministry of Public Health	Provincial hospital	433
24.	Paholpolpayuhasena Hospital, Kanchanabui	Ministry of Public Health	Provincial hospital	404
25.	Maharaj Nakhon Si Thammarat Hospital, Nakhon Si Thammarat	Ministry of Public Health	Provincial hospital	863
26.	Surat Thani Hospital	Ministry of Public Health	Provincial hospital	760
27.	Hat Yai Hospital, Songkhla	Ministry of Public Health	Provincial hospital	700
28.	Trang Hospital	Ministry of Public Health	Provincial hospital	453
29.	Lop Buri Cancer Hospital	Ministry of Public Health	Cancer hospital	132
30.	Chon Buri Cancer Hospital	Ministry of Public Health	Cancer hospital	167
31.	Surat Thani Cancer Hospital	Ministry of Public Health	Cancer hospital	120
32.	Ubon Thani Cancer Hospital	Ministry of Public Health	Cancer hospital	91
33.	Ubon Ratchathai Cancer Hospital	Ministry of Public Health	Cancer hospital	114

5.2.3.2 Field of Study: Twelve university hospitals and 33 large-scale government hospitals (300-500 beds) and cancer hospitals.

#### 5.2.3.3 Data Collection

The major data sources for this research were the phenomenon of compulsory licensing in Thailand at the MOPH and government hospital levels. It was analyzed using the inductive method; and the results of the analysis were interpreted to form knowledge, principles, or theories. For a clearer understanding about the policy implementation, secondary data were studied from documents prepared by policymakers, as well as academic papers, books, and articles.

1) Concepts and theories from academic papers, books and articles were reviewed, such as human rights, equality, drug patents, compulsory licensing, procedures for public policy implementation, models of study of public policy implementation, the compulsory licensing policy and guidelines for the policy implementation, and guidelines for evaluating the policy process. This was intended to define an appropriate framework to evaluate the policy implementation and to study details about the compulsory licensing policy of the MOPH and implementation plans on compulsory licensing in government hospitals. This analysis was conducted in order to have a better understanding about the policy and guidelines for the policy implementation in government hospitals and university hospitals that the MOPH provided for practitioners in the hospitals.

2) In-depth interviews-Face-to-face and phone interviews were carried out using open-ended questions and semi-structured interviews according to the research conceptual framework regarding compulsory licensing. Details and topics of these interviews about the compulsory licensing policy are included in Appendix A and Appendix B. The questions varied for each of the key informants.

5.2.3.4 Validity-In this research, the triangulation method was used for validating data from different sources by means of comparisons (Supang Chantavanich, 2003).

5.2.3.5 Period of Field Data Collection-The period from contacts with interviewees until the completion of the interviews of the key informants in the 300-500 government hospitals, university hospitals and cancer hospitals was from June to December 2013.

5.2.3.6 Data Analysis-Qualitative data analysis comprised three major components, which included data organizing; data display; and conclusion, interpretation, and verification. Each component is described more fully below (Mile and Huberman, 1994).

1) Data organizing-It was done using different processes and was divided into two parts: 1) Physical process-It mostly occurred while data were collected in the field. Tasks included transcribing, writing notes, forming conclusions, and storing data; 2) Content process-This was intended to explore the meanings of messages in the data in order to facilitate data organizing according to the meanings. Data organizing revealed meanings that might be implications of matters that had to be analyzed or encoded.

2) Data display-Data in the research was mostly presented as narratives, as a result of linkage of data organized according to the conceptual framework for the analysis. This process was intended to tell stories of what is being studied and the meanings of the well-organized data. In other words, data encoding was fragmenting a big block of data, while data display dealt with gathering the fragmented data to form a block of data.

3) Conclusion, interpretation and verification

(1) Conclusion-The process of identifying the following in the findings: patterns, probability, relationship, as well as differences and similarities, which had to be consistent with the facts.

(2) Interpretation-This process showed how important the findings or conclusions were in terms of concepts, theories and guidelines; and what implications the findings have in terms of the policy or activities.

(3) Verification-This process proved how accurate and reliable the conclusions were. It was divided into two types:

a) Internal verification, which focused on the quality of data sources and data collection methods.

b) External verification, which involved triangulation -The principle was that the researcher must not assume that the first source of data was reliable, but had to seek other sets of data. The data had to fall into three types- data that were similar to that from the first source (thesis), data that were different

from the first source (antithesis), and data that were different from the first two sets of data (synthesis) (Supang Chantavanich, 2003).

#### 5.2.3.7 Research Ethics

The researchers' codes of ethics and protection of informants' rights were taken into account. Considering the informants' consent to provide information, the author informed them of the right to make decisions on participating in the research. During the interviews, if any of the informants were not ready to provide their information, they could reject or leave the research at any time, without adverse effects or damage to them or others involved. This was based on two key principles:

##### 1) Privacy

The author respected the informants' privacy, opinions, feelings, and attitudes that comprise their confidential information, especially in issues that might affect their feelings and privacy. In addition, the private atmosphere during the interviews was maintained; distractions during the interviews were avoided, and the conversations were made to be natural. Great importance was given to manners, honor, and sincerity in order to create trust. The informants' privacy was not transgressed, whereby their needs and mental comfort were a top priority.

##### 2) Confidentiality

The author promised to maintain confidentiality and protect the privacy of the informants. Before the tape recording began, their consent had to be received. They were provided with an explanation that the tape recording was intended to provide detailed data with validity. Data in the tape were deleted after they were analyzed. In addition, the informants' names and workplace were not indicated because revealing this information might embarrass them or have psychological, social and economic impacts on them.

## 5.3 Quantitative Method

### 5.3.1 Quantitative Research Methodology

In this research, the purpose of the quantitative research methodology was to collect and verify collected data, as well as analyze the data to answer the research questions concerning the evaluation of the implementation of the compulsory



licensing policy. Data studied were indicators of patients' drug access after the promulgation of the compulsory licensing policy. The indicators are as follows:

#### 5.3.1.1 Data Used in the Research

1) A comparison was conducted on the number of new patients with better access to each drug after the promulgation of the compulsory licensing policy from 2006 to 2012 in the 33 large government hospitals and 12 university hospitals.

2) A comparison was conducted on the costs savings for each drug before and after the promulgation of the compulsory licensing policy from 2006 to 2012 in the 33 large government hospitals and 12 university hospitals.

#### 5.3.1.2 Data Analysis

1) A comparison was conducted on the number of new patients with better access to each drug after the promulgation of the compulsory licensing policy from 2006 to 2012 in the form of tables and bar graphs.

2) A comparison was conducted on the costs savings for each drug before and after the promulgation of the compulsory licensing policy from 2006 to 2012 in the form of tables and bar graphs.

## **CHAPTER 6**

### **IMPLEMENTATION OF THE COMPULSORY LICENSING POLICY IN THAILAND**

Secondary data and primary data from in-depth face-to-face and phone interviews with experts and qualified persons responsible for formation of the compulsory licensing policy in Thailand were collected. The findings extracted from the data included: reasons and needs for implementing the compulsory licensing policy in Thailand, reasons and needs for resolving the problem of patients' inaccessibility to drugs, solutions and policy formulation, the procedure for compulsory licensing, royalties for drug patentee companies for government use compulsory licensing, results of negotiations with drug patentee companies over the royalties, the management roles of the Government Pharmaceutical Organization (GPO) under the compulsory licensing policy, costs of production and development of drugs with compulsory licenses produced by the GPO, as well as costs of drugs with compulsory licenses that the GPO imported for sale in Thailand.

#### **6.1 Reasons and Needs for Implementing the Compulsory Licensing Policy in Thailand**

Public health statistics collected by the Bureau of Policy and Strategy indicated that from 2000, the rates of mortality, transmission and infection rates, as well as the growth rates of chronic diseases, especially AIDS, cardiovascular disease, and cancer had a sharp rise. They were among the top causes of deaths for Thai people (Ministry of Public Health, 2011). Therefore, these diseases constituted Thailand's major public health problems, which were mainly caused by the fact that their essential drugs were costly as a result of their patent protection. In 2001, on behalf of the Thai government, the MOPH promulgated the Universal Healthcare

Coverage Policy (Universal Healthcare Coverage Scheme (30 baht Healthcare Scheme)) to reduce drug expenses and improve the thoroughness and equality of the access to public health services for the Thai population with low-medium income. Also, the MOPH provided the Social Security Scheme and the Medical Benefit Scheme for Civil Servants and State Enterprise Employees to allow public health services to be accessed equally by the Thai population. Nonetheless, the subsidy for all patients in the entire public health welfare system was insufficient. This also had a chain effect on people without a right to medical care in the public health welfare system-they could not afford expensive drugs. Seeking solutions to the problem of patients' drug inaccessibility, the MOPH had to assess different relevant factors, including advantages, disadvantages, impacts, as well as unexpected results, and then chose the optimal solution for consideration of formulating a public policy. This complied with the process of the public policy formation according to Easton (1965: 9-16). As a matter of fact, many solutions to this problem were detected; for example, increasing public health budget monies every year and adding essential drugs to the National Essential Drug List. However, because these solutions failed to tackle this problem and could not reduce costs of essential drugs equally and thoroughly, the MOPH considered compulsory licensing according to Sections 51 and 52 in the Thai Patent Act, B.E. 2522 (1979). The GPO was assigned by the MOPH to import, produce and sell the essential drugs to feed into the national public health system and to promulgate compulsory licensing as a national public policy. Compulsory licensing must be conducted for any business that deals with public utilities, or is of vital importance to the defense of the country, or prevents or relieves a severe shortage of food drugs or other consumption items, or is for any other public service. In this regard, any ministry or department of the government may promulgate compulsory licensing without a need to negotiate with the patentee, but they shall notify the patentee in writing without delay and shall pay for remuneration for the use of the drug to the patentee and shall submit its offer setting forth the amount of remuneration and conditions for the use of the drug to the Director-General of the Department of Intellectual Property (Patent Act, 1979). Compulsory licensing cannot be imposed for any commercial purposes. Considering compulsory licensing as a public policy, the MOPH evaluated advantages, disadvantages, worthiness and reasons for using this

option. The MOPH appointed groups of people to consider this matter and take actions to maximize the patients' benefits and minimize negative impacts on people who would lose benefits from this policy. The groups consisted of four committees and subcommittees, namely the National Health Security Board (2006), the Subcommittee on the Selection of Essential Drugs and Medical Supplies with the Access Problem, the Committee on the Negotiation on Prices of Patented Essential Drugs, and the Committee on the Promotion of the Government Use Compulsory Licenses for Patents on Drugs and Medical Supplies. In this research, the author attached great importance to defining the scope or theme for analyzing reasons and needs for formation and implementation of the compulsory licensing in Thailand. Data studied in the research included secondary data, which were from documents and other reliable sources, as well as in-depth face-to-face and phone interviews with people from the four committees. They were studied to obtain significant details about the formulation of the compulsory licensing policy as a public policy to solve the problem of patients' drug inaccessibility. The author was allowed to interview five people from the committees:

- 1) One member of the National Health Security Board (2006), interviewed on 7 July 2013.
- 2) One member of the Subcommittee on the Selection of Essential Drugs and Medical Supplies with the Access Problem, interviewed on 18 July 2013.
- 3) Two members of the Committee on the Negotiation on Prices of Patented Essential Drugs, interviewed on 1 and 15 July 2013, respectively.
- 4) One member of the Committee on the Promotion of the Government Use Compulsory Licenses for Patents on Drugs and Medical Supplies, interviewed on 2 August 2013.

## **6.2 Reasons and Needs for Imposing Compulsory Licensing**

### **6.2.1 Reasons and Needs for Solving the Problem of Patients'**

#### **Inaccessibility to Drugs**

The in-depth interviews with people from the four committees suggested that to understand the major reasons and needs for solving the problem of patients'

inaccessibility to drugs, it was necessary to know its dominant factors, by considering public health indicators about the transmission rates, infection rates, and mortality rates of the diseases. In 2006, the spread of AIDS was the most serious threat in many countries, especially in developing and underdeveloped countries. This also existed in Thailand, where there was a gradual and uncontrollable increase in mortality and infection rates. AIDS was a top cause of death of the Thai population; it had higher mortality and risk rates, which were mainly caused by other chronic diseases, e.g., cardiovascular disease and cancer. Nonetheless, people could not access public health services continually, especially essential drugs for lifelong use. The MOPH, a macro agency with direct responsibilities for public health issues, considered the problem of patients' inaccessibility to drugs to be a public problem that needed to be solved urgently, and its major cause was the costliness of drugs as a result of patent protection. Patent protection is provided for companies that have new inventions or developed products that yield benefits for mankind. However, it has a major drawback. That is, drug patent-owner companies will have an exclusive right to produce, sell, and import their patented drugs. The protection grants them the right to price the drugs, which results in a monopoly of the growth of drug markets.

The interviewed member of the National Health Security Board stated that in the meeting of the National Health Security Board, a resolution about drugs was as follows:

Drugs are merit goods, so the right to access drugs is a fundamental legitimate human right, and it is ethical for all people to be granted the right equally and thoroughly. On the other hand, "one poor person" and "one rich person" have one life equally. Therefore, all people, no matter being poor or rich, have a right to access drugs and health services in Thailand's public health system equally and thoroughly.

From the resolution on "people's right to equal access to drugs" in the meeting of the National Health Security Board, the problem of patients' inaccessibility to drugs became a public problem, which directly affected most of the Thai population in terms of public health. Consequently, the National Health Security Board proposed

that the MOPH discuss the issue and consider solutions to this problem. The interviewed member of the National Health Security Board said, “With regard to the problem of drug inaccessibility, solving this problem needs careful consideration because it involves many factors. Potential advantages, disadvantages, outcomes and impacts must be evaluated before the optimal solution is chosen.

According to the World Health Organization (WHO, 2004a), the problem of patients’ inaccessibility to drugs can be divided into four dimensions, from the highest to the lowest degrees.

1) Dimension 1: The drugs are not available in the country, or they are not available at the medical service counters, despite being registered in the country.

2) Dimension 2: The drugs are available in the country but are costly, so most of the population, with low-medium incomes, especially in underdeveloped countries or developing countries, cannot access the drugs equally and thoroughly.

3) Dimension 3: The drugs are available in the country but are costly. The government’s budget to subsidize the public health system is insufficient for purchasing or providing drugs for patients continually, which results in the problem of patients’ inaccessibility to drugs.

4) Dimension 4: The drugs are available in the country, and they have reasonable prices that people, in general, can afford. In addition, the government budget is sufficient for subsidizing the drugs. Nonetheless, the drugs are misused, which causes inaccessibility to drugs, too.

Considering different indicators, e.g. drug use statistics, volume of imported drugs, infection rates, disease transmission rates, and mortality rates of patients in Thailand, the interviewed member of the National Health Security Board added that Thailand’s drug access problem is mostly characterized as Dimension 1 and 2, while Dimension 3 and 4 have been increasing (MOPH, 2009). As for the fact that this problem has been constantly serious, he added, “This problem has resulted from many weaknesses or defects in Thailand,” which are as follows:

Firstly, Thailand has no mechanisms for controlling drug prices or for pricing drugs clearly and carefully in an efficient way. Instead, it focuses on mechanisms for controlling prices of other products, e.g. rice and other products. This may be because the Price Control Commission, under the Ministry of Commerce, has inadequate

knowledge about the necessity for some drugs, which leads to free mechanisms of drug markets. For example, the cost of a tablet is one baht, but its selling price may reach 100 or 1,000 baht or more. Also, there is no management for clear and careful price control. This allows drug patent-owner companies with legal patent protection to price their patented drugs freely. Their action is characterized as “monopolizing drug prices,” which has mainly resulted from the change in patent protection in 1992, from the process protection to the product protection with the protection period being extended from 15 to 20 years. This has apparently resulted in changes in the ways drugs are used. The ratio of the value of drugs imported to the value of locally-produced drugs in Thailand in 1992 was 30:70. After the change in characteristics of patent registration and the protection period, this ratio changed to 75: 25 (Food and Drug Administration Thailand, 2007).

The growth rate of the overall drug costs in Thailand is similar to that of the overall health costs, which represents 7-8 percent per year. This growth rate is higher than the growth rate of the GDP, which is 5-6 percent per year. This makes drugs, which are an important factor of Thailand’s health system, tend to have higher costs. From 1995 to 1999, drug costs accounted for approximately 30 percent of the overall health costs and reached 40 percent in 2003 (Suwit Wibulpolprasert, 2008). The National Drug Account showed that the value of domestic drug consumption at customers’ price in 2010 was 144,570 million baht, and the drugs were distributed via different channels-hospitals, pharmacies, non-bed health institutions, and others, which represented 63, 26, 6 and 5 percent, respectively (Nusaraporn Kessomboon, 2002). Furthermore, a survey by the Intercontinental Marketing Service (IMS) revealed that that drug costs tend to increase quickly for the overall market shares in Thailand, which may result from the fact that some drugs are sold by a sole seller and must be imported (original drugs), and drug importation tends to rise sharply every year.

As for hospitals, which are a major drug distribution channel, the value of drugs distributed to patients via government and private hospitals in 2008 was approximately 70 billion baht, which was a 16 percent increase from 2008 (Plan on Mechanism for Monitoring and Development of Pharmaceutical Systems, 2009). The value gave huge profits to pharmaceutical companies, especially large pharmaceutical companies that patented essential drugs used by a large number of people across the

world. This resulted in a monopoly by the original drug business without competition under market mechanisms. The data of total sales of drugs revealed that the pharmaceutical industry could make the greatest profits, followed by the oil industry. The profit represented over 20 percent of the total sales (DIUS, 2007), especially pharmaceutical companies that had a monopoly on original drugs that they patented. Most pharmaceutical companies utilized different business tactics to gain the maximum benefits from drug sales (OECD, 2008). Some of the common tactics used include:

- 1) Continual applications for patenting a certain drug to prolong the monopoly in the drug markets.
- 2) Expansion of new original drugs, which is not to improve therapeutic efficiency but to stimulate the new market and register the new products to continue monopolizing the drug markets.
- 3) Litigation to prevent infringement upon patents, which is to protect their intellectual property.
- 4) Patent linkage to prevent the registration of generic drugs while the original drugs have patent protection, such as controlling information about raw materials and drug recipes.
- 5) Production of generic drugs for sale by original drug-manufacturing companies with cheaper prices, but still more expensive than other original drugs, in order to compete with another market.
- 6) Discounting drug prices to maintain the drug markets when they have competitors, for example, when their drug patent has expired or when a new drug has been launched to the market.
- 7) Prevention of price differential between countries within the same region by setting a single price within the region.
- 8) Negotiation over drug prices without data revelation in countries where price sensitivity exists.

In addition to the aforementioned business tactics aimed at generating profits, pharmaceutical companies are able to maintain or increase their drug sales. Their key tactics in sales promotion are access and presentation of features of drugs to medical professionals. This is to create reliability and draw feedback from the medical



professionals, both advantages and disadvantages, quickly and timely. Also, to communicate directly with consumers they invest in advertisements to promote products that focus on properties and effectiveness of their drugs. Most original drug companies spend 18 percent of their sales on sale promotions, which is similar to the money spent on drug research and development (Donohue et al., 2007).

As for the ratio of the drug import value, the interviewed member of the National Health Security Board said the following with respect to the locally-produced drug value: “The dramatically changing ratio of drug import value to locally-produced drug value and the growth of drug expenditures does not mean that the public health system and the Thai population switch to imported original drugs for a single reason. However, the higher ratio of the drug value can result from several reasons, as follows:

- 1) Doctors’ attitudes towards, and trust with, original drugs presented by pharmaceutical companies and their use on patients-It is said: “Patients in Thailand are usually ‘guinea pigs’ for new drugs.”

- 2) Different guidelines on drug use among medical professionals.

- 3) Setting excessively high prices of imported drugs by pharmaceutical companies that are drug patentees, as well as inefficient mechanisms for drug price control in Thailand. Therefore, the value of money used for imported drugs has increased significantly, if compared with the value of locally-produced drugs, whose prices do not change significantly.”

Secondly, there are no clear or appropriate guidelines for establishing the degree of intellectual property protection for new inventions or new products. This is because new inventions or products have value to society and there are ethical and humanitarian impacts, especially inventions or products that provide basic necessities and affect peoples’ lives. For instance, “drugs” are one of four basic necessities that relieve men’s suffering and improve their quality of life. The problem may be derived from the Thai Commissioner of Patents’ inadequate knowledge and understanding about drug patents and intellectual property, especially in drugs, as well as economic and political pressure from global superpowers.

Thirdly, there is a lack of support for building the production capacity for the domestic pharmaceutical industry to allow it to compete with foreign pharmaceutical companies, especially funding support from the government sector for research of

new drugs and for personnel development to generate knowledge about drug manufacturing technology. More importantly, the government sector has failed to boost the public's confidence in locally-made drugs, so Thailand has to import drugs. This results in a huge expenditure of public health budget monies for drugs.

### **6.3 Solutions and Policy Formulation**

After the MOPH, the National Health Security Board, and other stakeholders assessed the reasons and needs related to the problem of patients' drug inaccessibility, they identified different solutions for consideration. Solutions taken into consideration by the National Health Security Board are as follows:

The interviewed member of the National Health Security Board said, "The MOPH and the National Health Security Board took into account four potential solutions to the problem of patients' inaccessibility to drugs. The results of, and reasons for, the identified solutions are as follows:

1) Solution 1: Negotiating with drug companies to reduce the prices of essential drugs that patients cannot access, because the government sector could not sufficiently subsidize the expensive drug costs.

2) Solution 2: Allocating more budget monies for public health, especially for drug costs with the objective to procure essential drugs to improve patients' drug access. Nonetheless, despite an increase in budget monies for drug procurement, it was inadequate. Furthermore, the demand for essential drugs among patients in Thailand varied to morbidity rates.

3) Solution 3: Adding the essential drugs to the National Essential Drug List for patients under the public health care schemes, i.e. the Universal Healthcare Coverage Scheme (30 baht Healthcare Scheme), the Social Security Scheme, and the Medical Benefit Scheme for Civil Servants and State Enterprise Employees. However, because of patent protection, most essential drugs were costly. Many essential drugs were not added to the National Essential Drug List as a result of the government's insufficient budget monies for the drug costs.

4) Solution 4: Imposing compulsory licensing, which was specified in Section 51 and 52 of the Thai Patent Act, as follows:

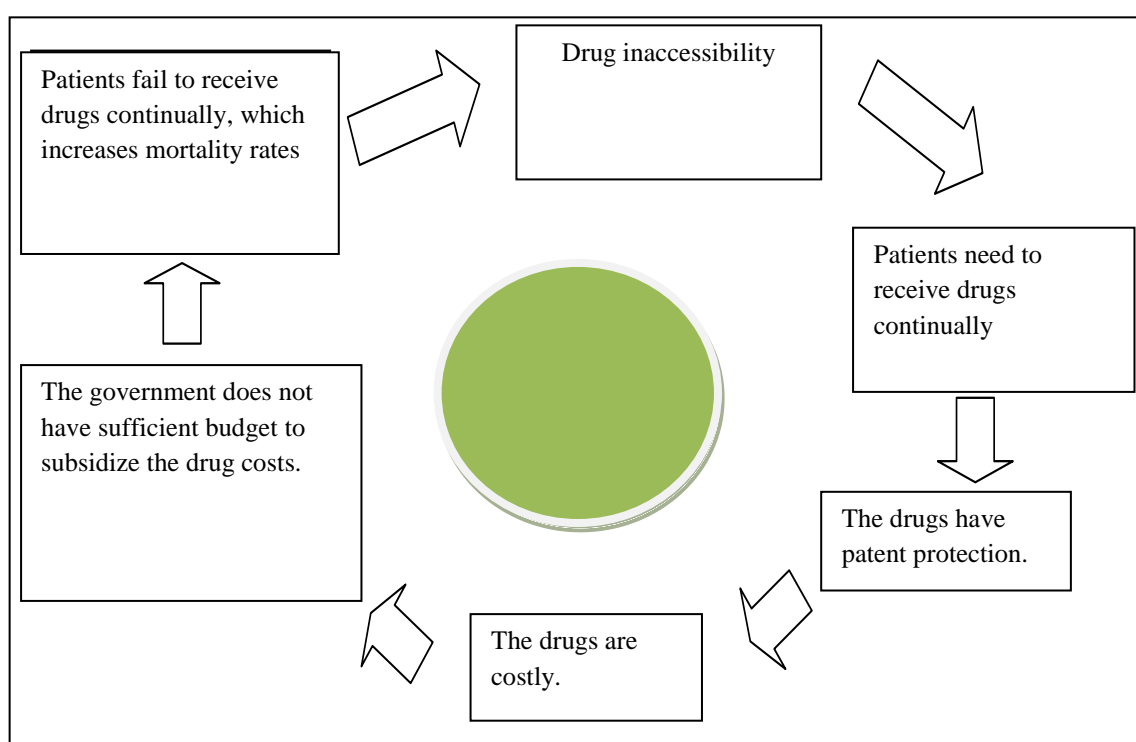
In order to conduct any business that deals with public utilities or is of vital importance to the defense of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service, any ministry, bureau or department of the government may, by themselves or through others, exercise any right by paying a royalty to the patentee or his exclusive licensee and shall notify the patentee in writing without delay. In the circumstances listed in the above paragraph, the ministry or bureau or department shall submit its offer setting forth the amount of remuneration and conditions for the use of patented drugs to the Director-General. The royalty rate shall be as agreed upon by the ministry or bureau or department and the patentee or his licensee.

Section 52: During a state of war or emergency, the Prime Minister, with the approval of the Cabinet, shall have the power to issue an order to exercise any right held under any patent which is necessary for the defense and security of the country by paying a fair remuneration to the patentee and shall notify the patentee in writing without delay. The patentee may appeal the order or the amount of remuneration to the court within sixty days from the receipt of the order.

Among the four solutions, it was noted that “the national public health budget” had a great influence on these solutions. As for Solutions 1, 2, and 3, the national public health budget was a key factor that pushed Solutions 1, 2, and 3 to cope with the problem. That is, if public health budget monies could be increased without limits and were sufficient for drug costs for patients in the entire public health system (despite an increase in the number of patients in the system) negotiation over drug prices was not needed, and the essential drugs could be added to the National Essential Drug List to provide equal and thorough treatment. Augmenting public health budget monies was impossible. As a developing agricultural country, not an industrial country, Thailand’s revenue was in the medium range, and it needed to be allocated for the country’s survival and development. Most of budget monies could not be allocated for public health, and their amount could not vary according to the increasing numbers of patients. Therefore, Solutions 1, 2 and 3 were not practical. As for Solution 4, it was exploitation of practical exceptions that were internationally recognized under law and agreements, with no need to increase public health budget

monies. On the contrary, Solution 4 might reduce the use of budget monies for the drugs; however, this included a risk to the country's image concerning intellectual property infringement unless ample explanations or clear communication were provided. Also, this could result in pressure, especially economic pressure, from countries of the drug patent-owner companies. When the advantages, disadvantages, risks, and worthiness were taken into consideration, Solution 4 was considered to be the most practical solution.

Considering the above-mentioned information, the MOPH Minister, the National Health Security Board, and those involved in policy formulation were aware that this problem was like a circle without a way out, as shown in Figure 6.1.



**Figure 6.1** The Problem of Patients' Inaccessibility to Drugs in Thailand

Concerning decisions for choosing the alternatives for solutions, the interviewed member of the National Health Security Board said:

Figure 6.1 shows that this problem has three major causes: the budget of the country, per capita GDPs, and patented drugs. Accordingly, Solutions 1-3 are not

practical. As for Solution 1: Negotiation over drug prices, the government attempted to negotiate over prices in early 2006, when AIDS transmission was uncontrollable, and AIDS mortality rates rose sharply. Drug price negotiation was necessary because AIDS drugs needed to be used continually for a patient's entire life to reduce illness and suffering and to prolong their life. On behalf of the MOPH, the committee working on the procedure for formulating the policy to resolve this issue selected two drugs-Efavirenz and Lopimavir/Ritronavir-for price negotiation with patent-owner companies because the two drugs were first-line drugs for AIDS patients in the early stage. If they were not therapeutically effective, or their side effects were too strong to tolerate, other effective drugs with fewer side effects would be used. The committee negotiated over drug prices to the levels that the government sector and patients could afford, while allowing patent-owner companies to survive-the situation was called a "win-win" situation. However, the negotiation was not satisfactory because the patent-owner companies "offered a 0.01% discount off the selling prices." One reason was that they had been granted legal protection for the drugs. Another important reason was the demand for the drugs of patients suffering from chronic diseases exceeded the drug supply in the country's public health system. The patent-owner companies took advantage of this situation, considering that "whether the drug prices are the same or reduced," these drugs were needed in the country. As the per capita GDP of the Thai population was mostly medium-low, they could not afford higher drug costs when added to their living costs.

For a clearer picture, the interviewed member of the National Health Security Board provided an example: "For example, per capita GDP = drug prices per year/affordability for drugs per year. Annual per capita GDP of the Thai population was approximately 600,000 baht; however, the expense for Imatinib for leukemia and colon cancer was 600,000 baht for two years. If they paid for the drugs for two years, they could not afford other necessities. This was the conclusion about the inaccessibility to drugs among the Thai population. The patented essential drugs were costly, and the government sector could not allocate budget monies unlimitedly to subsidize the drug costs. This was why Solution 2, increasing public health budget to subsidize the drug costs, was impossible. As for Solution 3, adding drugs to the National Essential Drug List for patients under any right to any public health care schemes-the Universal

Healthcare Coverage Scheme (30 baht Healthcare Scheme), Social Security Scheme, and the Medical Benefit Scheme for Civil Servants and State Enterprise Employees, this choice would be impractical, too, due to the government's insufficient subsidy to the drug costs.

For this reason, the MOPH Minister, the National Health Security Board, and people involved in the policy making assessed Solution 4: Compulsory licensing. The MOPH conducted research for the evaluation of potential effects, advantages, disadvantages, risks, and impacts as a result of compulsory licensing from 2006 to 2008 (Intira Yamabhai, 2006b). It also studied legal agreements concerning the patent-owner companies, economic advantages and disadvantages, as well as resistance or support from stakeholders within and outside the country. An informant said:

Comparing potential advantages, disadvantages and risks, the MOPH Minister, the National Health Security Board, and people involved in policy making agreed that 'Solution 4: Compulsory licensing' may be the most appropriate and practical, when compared with the other solutions." A ministerial order was issued by the National Health Security Board to appoint three committees to be responsible for the procedure for government use of compulsory licensing in Thailand. The committees included the Subcommittee on the Selection of Essential Drugs and Medical Supplies with the Access Problem, the Committee on the Negotiation on Prices of Patented Essential Drugs, and the Committee on the Promotion of the Government Use Compulsory Licenses for Patents on Drugs and Medical Supplies. They were designated to operate under agreements, regulations, and requirements for the procedure for government use of compulsory licensing in Thailand so as to be compliant and pose minimal disadvantages to the country. They prepared a proposal for imposing government use compulsory licensing as a policy and submitted it to the MOPH Minister for consideration. The policy was first promulgated for three drugs: Efavirenz, Lopinavir/Ritonavir and Clopidogrel in 2006. In 2008, it was imposed for four drugs: Imatinib,

Erlotinib, Doxetrexel and Letrozole. The GPO, affiliated with the MOPH, acted as the representative of the government to produce or import drugs with compulsory licenses to sell to government hospitals in Thailand.

## **6.4 Compulsory Licensing Procedure**

### **6.4.1 Selection of Essential Drugs for Compulsory Licensing**

The Subcommittee on the Selection of Essential Drugs and Medical Supplies with the Access Problem had the responsibility for studying the needs of drug use and selecting essential drugs under criteria set forth. The interviewed member of the Subcommittee stated that to select drugs to impose compulsory licensing on, their need must be taken into account. Essential drugs have clear criteria: essential drugs must be on the National Essential Drug List, or drugs that are essential for solving a public health problem or emergency, or drugs that are needed during epidemics or for saving patients' lives. Non-drug medical supplies are also included. The consideration requires surveying the problems and needs of patients, needs of disease experts, and other stakeholders. After that, drugs are prioritized in terms of their need and worthiness for compulsory licensing. Factors that are considered include the public health problem that impacts the mortality rates of the Thai population, drug prices, and the comparison between original drugs and generic drugs in terms of costs and therapeutic efficiency. After a conclusion is reached, the list of essential drugs proposed for compulsory licensing is submitted to the MOPH Minister for reconsideration of the need for drug use and of essential drugs that must have compulsory licenses. The interviewed member of the Subcommittee on the Selection of Essential Drugs and Medical Supplies with the Access Problem said that in 2006, the AIDS infection and mortality rates in Thailand increased continually and were uncontrollable. This resulted from the fact that essential drugs used for AIDS during the early treatment stage-Efavirenz and Lopinavir/Ritonavir-were patented drugs. As an essential AIDS drug under the trade name Socrin 600 mg, Efavirenz belongs to Merck Sharp & Dohme Co., Ltd. and it has therapeutic efficiency for patients who are allergic to, or cannot tolerate side effects of, the first-line drug-GPOVIR. GPOVIR

contains Nevirapine, which can result in allergic reactions and has side effects, and it is on the National Essential Drug List. As for Lopinavir/Ritonavir, its trade name is Keletra<sup>®</sup> and belongs to Abbott Laboratories Co., Ltd. It is an essential drug for patients who have resistance to GPOVIR. Also, GPOVIR causes complications called “opportunistic diseases,” which are fatal if patients do not receive other essential drugs. In the meantime, the incidence and mortality rates of cardiovascular disease increased gradually, too. Essential drugs for this disease must be used for preventing coagulation and blood clots, especially for myocardial ischemia and cerebrovascular accidents. The failure to receive preventive drugs can cause a heart attack or paralysis and can be life-threatening. Its essential drug is Clopidogre, the trade name of which is Plavix<sup>®</sup> and belongs to Sanofi-Synthélabo Co., Ltd. This is why these three drugs were so expensive that patients could not access equally and thoroughly.

Furthermore, the interviewed member of the Subcommittee on the Selection of Essential Drugs and Medical Supplies with the Access Problem said that in 2008, four essential drugs for cancer were proposed for compulsory licensing because of a sharp rise in the cancer incidence and mortality rates, especially breast cancer, lung cancer, gastrointestinal cancer, and leukemia. The essential drugs have therapeutic efficiency during the early treatment stage. Due to patent protection, the drugs were expensive, which resulted in the problem of drug inaccessibility. This was similar to the first three drugs considered for compulsory licensing in 2006. Finally, compulsory licensing was considered for the following four cancer drugs.

- 1) Imatinib (trade name or original drug: Glivec<sup>TM</sup>), which was used for treating leukemia and GIST and patented by Novartis Co., Ltd., Switzerland.
- 2) Docetaxel (trade name or original drug: Taxotere<sup>TM</sup>), which was used for treating lung cancer and breast cancer and patented by Sanofi-Avantis Co., Ltd., France.
- 3) Erlotinib (trade name or original drug: Tarceva<sup>TM</sup>), which was used for treating lung cancer and patented by Novartis Co., Ltd., Switzerland.
- 4) Letrozole (trade name or original drug: Femara<sup>TM</sup>), which was used for treating breast cancer and patented by Roche Co., Ltd., Switzerland.



#### **6.4.2 Negotiation with Patent-owner Companies over Prices of Drugs Considered for Compulsory Licensing**

The Committee on the Negotiation on Prices of Patented Essential Drugs, chaired by the Secretary General to the Thai FDA, was set up to be in charge of drug price negotiation with patent-owner companies. An interviewed member of the Committee on the Negotiation on Prices of Patented Essential Drugs stated that Section 31B of the TRIPs Agreement identifies a requirement for negotiations with patentees about compulsory licensing: “Exercising the right is allowed when beforehand; the applicant has shown an attempt to receive a license from the patentee under reasonable commercial requirements and conditions. If this attempt fails within a reasonable timeframe, the requirements can be waived in the case of emergencies or non-commercial public interest” (WHO, 2005). The Patent Act, B.E. 2522 (1979) and amended version, B.E. 2535 (1992) and B.E. 2542 (1999), in Part 2, which states that obligations related to negotiations with the patentees in the case when government use compulsory licenses are issued for non-commercial public purposes can be exempted from prior mandatory negotiation. As a matter of fact, according to the TRIPs Agreement, Section 31 B, and Thai Patent Act, B.E. 2522 (1979) and amended version, B.E. 2535 (1992) and 2542 (1999), in Part II, in practice, the MOPH was not required to negotiate over the prices with patent-owner companies. Nonetheless, the MOPH regarded that negotiations should be conducted to honor the patent-owner companies and to ensure minimal impacts. Therefore, the Committee on the Negotiation on Prices of Patented Essential Drugs was set up to represent the government to negotiate over drug prices before imposing compulsory licensing. If the Committee succeeds in negotiating to reach affordable drug prices for patients and the government sector to ensure patients’ thorough and equal drug access, while keeping the patent-owner companies’ survival (win-win situation), compulsory licensing does not need to be continued. If drug price negotiations fail, the Committee will reassess and make a conclusion, by collecting negotiation-related information and submitting it to the MOPH Minister for reconsideration. An interviewed member of the Committee said that for the seven drugs considered for government use compulsory licensing, the Committee attempted to negotiate with patent-owner companies over ten times within three months until the patent-owner companies

confirmed the reduced prices. Negotiations with each patent-owner company involved different details, conditions and issues, which included the following:

1) Drug patent-owner companies that did not agree with, or cooperate in the negotiation as expected, and they disagreed with compulsory licensing. Sanofi-Aventis Co., Ltd., the patentee of Clopidogrel (Plavix<sup>®</sup>), was in this case. The company thought that there were other efficient alternatives for treating cardiovascular disease, and this was not different from compulsory licensing for Clopidogrel (Plavix<sup>®</sup>). Similarly, Abbott Laboratories Co., Ltd., the patentee of Lopinavir/Ritonavir (Kaletra<sup>®</sup>), asked why compulsory licensing had to be imposed on Lopinavir/Ritonavir (Kaletra<sup>®</sup>). They stated that they had gradually lowered the prices of Lopinavir/Ritonavir (Kaletra<sup>®</sup>) from 2005 to November 2006, from 8,907.75 baht/bottle to 5,938.50 baht/bottle. Also, they said they had not been contacted by the MOPH for drug price negotiation (Office of the Secretary of the Senate, 2011). Furthermore, Abbott Laboratories Co., Ltd. responded to Thailand's actions by not registering ten new efficient drugs.

2) Price negotiation occurred, but the discount offered by the patent-owner the companies was just a slight change, when compared to generic drugs with therapeutic equivalence. It was found that the prices of original drugs of the patent-owner companies were very expensive compared to the generic drugs, such as Efavirez (Stocrin<sup>®</sup>) of Merck Sharp & Dome Limited and Letrozole (Femara<sup>®</sup>) of Roche Co., Ltd. (Secretariat of the Senate, 2011).

3) The patent-owner companies reduced drug prices under conditions – Prior to the negotiation, Sanofi-Aventis Co., Ltd. submitted a proposal to the MOPH by offering complementary Docetaxel 80 mg injections (Taxotere TM<sup>®</sup>) for 3,000 lung cancer patients in the health security system per year. As for breast cancer patients, Sanofi-Aventis Co., Ltd. said they would be responsible for 75 percent of their drugs costs and leave the remaining costs to be the burden of the Thai government. They did not propose discounts for Doxetrel 80 mg injection (Taxotere TM<sup>®</sup>). Sanofi-Aventis Co., Ltd. stated that they did not receive a response from the Thai government about this offer (Office of the Secretary of the Senate, 2011).

The Committee on the Negotiation on Prices of Patented Essential Drugs reasoned that during that time, the MOPH, on behalf of the Thai Government,

considered the fact that the MOPH had to be responsible for the remaining costs without receiving any discounts for the drugs. Considering that Sanofi-Aventis Co., Ltd. offered free drugs to only 3,000 patients in the health security system, the MOPH thought “this was almost useless.” This was because the number of lung cancer patients each year was tens of thousands. Under their offer, the MOPH had to be responsible for their drug costs at high prices as the same. As for the proposal for patients suffering from breast cancer, a disease with a high incidence rate, it implied that the MOPH had to bear the remaining 25 percent of the drug cost, which was still a great burden. Finally, the Committee considered that the company’s offer was not intended to seriously improve the patients’ drug access, and the MOPH’s burden of drug costs would not be different than before. Thus, the MOPH did not send a response back to Sanofi-Aventis Co., Ltd.

As a result, the MOPH implemented the procedure for imposing compulsory licensing. The MOPH assigned the Committee on the Negotiation on Prices of Patented Essential Drugs Negotiation to negotiate with Sanofi-Aventis Co., Ltd. over the drug prices. Later, Sanofi-Aventis Co., Ltd. submitted a new proposal, which included a reduction of drug prices under some conditions – a reduction of drug prices in relation to the quantities of order, and a reduction of drug prices which was bound to the number and conditions of patients. Sanofi-Aventis Co., Ltd. offered a discount for Doxetrel 80 mg injections (Taxotere TM®) from 25,000 to 3,750 baht per injection in the same strength. The condition was that each patient had to use the drug valued at least 1,500 baht per year under a yearly contract, and the drug must be included on the National Essential Drug List. Similarly, Navotis Co., Ltd. proposed lowering drug prices under certain conditions. In the case of Erlotinib 150 mg (TarcevaTM®), they proposed a discount to the drug, from 230 to 150 baht per tablet under the condition that at least 60,000 boxes of the drug be purchased per year.

An interviewed member of the Committee on the Negotiation on Prices of Patented Essential Drugs said that the Committee did not accept conditions included in the proposal by Sanofi-Aventis Co., Ltd. The Committee reasoned that these conditions resulted in a monopoly of drugs with reduced prices in exchange for large number of orders. For example, in the case of Doxetrel 80 mg injections, the condition was bound to the number of patients, and it was a yearly contract. Similarly,

Navotis Co., Ltd's proposal for Erlotinib 150 mg (TarcevaTM®) was characterized as a monopoly, whereby a drug price reduction was determined by the number of orders, which was not different from a yearly contract. In addition, under the conditions, the Thai government would be not able to purchase cheaper drugs during the contract, even though equivalent drugs could be imported from India at cheaper prices without conditions. Finally, the Committee considered that the negotiation over drug prices and conditions offered by these companies "was unacceptable, so the government use compulsory licenses must be imposed."

For Imatinib 100 mg (GlivecTM®), which treats leukemia and gastrointestinal cancers, Navotis Co., Ltd. offered a conditional proposal. This was because Imatinib 100 mg (GlivecTM®) was under the Glivec® International Patient Assistance Program (GIPAP) with the support by the MAX Foundation. Their condition included offering free drugs to "patients who are not under any health security system and they their yearly household income must not be over 300,000 baht." This criterion made it impossible for most of the Thai population to access the drug equally and thoroughly.

Concerning the negotiation on Imatinib 100 mg (GlivecTM®) under the Glivec® International Patient Assistance Program (GIPAP), an interviewed member of the Committee on the Negotiation on Prices of Patented Essential Drugs added that the drug had been supported by the MAX Foundation for a long time, so the negotiation was focused on "the revision of criteria and conditions to offer free drugs to patients more comprehensively." The old criterion covered only patients who have no medical care right in any public health care schemes and have low-very low household income. It supported only a certain number of patients, excluding patients who are eligible for medical care under a public health care scheme and who have moderate income, who are the majority population of the country. As a matter of fact, generic drugs at cheaper prices to replace Imatinib 100 mg (GlivecTM®) can be found. For Imatinib 100 mg (GlivecTM®), the Committee considered imposing a government use compulsory license on it. Later, the company offered a modified condition which included "offering free drugs to patients under the Universal Healthcare Coverage Scheme that have higher household income, from 300,000 to not over 1.7 million baht per year. This was applicable to patients who needed Imatinib 100 mg (GlivecTM®) for 400 mg per day and had an annual household income of not

over 2.2 million baht per year. In the case of Imatinib 100 mg (Glivec™<sup>®</sup>) amounting 600 mg per day, which operated under the Novartis' GIPAP, the Committee decided not to impose compulsory licensing for it, under the GIPAP. However, to ensure patients' regular drug use, the Committee considered imposing no compulsory licensing for Imatinib 100 mg (Glivec™<sup>®</sup>) under the condition: the government use compulsory licensing will be imposed on Imatinib 100 mg (Glivec™<sup>®</sup>) when the GIPAP ends or when Novartis does not comply with the agreement submitted to the MOPH.

#### **6.4.3 Promulgation and Implementation of the Government Use Compulsory Licensing Policy**

After the Committee on the Negotiation on Prices of Patented Essential Drugs conducted the drug price negotiation, which failed, they summarized the details and results of the negotiation and drafted and submitted a notification to the Committee on the Promotion of the Government Use Compulsory Licenses for Patents on Drugs and Medical Supplies for consideration to prepare a proposal to submit to the MOPH Minister. The proposal would assist the MOPH Minister in making decisions about endorsing the compulsory licensing policy for essential drugs that passed the price negotiation process. The GPO was designated as the government's representative to produce or import the drugs for sale at a fair price without surcharge as its profits – the drug price had to be based on drug and management costs only. On the other hand, “the GPO acted as the agent for delivering drugs with compulsory licenses only.” More importantly, they were not allowed to exploit these drugs commercially.

The interviewed member of the Committee on the Promotion of the Government Use Compulsory Licenses for Patents on Drugs and Medical Supplies said that the Committee was like a screening committee, which scrutinized all relevant details, including essential drugs and price negotiation of drugs on which compulsory licensing would be imposed. The Committee also provided supporting factors for operations related to compulsory licensing, notified operating units of relevant information, and coordinated work. Also, they prepared a proposal to assist the MOPH Minister in making decisions about endorsing the policy promulgation.

The interviewed member of the Committee added that the case of the four cancer drugs happened during a transition period from an appointed government to an elected government, with the change in the Prime Minister and cabinet. During this time, the policy implementation was ordered to be delayed. The Committee on the Negotiation on Prices of Patented Essential Drugs conducted price negotiations again to avoid economic impacts on the country, as happened in the case of the first three drugs that were issued compulsory licenses earlier. The second negotiation was a failure. Due to this failure, in conjunction with pressure from the general public, cancer patients and foundations, the MOPH Minister decided to endorse the promulgation of compulsory licensing policy for the four cancer drugs.

6.4.3.1 MOPH assigned “the GPO” to be the government’s representative to produce and import drugs for sale under the government use compulsory licensing policy

The interviewed member of the National Health Security Board said, “The MOPH assigned the GPO to represent the government to produce or import drugs for sale under the compulsory licensing policy. Private pharmaceutical companies were not authorized to do this because the GPO was assigned to act just like an “an agent taking charge of bidding and delivery for the drugs” to feed into the country’s public health system. The GPO had no capacity for producing drugs with compulsory licenses; transfer of drug production technology from countries equipped with high drug manufacturing standards took some time. Concerning the research and development that allowed the GPO to produce these essential drugs, inspections of quality standards of drug production and products was needed. These essential drugs needed to be the therapeutic equivalent to their original drugs. The inspection was similar to that carried out by the Thai FDA for other generic drugs or original drugs imported for registration in Thailand.

The interviewed member of the National Health Security Board provided another important piece of information-the most important agreement for compulsory licensing is that the GPO, a MOPH-affiliated state enterprise, shall comply with ministerial orders for producing or importing drugs with compulsory licenses to sell to hospitals, whereby profit making is strictly prohibited. Violation of the orders is against Doha’s TRIPs Agreement and the Thai Patent Act (Patent Act,

1979) in relation to the drug-patentee companies. This will pose serious impacts in terms of the law, reputation and image of compulsory licensing with the aim to improve patients' access to drugs for the Thai population.

Drug importation or production costs must be based on administrative costs, logistics costs, and other relevant costs; profit-making is not allowed. Private pharmaceutical companies cannot do this because they have different costs, such as water, electricity, logistics and overhead costs, as well as other costs, which can have an impact on their business.

#### 6.4.3.2 Royalties for patent-owner companies under government use compulsory licensing

Under the compulsory licensing policy, by the government or non-government bodies, such as the private sector, royalties shall be granted to patent-owner companies as their remuneration or compensation according to the Thai Patent Act (Patent Act, 1979), and Doha's Declaration in the TRIPs Agreement and Public Health. In Thailand, the royalties are approximately 0.5-2 percent of the sales for a generic drug. In Thailand, it is determined by the Committee on the Negotiation on Prices of Patented Essential Drugs.

The previous negotiations over royalties were conducted between the Committee on the Negotiation on Prices of Patented Essential Drugs and patent-owner companies after compulsory licensing was imposed. The interviewed member of the Committee on the Negotiation on Prices of Patented Essential Drugs suggested that typically the royalty is approximately 0-10 percent. This royalty rate comes from the rate for drug patentees whose drugs were issued compulsory licenses in foreign countries, such as Canada, Germany, and the United States. The calculation of this royalty for government or private use compulsory licensing is based upon the following criteria:

- 1) Compulsory licensing must be for public purposes to increase patients' access to drugs, not for commercial profit-making purposes.
- 2) The guidelines applied in countries with experience in compulsory licensing to increase patients' access to drugs should be applied accordingly.

3) The guidelines developed to respond to the spirit of the Doha's TRIPS Agreement and Public Health in countries that lack or have inadequate capacity to produce drugs for compulsory licensing should be considered.

4) Rates of royalty and practices for compulsory licensing to increase patients' access to drugs among developing countries should be compared.

5) Flexibility for royalties should be considered during the negotiation process.

#### 6.4.3.3 Results of negotiations over royalties for compulsory licensing with patent-owner companies

An interviewed member of the Committee on the Negotiation on Prices of Patented Essential Drugs discussed events and results of previous royalty negotiations. He said after the government use compulsory licensing was imposed, the Committee invited the drug-patentee companies to negotiate with the Committee three times. The result was these companies did not cooperate in the royalty negotiations. Instead, they tried to negotiate over the price of drugs on which compulsory licensing had been imposed. Each of the companies was ready to provide a proposal and offer drug prices that were lower than those proposed during the negotiation before the policy promulgation." (Thai FDA, 2007). Examples of confirmation of each of the companies are as follows:

Merck Sharp & Dohme Co., Ltd. stated that there was no need for negotiations over the royalties for compulsory licensing. Instead, they wanted to negotiate over the prices of drugs under the compulsory licensing policy. If the prices were agreed upon, the government use compulsory licensing was no longer needed.

Abbott Laboratories Co., Ltd. insisted on no royalty negotiations for compulsory licensing, but they were ready to negotiate on the prices of drugs under the compulsory license policy and offer new prices for consideration.

Sanofi-Aventis Co., Ltd. thought that there was no need to negotiate over royalties. They had a program to improve the access to their drugs with compulsory licensing. If the new program could meet



the MOPH's needs, there was no need to impose compulsory licensing or negotiate over the royalties.

The interviewed member of the Committee on the Negotiation on Prices of Patented Essential Drugs discussed the companies' non-cooperation in the royalty negotiations. Again, each of these companies tried to negotiate about the prices of drugs to which compulsory licenses were issued. Each was ready to provide a new proposal and offer drug prices that were lower than those proposed during the negotiations before the compulsory licensing policy was imposed for different reasons, as follows:

- 1) The patent-owner companies expressed their disagreement with compulsory licensing from the very beginning, so they did not express any intention to join the negotiations.

- 2) The patent-owner companies might have good intentions to provide support and cooperation to solve the problem of patients' inaccessibility to drugs.

- 3) It was the patent-owner companies' strategy to create uncertainty for the government use compulsory licensing policy.

- 4) It was the patent-owner companies' strategy to warn other developing countries that wished to impose compulsory licensing similar to Thailand. These companies did not pay attention to any of the negotiations or comply with any procedures. They might counter with certain trade measures, as Abbott Laboratories Co., Ltd. Did-they did not register ten new drugs having better effectiveness and stability in Thailand after this policy was imposed.

Political changes in Thailand" were a factor that had direct or indirect impacts of determination and implementation of this policy. During the selection of solutions to cope with the problem of patients' inaccessibility to drugs by means of the compulsory licensing policy until the policy promulgation for the seven drugs, political changes occurred in Thailand. The interviewed member of the National Health Security Board discussed this issue.

The fact that political changes in Thailand had impacts or no impacts on the formulation or implementation of the government use compulsory licensing

policy depended on the vision, ideas, and aims of the government administration in power. This was concerned with the government's "focus between the Thai population's life and commercial and economic benefits." This policy was related to, and took into account, the Thai population who suffered from the top five diseases with high mortality rates. The incidences of patients from these diseases were high, but they could not access essential drugs equally and thoroughly. This would have impacts on patent-owner companies, which were mostly in countries that were Thailand's economic partners, including the U.S.A. Thai governments during different time periods had to make decisions and assess risks and worthiness of each choice they would make. Their decisions could affect their administrations positively or negatively. Therefore, their review, change, or delay of the policy formulation might make some groups of people, especially the general public, think that they "cared about commercial benefit rather than humanity," too.

From the time when compulsory licensing policy was selected until the time the policy was promulgated, the first three drugs issued with compulsory licenses were AIDS and cardiovascular drugs, and the second set of drugs was four cancer drugs. During the policy formulation and promulgation, three political changes occurred in Thailand. The first change arose in 2006, under the administration of Prime Minister Police Lieutenant Colonel Thaksin Shinawatra and the MOPH Minister Dr. Mongkol Na Songkhla. During that time, compulsory licensing was imposed for the first three drugs, as stated. Subsequently, another political change happened as a result of a coup. The previous government was changed to an appointed government, in which General Surayud Chulanont served as the Prime Minister and Dr. Mongkol Na Songkhla as the MOPH Minister. This change did not impact the policy formulation and promulgation because the MOPH Minister remained the same person, and he had a clear policy towards universal healthcare coverage and encouraged the implementation of the policy for the three drugs to address the issue of drug access. The result of the policy implementation was better access to these three drugs for the public. This was the reason why the government use compulsory licensing policy was considered for the four cancer drugs, because of patients' inaccessibility to drugs while the incidence and mortality rates continued.

Another political change happened when the appointed government's rule came into an end, and an election was held according to the Thai Constitution, B.E. 2007 (2007). The newly elected government had Mr. Samak Sundaravej as Prime Minister and Mr. Chaiya Sasomsap as the MOPH Minister. This government had different ideas, opinions, and vision compared to the old government. The policy promulgation for the four cancer drugs was delayed to review potential impacts on the country's economy, especially cutting of the Generalized System of Preferences (GSP) with Thailand and the U.S.A.'s threat to shift Thailand's rank on the watch list for piracy. Nonetheless, the advocacy to this policy for the four cancer drugs by the civil society, cancer patients, and foundations augmented the pressure on the Thai government, by means of protesting and filing letters to meet for clarification on the policy delay. This forced the government to review this policy by considering the advantages, disadvantages, impacts, as well as worthiness of the policy. Then, in 2008, the government promulgated the government use compulsory licensing policy for these four cancer drugs.

The interviewed member of the National Health Security Board said, "political changes will have no impact on a public policy that affects the majority of the Thai population. As for the compulsory licensing policy, GSP cutting did not have a significant impact on Thailand because Thailand was not a major exporter of products suffering from GSP cutting. Furthermore, the U.S.A.'s pressure on Thailand by consideration of shifting Thailand's rank on the watch list for piracy was just a threat. Therefore, the economic impacts on Thailand were not apparent. More importantly, drugs with the compulsory licenses did not decrease but increased the total sales of the original drugs because their prices were lowered by the patent-owner companies. For example, the sales of Imatinib increased from 200 million baht to 500 million baht (FDA, 2007).

The interviewed member of the National Health Security Board said, "political changes don't have an impact on the policy, but they will have impact when the government is commercial interest-oriented over the Thai population's life. The promulgated compulsory licensing policy will still be effective, but it will not be adopted for more drugs in the future. This is because today, the world's thinking has changed. Among everything in the world, "money" is the most important thing."

## **6.5 Roles of the GPO in Administration Under the Compulsory Licensing Policy**

### **6.5.1 Study of the GPO's Opinions and Understanding About the Compulsory Licensing Policy, Administration Related to Drugs with Compulsory Licenses, As well as Positive and Negative Impacts on the GPO.**

On 24 October 2012, the GPO Director was interviewed about these issues, the details of which are set forth below.

First: Using compulsory licensing to improve patients' access to drugs was the most practical option given that circumstance. It could solve the problem of patients' inaccessibility to drugs, and the GPO was designated to represent the government to produce and import drugs and was ready to fully support the compliance with the policy.

Second: As for administration, the GPO received a notification from the MOPH concerning appointing the GPO to represent the government for production or importation of seven drugs under the compulsory licensing policy. Out of these seven drugs, the GPO was allowed to produce two of them for sale, which were AIDS drugs -Efavirenz and Lopinavir/Ritronavir. As for the cardiovascular drugs, the GPO was conducting research and trying to produce them in conjunction with bidding to import them for sale. Nonetheless, the GPO's facilities were not available to produce cancer drugs, so the GPO had to be the agent for bidding to import them.

For these seven generic drugs, whether produced or bid upon for importing for sale by the GPO according to the policy, the most important thing (apart from support and compliance with the compulsory licensing policy) was the fact that generic drugs that the GPO produced or bid for sale had to be equipped with quality and therapeutic efficiency and effectiveness that were equivalent to the original drugs. There had to be strict control of the generic drugs' properties as they had an impact on the life of patients with chronic diseases. On behalf of the MOPH, the Thai FDA, which had a direct responsibility for regulating drugs in Thailand, stipulated that original drugs and generic drugs had to be registered before being used or sold in Thailand (pre-marketing control). Their quality, standards, effectiveness, and safety after use had to

be monitored (post-marketing control). Their regulation included drugs that were issued with compulsory licenses by the MOPH.

The GPO Director concluded that for generic drugs which the GPO produced or imported under this policy, different documents had to be filed for applying for registration with the Thai FDA before they were produced or imported, as is the case with other drugs sold or used in Thailand. This is intended to measure their quality, standards, effectiveness and safety under requirements, without exception. Concerning the registration of generic drugs under the compulsory licensing policy, the Thai FDA's Notification on New Drugs and New Generic Drugs dated 3 August 2004 stipulated that drugs urgently needed for solving the country's public health problems or drugs used for treating fatal diseases, such as AIDS drugs, cancer drugs and others, required accelerated or priority review. This means that documents submitted for applying for registration had to be complete and comply with established criteria. A difference was that the application period for registration of these drugs was shorter.

The Thai FDA classified the seven drugs with compulsory licenses as drugs urgently needed for solving the country's public health problems. The Thai FDA developed criteria for a bioequivalence study for new generic drugs conducted by institutes or laboratories in foreign countries. This is divided into two cases. The first case is urgent essential drugs used for preventing and treating diseases that are the country's significant public health problems. The drugs include AIDS drugs, cancer drugs, and others. The second case is generic drugs that are not urgently needed. If a bioequivalence study for any of these drugs cannot be conducted in Thailand due to some limitations, their producers or importers must inform the Thai FDA. The Thai FDA classifies drugs with compulsory licenses as urgent essential drugs for registration to solve the country's public health problems (Thai FDA, 2009).

The GPO Director said "Despite classifying the seven drugs as urgent essential drugs, it didn't mean that the Thai FDA neglected their quality control. They were still strict about it. They stipulated that documents for applying for registering the seven drugs must be complete as in the case of new generic drugs, and their bioequivalence study must comply with minimum criteria for a bioequivalence study of generic drugs, as defined by the Thai FDA." Documents used for the application for registering new generic drugs are as follows (Thai FDA, 2004):

- 1) Application form for drug registration.
- 2) Drug labels and medication information leaflet in Thai/English.
- 3) Certificate of free sale, which certifies that the products are allowed to be sold in the producer country.
- 4) Certificate of GMP, which shows that the drug producers have been granted the certificate for good manufacturing practice.
- 5) Documents on quality control for drug standards.
  - (1) Active and non-active ingredients.
  - (2) Production process.
  - (3) Details of standard control for raw materials and finished drugs.
  - (4) Certificate of analysis for raw materials and finished drugs.
  - (5) Data about the study of drug stability.
- 6) Published and publicized reference documents showing drug effectiveness and safety.
- 7) Bioequivalence study report by institutes or laboratories in foreign countries, whereby such laboratories have international standard certification.

These seven drugs all were generic drugs, and their original drugs were registered in Thailand. It was only Lopinavir/Ritonavir, which was produced by the GPO, where its original drug was not registered in Thailand. Therefore, the Thai FDA requested complete documents for registering them under the established criteria. Also, the Thai FDA requested additional documents to certify the quality and effectiveness of these drugs, which are as follows (FDA, 2004):

- 1) Documents on the pharmaceutical chemistry of drug products applied for registration.
- 2) Published or non-published documents on pharmacology and toxicology of active ingredients.
- 3) Documents on clinical data
  - (1) Data on the bioequivalence study of tablets applied for registration compared with original tablets or Kaletra<sup>®</sup> tablets allowed to be sold in the U.S.A.
  - (2) Published data on the clinical research of drugs that contain the same active ingredients and have the same form and strength that apply for registration.

4) For the registration of Lopinavir/Ritonavir, additional conditions are required, as follows:

(1) The applicants for the drug registration must monitor the therapeutic effectiveness and safety of their drugs for approximately two years after the registration is approved. In addition, they must summarize the monitoring results periodically, for at least every 6, 12 and 24 months. They must submit the draft document on monitoring the therapeutic effectiveness and safety of the drugs to the Thai FDA before the approval of the registration.

(2) Monitoring of therapeutic levels among 100 patients-Data of the first 30 patients are reported, and later data of all the 100 patients are reported. Clinical data on therapeutic effectiveness for the 100 patients are collected, and an academic paper is prepared.

The Thai FDA focused on controlling drug quality before and after the registration, especially for generic drugs with compulsory licensing, in order to make doctors and medical personnel trust their quality-to make them believe that these drugs have equivalent properties and therapeutic effectiveness when compared to the original drugs. The GPO had to send samples of generic drugs that they produced or imported for quality examination at the Bureau of Drug and Narcotic, Department of Medical Sciences (affiliated to the MOPH) to ensure that their quality meets the standard criteria for drug quality control. The Department of Medical Sciences mostly referred to the drug recipes announced by the MOPH Minister-BP (British Pharmacopieia) and USP (The United State Pharmacopiea) or the drug recipes approved by the Thai FDA based on technical knowledge with references. As for drugs without details and standard criteria in their recipe, which included Efavirenz and Lopinavir/Ritonavir, the Bureau of Drug and Narcotic tested their quality using their producers' methods and standard criteria with internationally-recognized technical data. Topics for quality measurement vary to dosage forms. The main items for all dosage forms include appearance, drug identification, the amount of active ingredients, drug solubility, and other related substances that arise during synthesis or dissipation of active ingredients. Therefore, if the quality meets the standard criteria, the drug can be registered and sold in Thailand.

The generic drugs on which the compulsory licensing policy was imposed (produced and bid on by the GPO for sale) have been registered, which is presented in Table 6.1 (as per 15 June 2009) (FDA, 2009).

**Table 6.1** Status of Generic Drugs under the Compulsory Licensing Policy

No	New Original Drugs	New Generic Drugs	Registration Status
1.	Efavirenz (Stocrin <sup>®</sup> )		
1.1	Stocrin (50 mg/capsule), Reg. No. 1C156/47 (N), MSD (Thailand) Co., Ltd.	1.1 Efavirenz Tablets 600 mg, produced by Ranbaxy Laboratories Ltd., India imported by the GPO.	Registration no. 1C 1/51 (NG), issued on 18 January 2007.
1.2	Stocrin (50 mg/capsule), Reg. No. 1C 69/42 (N), M & H Manufacturing (Thailand) Co., Ltd.	1.2 Efavirenz Tablets 600 mg, produced by Emcure Pharmaceutical Ltd., India imported by the GPO.	Registration no. 1C 34/51 (NG), issued on 9 August 2008.
1.3	Stocrin (100 mg/capsule), Reg. No. 1C157/47 (N), MSD (Thailand) Co., Ltd.	1.3 Efavirenz Capsules 200 mg, produced by Ranbaxy Laboratories Ltd., India imported by the GPO.	Registration no. 1C 29/50, issued on 15 June 2007.
1.4	Stocrin (200 mg/capsule), Reg. No. 162/47 (N), MSD (Thailand) Co., Ltd.		
1.5	Stocrin (200 mg/capsule), Reg. No. 1C71/42 (N), M & H Manufacturing (Thailand) Co., Ltd.		-



**Table 6.1** (Continued)

No	New Original Drugs	New Generic Drugs	Registration Status
	1.6 Stocrin (50 mg/tablet), Reg. No. 1C89/50 (N), MSD (Thailand) Co., Ltd.		-
	1.7 Stocrin (200 mg/tablet), Reg. No. 1C90/50 (N), MSD (Thailand) Co., Ltd.		-
	1.8 Stocrin (600 mg/tablet), Reg. No. 1C34/49 (N), MSD (Thailand) Co., Ltd.		-
	1.9 Stocrin (600 mg/tablet), Reg. No. 1C23/46 (NC), M & H Manufacturing (Thailand) Co., Ltd.		-
2.	Lopinavir and Ritonavir (Kaletra <sup>®</sup> or Aluvia <sup>®</sup> )		
	2.1 Kaletra (Lopinavir 200 mg and Ritonavir 50 mg soft capsule), Reg. No. 2C 29/44 (N), Abbott Laboratories (Thailand) Co., Ltd.	2.1 Lopinavir 200 mg and Ritonavir 50 mg, produced by Matrix Laboratories Ltd., India imported by the GPO.	Registration no. 1C 24/50 (NC), issued on 12 October 2007.
	2.2 Kaletra (Lopinavir and Ritonavir 80/20 mg per ml oral solution), Reg. No. 2C 30/44 (N), Abbott Laboratories (Thailand) Co., Ltd.	-	-

**Table 6.1** (Continued)

No	New Original Drugs	New Generic Drugs	Registration Status
	2.3 Aluvia (Lopinavir 100 mg and Ritonavir 25 mg film coated tablet), Reg. No. 2C 29/51 (NC), Abbott Laboratories (Thailand) Co., Ltd.	-	-
3.	Clopidogrel (Plavix <sup>®</sup> )	3.1 Clopidogrel 75 mg, produced by Cadia Healthcare Ltd., India imported by the GPO.	Registration no. 1C 1/51 (NG), issued on 4 January 2008.
	3.1 Plavix (Tablet 75 mg ), Reg. No. 1C 156/49 (N), Sanofi-Aventis Co., Ltd.	3.2 Clopidogrel 75 mg, produced by Emcure Pharmaceutical Ltd., India imported by the GPO.	Registration no. 1C 30/51 (NG), issued on 1 September 2008.
4.	Imatinib (Glivec <sup>®</sup> )	No new generic drug has been registered yet. Note: Novartis (Thailand) Co., Ltd. distributed the drugs to patients under the GIPAP – for those who could not access the drug.	-
	4.1 Glivec 100 mg (capsule), Reg. No. 1C 115/44 (N), Novartis (Thailand) Co., Ltd.		

**Table 6.1** (Continued)

No	New Original Drugs	New Generic Drugs	Registration Status
	4.2 Glivec 100 mg (tablet), Reg. No. 1C 134/47 (N) Novartis (Thailand) Co., Ltd.	-	-
	4.3 Glivec 400 mg (tablet), Reg. No. 1C135/47 (N), Novartis (Thailand) Co., Ltd.	-	-
5.	Docetexel (Taxotere <sup>®</sup> )		
	5.1 Taxotere Reg. No. 1 C 56/43 (N) Sanofi-Aventis (Thailand) Co., Ltd.	5.1 Docetexel, produced by Dabur Pharma Limited., India imported by the GPO.	Registration no. 1C 22/51 (NG), issued on 26 June 2008.
6.	Erlotinib (Tarceva <sup>®</sup> )		
	6.1 Tarceva (tablets 25 mg), Reg. No. 1C 66/48 (NC), Roche Thailand Co., Ltd.	No new generic drug has been registered yet.	
	6.2 Tarceva (tablets 100 mg), Reg. No. 1C 67/48 (NC), Roche Thailand Co., Ltd.	-	-
	6.3 Tarceva (tablets 150 mg), Reg. No. 1C 68/48 (NC), Roche Thailand Co., Ltd.	-	-
7.	Letrozole (Femara <sup>®</sup> )		
	7.1 Femara (tablet 2.5 mg), Reg. No. 1C 142/41 (N)	7.1 Letrozole tablet 2.5 mg, imported by the GPO.	Registration no. 1C 10/52 (N), issued on 18 March 2009.

The GPO Director said that despite quality examination and control of generic drugs in accordance with established standards, another important procedure defined by the Thai FDA was safety surveillance. The Thai FDA established the Health Products Vigilance Center (HVC) as an agency responsible for monitoring the safety of health products, including food, drugs, and herbal drugs, addictive substances, cosmetics and medical devices. This agency's work is collaboration between the Thai FDA, which is the central agency, and six regional hospitals affiliated to the MOPH across the country. Public health personnel, including doctors, pharmacists, nurses and other relevant personnel have to monitor, observe, and collect data about undesirable symptoms and unsafe effects from the use of health products, including drugs with compulsory licensing. They will report the information to the HVC, the Thai FDA, and MOPH for further consideration.

## **6.6 Costs of Production, Development and Research of Drugs Produced by the GPO Under the Compulsory Licensing Policy, and the Costs of Drugs Imported by the GPO under the Compulsory Licensing Policy**

To study these issues, an in-depth interview was conducted with the GPO Director on 24 October 2012. The GPO Director said, “the costs of drug production and importation are the GPO’s confidential information.” This was a limitation to the collection of data on the actual costs of production and importation of drugs under the compulsory licensing policy. Data that could be disclosed was the structure and method of calculating the costs. There is only one key principle to the calculation of the costs and prices of drugs under the policy:

“Price = Drug costs + administrative costs + VAT, as defined by the government without charging profits from sales”

### **6.6.1 Costs of Imported Drugs Under the Compulsory Licensing Policy**

The royalty to the drug patentees was at 0.5-2 percent of the sales of each drug. The GPO had to consider and examine companies that would bid for drugs imported under the compulsory licensing policy. This process involved experts from

several agencies, including the Thai FDA, the GPO, and the Department of Medical Science. They had to visit drug production facilities of pharmaceutical companies that would bid, in order to check the reliability of the production, support and document systems for drug manufacturing and check if the product met the GMP standard. If it failed to meet GMP requirements, the drug producers would not be allowed to introduce their drugs into the bidding process. If it complied with GMP requirements, they were allowed to do so. The GPO would act as the intermediary in the bidding, as well as selling and distributing the drugs to the governments as stipulated by the MOPH. To ensure the quality of imported drugs before being sold and distributed to hospitals, the drugs had to be analyzed in terms of quality and therapeutic efficiency according to established standards. In addition, drug samples had to be collected for testing stability in relation to their life defined by the drug import companies. The calculation of costs and prices of drugs imported and produced by the GPO under the compulsory licensing policy is outlined in Table 6.2 and 6.3, respectively.

**Table 6.2** Calculation of Costs and Prices of Drugs Imported by the GPO under the Compulsory Licensing Policy

Costs and Prices of Imported Drugs			
Exchange rate on the drug order date	A (Subject to change to factors, e.g. money value and the world's economic fluctuation)		
Royalties	0.5 %	2 %	Remark
Total costs			
Product costs	B1	C1	(Imported drugs)
Insurance premium	B2	C2	
Clearing expense	B3	C3	
Sample analysis costs	B4	C4	(Checking drug quality)
Retained sample costs	B5	C5	(Costs of sample collection to check drug stability)
Retained sample analysis costs	B6	C6	(Drug stability examination cost)
Logistics costs (5%)	B7	C7	
Other administrative costs (6 % )	B8	C8	

**Table 6.2** (Continued)

<b>Costs and Prices of Imported Drugs</b>			
Exchange rate on the drug order date	A (Subject to change to factors, e.g. money value and the world's economic fluctuation)		
Total costs	D = Total of B1- B8	E= Total of C1- C8	
Net profit (loss)	0.00	0.00	Commercial profit- making is prohibited.
% Net profit (loss)	0.00	0.00	
<b>Price = (Total costs + VAT 7% + royalty)</b>			
VAT 7%	B9	C9	VAT 7% of total costs
Total prices with VAT 7%	F = (D + B9)	G = (E + C9)	
Royalty	H	I	H = Total costs* 0.5% I = Total costs* 2%
Total royalty with VAT 7%	J (F + H)	K (G + I)	

**Table 6.3** Calculation of Costs and Prices of Drugs Produced by the GPO under the Compulsory Licensing Policy

<b>Costs and prices of drugs produced by the GPO</b>			
Exchange rate on the raw material order date	A (Subject to change to factors, e.g. money value and the world's economic fluctuation)		
Royalties	0.5 %	2 %	Remark
Total costs			
Raw material costs	B1	C1	(Materials for mixing of drug formulas)
Costs of testing and research and development of drug recipes	B2	C2	
Drug production costs	B3	C3	
Drug sample analysis costs	B4	C4	(Quality examination costs)
Retained sample collection and analysis costs	B5	C5	(Drug stability examination cost to define the expiry date)
Overhead costs, e.g. water, electricity and labor costs	B6	C6	

**Table 6.3** (Continued)

Exchange rate on the raw material order date	Costs and prices of drugs produced by the GPO		
	A (Subject to change to factors, e.g. money value and the world's economic fluctuation)		
Logistics costs ( 5% )	B7	C7	
Other administrative costs (6 %)	B8	C8	
Total costs	D = Total (B1- B8)	E= Total (C1- C8)	
Net profit (loss)	0.00	0.00	Commercial profit-making
Percentage of the net profit (loss)	0.00	0.00	is prohibited.
<b>Price = (Total costs + VAT 7% + royalty)</b>			
VAT 7%	B9	C9	VAT 7% of total costs
Price with VAT 7%	F = (D + B9)	G = (E + C9)	
Royalty	H	I	H = Total costs* 0.5% I = Total costs* 2%
Total royalty with VAT 7%	J (F + H)	K (G + I)	

The calculation of the cost and prices of drugs produced and imported by the GPO under the government use compulsory licensing policy, as shown in Tables 6.2 and 6.3, depended on factors that affected the GPO. The GPO Director added that the GPO had to be responsible for changes, variation or obstacles arising from the following factors.

1) Volatility of the exchange rate on the date of purchasing raw materials for mixing of drug formulas and the exchange rate on the date of purchasing drugs from pharmaceutical companies that won the bidding-No matter how the currency exchange rates fluctuate, the GPO has to be responsible for the differential whenever drug orders are issued by government hospitals across the country for patients who are entitled to the National Health Security Scheme, the Social Security Scheme, and the Medical Benefit Scheme for Civil Servants and State Enterprise Employees. This results from the fact that the price of a drug is fixed based on a certain exchange rate, and when the exchange rate becomes higher, the costs of the drug will increase while its price must remain the same. Hospitals consider old prices as central prices for purchasing and distributing drugs under the compulsory licensing

policy. The GPO cannot adjust the prices according to the variation of the exchange rate, and the GPO has to be responsible for the difference in the costs. If the currency rate becomes lower, it will be beneficial for the GPO. However, if it becomes higher, it will become the GPO's burden immediately.

2) Losing the opportunity for the GPO to produce other essential drugs to support the country's public health system-Drugs under the government use compulsory licensing policy were essential drugs at the policy level that required bidding to support the country's public health system according to the policy's objective. However, there were many medications that were produced by the GPO, such as orphan drugs, household generic drugs, and other drugs that needed to be manufactured for patients in the public health system. Nonetheless, manufacturing of these drugs had to be halted for drugs under the compulsory licensing policy. This affected the GPO's image as well.

3) Royalty-When a government or private use compulsory licensing policy is announced and imposed, a royalty must be granted to patent-owner companies according to Thailand's Patent Act (Thai Patent Act, 1979) and the Doha's Declaration on the TRIPs Agreement and Public Health. This royalty is derived from the sales of generic drugs that the GPO acts as the government's agent to import or produce for sale in the public health system. The royalty accounts for two percent of the sales of each generic drug for patients under the National Health Security Scheme, and 0.5 percent of the sales of each generic drug for patients eligible for medical care in the Social Security Scheme.

The Committee on the Negotiation on Prices of Patented Essential Drugs has negotiated over the royalties since 2007, when the compulsory licensing policy was imposed for the first three drugs. The negotiations have not ended and a conclusion has not been reached. Since Thailand imposed compulsory licensing for the seven drugs in 2006, no actions have been taken about the royalties deducted for the patent-owner companies. Thailand must wait for the completion of the negotiation process with pharmaceutical companies to know whether or not they will accept the royalties. However, this problem is beyond the GPO's authority.



## **CHAPTER 7**

### **GUIDELINES AND RESULTS OF THE POLICY IMPLEMENTATION IN THAILAND**

Chapter 7 presents details and guidelines for implementing the compulsory licensing policy at the macro and micro stages, factors affecting the policy implementation at the macro and micro stages, and results of the policy implementation.

A focus of this study was themes for the policy evaluation according to Berman's principles, with an interest in the implementation of the compulsory licensing policy at the macro and micro stages. The macro stage dealt with the Ministry of Public Health (MOPH), the central agency directly responsible for solving the problem of patient's drug inaccessibility by means of the compulsory licensing policy. This stage was studied to reveal how the MOPH formulated and mobilized implementation plans to make frontline units comply with the policy appropriately. The micro stage was concerned with operating units-government hospitals. This stage was studied to identify what their practice guidelines were in the adoption and compliance with the policy or implementation plans delivered by the central agency. The research, data collection, and evaluation were conducted through face-to-face interviews with directors of 33 large hospitals and 12 university hospitals. It was intended to reflect the guidelines for the formulation of implementation plans from the MOPH-to see if they were clear and could raise an understanding to achieve proper policy implementation according to the policy objective. As mentioned, government hospitals that were required to comply with the compulsory licensing policy were studied to see if they adopted the policy and established proper implementation guidelines according to the objective to improve patients' access to drugs. The author aimed to describe and assess the guidelines for policy implementation and the results of the policy implementation in Thailand and consider different factors affecting the policy implementation in each step. Data from the in-depth interviews about the policy implementation at the macro and micro stages are outlined below.

## **7.1 Guidelines for Policy Implementation at the Macro Stage**

This dealt with evaluation of the policy implementation at the ministerial level. The MOPH had direct responsibility for implementing this policy. This section aims to reveal the MOPH's guidelines for making government hospitals comply with the policy appropriately according to the policy objective. Details about the transformation of the policy from the central agency to the implementation plans of the operating units are

### **7.1.1 Policy Characteristics**

7.1.1.1 Details of the policy and its objective were clear – In 2006, the MOPH Minister, Dr. Wichai Chokwiwat, promulgated the government use compulsory licensing policy for three drugs-two AIDS drugs and one cardiovascular drug. In 2008, the policy was announced for four cancer drugs, and the MOPH assigned the GPO to represent the government to produce or import generic drugs to replace the original drugs and distribute them to government hospitals. Government hospitals were the operating units that implemented the compulsory licensing policy by distributing drugs to the target patients to achieve the objective to solve the problem of drug inaccessibility among patients. This was intended to reduce their suffering and promote their quality of life. The MOPH prepared a written notification ("The MOPH's Notification") concerning exercising rights over drug and non-drug patents for seven drugs considered for compulsory licensing. This notification was submitted to government hospitals, the GPO, the Department of Intellectual Property, and patent-owner companies. This mission was one important mission of government hospitals and the GPO, an important supporting agency. Conditions that are applicable to each of the generic drugs are outlined below (MOPH's Notification, 2006) (MOPH's Notification, 2007).

- 1) This right is imposed from the policy promulgation date until the expiry date of the drug patents or when the drugs are no longer necessary.

- 2) To provide sufficient quantities of the generic drugs for patients who need these drugs, exclusively for those with the rights for medical care under the National Health Security Act, B.E. 2545 (2002), the Social Security Act,

B.E. 2533 (1990), and the Medical Benefit Scheme for Civil Servants and State Enterprise Employees. The number of the patients is not limited, and this is subject to the consideration of the doctors on duty.

3) The royalty for patentees accounts for 0.5-5 percent of the sales of each generic drug sold by the GPO.

The above three conditions were applied to all the seven drugs, except for Imatinib (Glivec™<sup>®</sup>) of Navotis Co., Ltd., from Switzerland. This was because Imatinib (Glivec™<sup>®</sup>) was under the Glivec<sup>®</sup> International Patient Assistance Program (GIPAP). Its conditions under the compulsory licensing policy are as follows (MOPH's Notification, 2007):

1) The policy will be promulgated when the GIPAP ends, or when the program implementation does not comply with the company's letter as mentioned above, or when the implementation fails to allow all patients under the Universal Health Coverage Scheme to access the drug.

2) This is applicable to any cases that fall within Section 1) until the expiry date of the drug patents or when the drugs are no longer necessary.

3) To provide sufficient quantities of the generic drugs for patients who need these drugs, exclusively for those with the medical care right under the National Health Security Act, B.E. 2545 (2002), the Social Security Act, B.E. 2533 (1990), and the Medical Benefit Scheme for Civil Servants and State Enterprise Employees. The number of the patients is not limited, and this is subject to the consideration of the doctors on duty.

4) The royalty for patentees accounts for 0.5-5 percent of the sales of each generic drug sold by the GPO.

Details of the compulsory licensing policy for the seven generic drugs are presented in Table 7.1

**Table 7.1** Details of the Compulsory Licensing Policy in Thailand

No.	Date of Promulgation	Drug	Patent-owner Companies	Compulsory Period	Royalty for Patentees
1.	29 Nov 2006	Efavirenz	MSD (Thailand) Co., Ltd.	31 Dec 2011	Not over 0.5 percent
2.	24 Jan 2007	Lopinavir/ Ritonavir	Abbott Laboratories (Thailand) Co., Ltd.	31 Dec 2012	0.5 percent
3.	25 Jan 2007	Clopidogrel	Sanofi-Aventis Co., Ltd.	Until the expiry date of the drug patent or when the drugs are no longer necessary.	0.5 percent
4.	4 Jan 2008	Doxetrexel	Sanofi-Aventis Co., Ltd.	Until the expiry date of the drug patent or when the drugs are no longer necessary.	3 percent
5.	4 Jan 2008	Letrozole	Novartis (Thailand) Co., Ltd.	Until the expiry date of the drug patent or when the drugs are no longer necessary.	3 percent
6.	4 Jan 2008	Erlotinib	Roche Thailand Co., Ltd.	Until the expiry date of the drug patents or when the drugs are no longer necessary.	3 percent
7.	25 Jan 2008	Imatinib	Novartis (Thailand) Co., Ltd.	When the GIPAP ends, or when the program implementation does not comply with the company's letter as mentioned above, or when the implementation fails to allow all patients in the Universal Health Coverage Scheme to access the drugs.	5 percent

Remark: Royalties for patent-owner companies is based on the percentage of sales of each generic drug sold by the GPO.

In addition, the MOPH publicized details of the compulsory licensing policy through different media, such as newspapers, television and the Internet to communicate with medical personnel and the public to boost their knowledge and understanding.

Interviews with the director of each government hospital about details of the compulsory licensing policy showed that their views were in the same direction. That is, they said the MOPH held a meeting to inform details about the promulgation of the compulsory licensing policy-objective and goals, monitoring, and evaluation of the policy implementation. This aimed to generate the guidelines for the implementation in order to solve the problem of patients' inaccessibility to drugs. The target groups of this policy included patients under the three public health care schemes. This led to an understanding that was clear and was in the same direction among the hospital directors. It was concluded that:

The meeting clarified the problem of patients' inaccessibility to drugs and its severity with the clear objective to resolve the problem, reduce mortality rates, and reduce drug costs for both the government sector and the general public. They focused on, and campaigned for, the use of generic drugs and drugs on the National Essential Drug List as priority in treatment. Also, they formulated strategies for universal healthcare coverage to support this.

The interviews showed that all the informants shared the view that all government hospitals agreed with the MOPH's meeting with directors of government hospitals across the country to clarify the source of the problem, as well as the objective and goals of the policy promulgation for the seven drugs – to solve the problem of patients' inaccessibility to drugs, especially patients with serious chronic diseases who needed to take medication continuously throughout the treatment period for their social integration.

However, actions taken by the MOPH from the date of the meeting with the government hospital directors to clarify the policy, before the MOPH's "Notification" concerning exercising rights over drug and non-drug patents for seven drugs, were very slow. Most hospitals heard this matter from newspapers, television and other sources, instead of the MOPH's written Notification. When the Notification was launched, each of the hospitals adopted it as a broad guideline for their

implementation. Individual hospitals had to study details and formulate implementation guidelines by themselves. As for patients under the three public health care schemes, details about their medical care rights were different, which might lead to problems related to the policy compliance. The directors of government hospitals said:

Hospitals learned about the cause of the problem, as well as the objective and goals of the policy very clearly from the meeting. However, they didn't know when the policy would be imposed from the MOPH's Notification, but learned of it from television or newspapers. This made it very difficult for management of hospitals. (Director of a university hospital, 6 June 2013)

The objective, goals and target groups were very clear, but the direction for hospitals was not. The process of imposing the MOPH's Notification was very slow, so hospitals didn't know the exact guidelines or details about their responsibilities, especially differences in the medical care rights among the patients. (Director of a government hospital, 16 June 2013)

The MOPH's written Notification was very slow. There was no clear guideline. The implementation relied on management of each hospital, which used the Notification as a board guideline. Hospitals have to deal with other details. The only thing that was clear was the objective and goals to address the problem of patients' inaccessibility to drugs. (Director of a government hospital, 8 May 2013)

7.1.1.2 Policy and objective were consistent with the situation and could solve the problem of patients' inaccessibility to drugs-The number of cases of illness, mortality, and infection of AIDS, cardiovascular disease and cancer steadily increased. The diseases were among top causes of the death for Thai people, for which a major reason, as assessed by the MOPH, was their inaccessibility to their lifelong use of drugs in thorough and equal manners. The patent protection made these drugs too costly to be afforded by the government sector and the general public.

As a result, the MOPH decided to impose compulsory licensing on seven essential medications for these diseases. In addition, the government formulated strategies for universal health coverage, which would allow the Thai population to access to health services and medications equally and thoroughly.

The interviews suggested that the directors of the government hospitals had an agreement in their thoughts. They believed that the compulsory licensing policy was a solution to the problem of inaccessibility to drugs for the public according to the policy objective. This resulted from cheaper drugs by importation or local production, following the Thai Patent Act and the DOHA's Declaration. In addition, during that time, the Thai government and patients could not afford the essential drugs. Overall, the hospital directors agreed that the compulsory licensing policy and the objective of the policy implementation were in line with existing situations and problems and could solve the problem of patients' inaccessibility to drugs. Nonetheless, they had some disagreement in these issues:

- 1) Impacts on Thailand's image and economy in the eyes of countries that have patent-owner companies whose drugs were under the compulsory licensing policy.

This issue can be divided into two groups:

- (1) First group-The first group of hospital directors thought that Thailand's issuance of compulsory licenses was a courageous act to fight against the power of superpower countries which are home to the patent-owner companies. The superpowers had influence and negotiating power that could deter this policy, in terms of, for example, economic and trade impacts, legal impacts, and adverse impacts on the country's image. Assessing these impacts, the government decided to promulgate this policy. It can be said that the Thai government attached greater importance to human life than commercial interest associated with GSP cutting and the bad image caused by the public misunderstanding that the Thai government was infringing on patentee's intellectual property although the actions were legitimate and explicable.

I strongly agree with the policy promulgation because the spread of AIDS 2006 was globally serious. Underdeveloped and developing

countries, including Thailand, were affected the most because in these countries, most of the population had low-medium revenue and governments didn't have a lot of budget monies to subsidize the costs of essential drugs for AIDS drugs. As they had patent protection, they were costly, which caused a continual increase in mortality rates of AIDS patients. Furthermore, the infection rates of new HIV-infected people increased sharply. This situation in Thailand was uncontrollable. After considering the situation, the Thai government believed that the compulsory licensing policy was the most practical solution to the problem of inaccessibility to AIDS drugs, and the government strongly believed that generic drugs imported or produced by the GPO under the compulsory licensing policy were of high quality and had therapeutic efficiency in the extent that they could be substituted for original drugs. They viewed that other drugs were also essential, but due to patent protection, they were expensive. This was followed by promulgation of this policy for the other four drugs. (Director of a government hospital, 16 May 2013)

Some hospital directors added that after the policy promulgation, the patent-owner companies came to negotiate about lowering their prices of drugs to which compulsory licenses had been issued and other drugs. This was beneficial to patients, especially AIDS patients. Some AIDS patients did not use their medical care right in the public health system, but they chose to visit an institution that they felt comfortable with and relied on because the place did not disclose their name, information or personal profile. It was a government institution under the Thai Red Cross; it was set up for AIDS patients, serving as a refuge and counsellor for them. This institution provided examination and treatment services and referred patients to hospitals in which they were eligible for medical care. In the process, including counselling, treatment and referral, the patients had to pay for drugs on their own. The director of this institution said:



I strongly agree with the issuance of the compulsory licensing policy. AIDS patients choose to receive treatment here because they don't want to disclose their identity, although they don't receive any benefits from the public health system. The compulsory licensing policy made the patent-owner companies reduce their drug prices immediately. Some drugs that weren't under the policy were discounted. The prices of some drugs reduced by half, which allowed patients to have better access to the drugs, and then their treatment costs reduced. This prolonged their life. This is an indirect impact of this policy. (Director of a university hospital, 1 May 2013)

(2) Second group-The group regarded that imposing the compulsory licensing policy for the seven drugs by the MOPH from 2006 was a solution to the problem. However, they believed that there might be some other solutions that would not impact the country's economy or trade and would not lead to the image of intellectual property infringement. Superpowers home to the patent-owner companies linked the policy to licensed products being pirated and sold in Thailand, such as bags, watches, CDs and DVDs. This might result in a bad image and reputation for the country. Most importantly, they did not trust the quality or therapeutic efficiency of generic drugs imported or produced by the GPO. They were not sure if the drugs could replace the original drugs because most drugs under the compulsory licensing policy were used to treat fatal diseases that were difficult to treat. They thought if an error occurred, it would affect patients' life. A government hospital director said:

I agree with solving the problem of patients' inaccessibility to drugs with the method, but there should be consideration of other ways that would not affect the country's economy, international relations, and image. For example, the Clinton Foundation offered free drugs for AIDS patients, which was another way that should have been taken into consideration before the policy was imposed. Another critical issue is reliability of generic drugs to replace the original drugs that

have high therapeutic efficiency. There is a question as to if they can be a real substitute. This is an unresolved question for most doctors.  
(Director of a government hospital, 20 May 2013)

7.1.1.3 The practice guidelines were in line with the target groups to solve the problem of patients' drug inaccessibility in a logical way according to the objective and goals of policy-The compulsory licensing was intended for patients eligible for medical health care under one of the three schemes, so as to cover almost all the Thai population.

1) The Universal Healthcare Coverage Scheme (30 baht Healthcare Scheme)-The medical care and drug costs from the government hospitals is disbursed by the National Health Security Office.

2) Social Security Scheme and the Medical Benefit Scheme for Civil Servants and State Enterprise Employees-The medical care and drug costs from the government hospitals is disbursed by the Social Security Office.

3) The Medical Benefit Scheme for Civil Servants and State Enterprise Employees-The medical care and drug costs from the government hospitals is disbursed by the Comptroller General's Department.

All the interviewed hospital directors worked in hospitals providing medical care services for patients under these three schemes.

The interviews showed that they shared the same view that "under the compulsory licensing policy and the MOPH's Notification about the policy of each drug, the target groups were clearly specified, and details about the use of generic drugs under the policy were elaborately described. Each of the hospital directors could apply the protocol guidelines for their budget and dispensing management for patients correctly."

Although the policy clearly specified the target groups and how to receive the budget, all the interviewed hospital directors agreed that the establishment of guidelines for preparing hospitals for compliance with the policy had many problems. For example, the names of some patients did not appear in the list of those eligible for the medical care, some patients used duplicated rights to medical care, and some had inadequate knowledge or understanding about their medical care right. This

resulted in problems related to operations, as well as confusion about keeping patients' history records, treatment, and medical care costs. Some patients did not inform service providers about their medical care right. All these issues obstructed the policy implementation in hospitals from achieving their objective.

The hospital directors suggested that the MOPH should educate the public and patients about their medical care rights and launched a campaign for encouraging the Thai population to inform service providers of their medical care eligibility in hospitals within their residential areas. This is intended to provide the public access to health services and drugs comprehensively, as well as a system of classifying and controlling patients under a single medical care right in each hospital to prevent errors and duplication.

### **7.1.2 Communication of the Policy**

7.1.2.1 Characteristics of communication about transformation of the policy into operating units

1) Transformation of the policy into implementation plans of operating units was still top-down. That is, guidelines and major details to deliver to government hospitals affiliated to the MOPH and universities were prepared by the MOPH. It was found that the broad guidelines might not be in line with actual situations in each hospital. There was lack of clear communication about relevant details, so operations in some areas were difficult. Breaking overall goals at the ministerial level into goals for individual government hospitals should take into account individual hospitals' characteristics and conditions to allow practitioners to work accordingly.

As for the MOPH's issuance of compulsory licenses and the MOPH's Notification, all the hospital directors agreed that:

The compulsory licensing policy is a practice based on "logic" or a "linear equation," which can definitely better patients' access to medicines according to its objective. As a matter of fact, there are other things involved, which cause problems and deviation from the equation.

The MOPH's compulsory licensing policy is a solution to the problem of patients' inaccessibility to drugs. If logic and a linear equation are taken into account, the drugs are 50-70% cheaper and the quantities of drugs that hospitals can purchase or procure for patients will increase despite the same amount of budget. Additionally, some remaining budget monies can be used for other public health services. This is a linear equation or a view from a single angle. When the policy is implemented in hospitals, it involves many factors. This may make the linear equation different from what is thought about (Director of a government hospital, 17 July 2013).

To solve the problem of patients' inaccessibility to drugs, compulsory licensing is a method that can solve the problem definitely and clearly under a causal concept. If drug prices decrease, hospitals' and patients' affordability will improve, which will allow patients to access drugs more equally and thoroughly. However, this method can solve the immediate problem within a certain time period. In practice, there are many factors associated to this problem. The achievement does not only come from the MOPH's notification and hospitals' policy implementation. This is not an easy thing. This calls for the creation of understanding, campaigns, cultural changes, and others among all stakeholders to achieve their acceptance of, trust in, and compliance with, the policy on a voluntary basis. Acting upon orders is not enough. (Director of a government hospital, 25 July 2013)

To solve the problem of patients' inaccessibility to drugs, there are three related factors, which are doctors, patients, and the MOPH. To deal with this problem, there are many methods that can be applied, and compulsory licensing is one of them. One obvious result is drugs for AIDS patients. It is apparent that patients can have better access to their drugs. Nonetheless, there are differences between government hospitals under the MOPH and university-affiliated hospitals. As for university-affiliated hospitals, medical instructors teach medical students and pharmacists to allow them to understand treatment and

use of medications for patients in the most efficient way. First, they prescribe first-line drugs, but they are not effective. Other more effective drugs must then be added to treat patients and save their life. This teaching culture may result medical personnel possessing a different view from what they have studied and the established policy. This can lead to problems about the policy implementation. (Director of a university hospital, 30 July 2013)

All the interviewed hospital directors agreed with the compulsory licensing policy as a solution to the problem of patients' inaccessibility to drugs; however, they believed that this solution took in account only a single cause and effect. For them, to gain the government hospitals' compliance with the policy implementation on a voluntary basis, it was necessary to develop their understanding of, trust in, and acceptance of this policy and establish clear implementation guidelines that would result in appropriate and adjustable practices for respective hospitals, based on the MOPH's Notification and regulations.

7.1.2.2 Lack of communication to build an understanding and prepare hospitals for compliance with the policy-Under the policy, the protocol guidelines- the main guidelines for administering drugs under the policy-were established, and the target group of this policy was patients eligible for one of the said three public health care schemes. The interviews showed that all the hospitals agreed with the policy, but they lacked preparedness for complying with its implementation guidelines.

There are government hospitals across the country. The MOPH imposed the compulsory licensing policy in hospitals with patients entitled to one of the three public health care schemes to improve their access to drugs. However, the MOPH didn't ensure or prepare adequate understanding and acceptance of this policy for the general public and operating units. The MOPH didn't check the preparedness of respective government hospitals, which differ in all aspects, including the IT systems for data collection. Neither did it provide for the general public's knowledge and understanding about their rights.

This might cause problems about the policy implementation.”  
(Director of a government hospital, 30 July 2013)

Government hospitals are different in readiness to implement the compulsory licensing policy. The outcomes of, and impacts on, external factors were evaluated. However, conditions of different hospitals weren't taken into account to forecast potential problems. Equipping medical staff with information, understanding and acceptance of this policy by changing their traditional attitudes and cultures was very difficult. Mass media, campaigns and policy promulgation, which was comparable to an order, were inadequate. More importantly, it was necessary to think about how to deal with the existing drug inventory. Some drug items remained in a large quantity. This might pose problems and obstacles that had a great direct impact on the policy implementation.” (Director of a government hospital, 9 August 2013)

There was no communication or clarification about patients' rights for those who didn't understand this policy. The computer system was not ready for operation, and how to manage existing drug inventories was not clear. How to change doctors' and patients' attitudes towards, and culture about, treatment to achieve their trust with generic drugs was not clarified. Therefore, this policy was just the guidelines, without incentives to implement it to achieve its objective. When the policy was transformed into work plans, there were many arguments and issues that needed to be clarified to ensure a better understanding and be aware of problems that could arise when this policy was implemented.” (Director of a government hospital, 17 August 2013)

The hospital directors believed that the policy involved only the evaluation of potential outcomes and impacts. There was no communication to operating units or other stakeholders, which could adversely impact the policy implementation, and there was no coordination of work to get essential information.

Also, there was no investigation of the levels of preparedness possessed by individual hospitals in the public health system, or factors that should be planned for to prepare operating units for the policy implementation. Issues that the government hospitals encountered in preparing work plans or guidelines for the policy implementation can be outlined as follows:

1) The general public lacked an understanding about their rights to healthcare services, so they did not exercise this right.

2) The sophistication of the IT system for collecting patients' data among hospitals in Thailand was not equal. The system in some hospitals was not ready, especially for tracking patients' eligibility for medical care, and some patients did not know about their rights. This resulted in some exercising no rights to medical care while others exercised duplicated rights.

3) There were no campaigns for enhancing the general public's knowledge and understanding about the objective and goals of this policy, especially about generic drugs that would be substituted for the old drugs. It turned out to be that it was the doctors and pharmacists in each hospital who responded to the policy by providing correct knowledge and understanding and by adjusting attitudes of medical personnel and patients simultaneously. This lack of information might result in the delay in policy implementation. Furthermore, the readiness for this matter among different hospitals was not equal.

4) There was a question about drug inventory management. When the MOPH imposed the compulsory licensing policy, the remaining drug inventories were in a large quantity, including original drugs or generic drugs that hospitals had reserved for patients prior to the policy promulgation. The guidelines for using the drug inventories were not clear-whether to use the entire drug inventory first before shifting to the compulsory-licensed drugs.

7.1.2.3 The policy implementation guidelines for respective hospitals served as board guidelines based on the MOPH's Notification and protocol guidelines, but management-related details varied.

Mostly, the policy implementation guidelines for different hospitals were similar, on the basis of the MOPH's Notification and protocol guidelines. However, details about their management were different. All personnel concerned

acknowledged this and were cooperative. Initially, they accepted the policy's objective and goals and protocol guidelines.

1) In MOPH- and university-affiliated hospitals, there was a committee in charge of considering and assessing drug administering in the hospital every month. This committee consisted of medical personnel with good knowledge about treatment, including doctors, pharmacists, and specialist nurses. When a new drug was added into the dispensing system, it would become an agenda item in the meeting. As stated, the generic drugs under this policy aimed to solve the problem of patients' inaccessibility to drugs. Thus, respective hospitals examined documents about these generic drugs as approved by the Thai Food and Drug Administration (Thai FDA) before agreeing to put them into the hospital system.

2) The directors of MOPH- and university-affiliated hospitals held meetings to clarify the policy implementation guidelines to medical personnel to ensure their correct understanding and practices. The following issues were presented in the meeting.

(1) This policy had a clear objective and goals-The objective was to solve the problem of patients' inaccessibility to drugs, and the goals were to allow patients to access essential drugs equally and thoroughly, to reduce their suffering, to promote their quality of life, and to reduce medical costs for the government sector and patients.

(2) The agencies responsible for public health budget disbursement for the public health care schemes had to assess their budgets to cover patients who were the target group in the policy implementation. Their budgets were calculated according to the number of patients under each scheme and then disbursed to the hospital where the patients were receiving treatment. Respective hospitals had to manage the budget monies for health service and drug costs on their own, and they had to report the number of patients, protocol guidelines, drug dosages, and medical care costs to these agencies every month.

(3) In the policy and the MOPH's Notification for the seven drugs, the target group was clearly specified-patients under the three public health care schemes (the Universal Healthcare Coverage Scheme, the Social Security Scheme, and the Medical Benefit Scheme for Civil Servants and State Enterprise



Employees). The MOPH established the protocol guidelines for drugs under the in-patient treatment policy. The drugs included first-priority drugs and other drugs on the National Essential Drug List. Accordingly, doctors were supposed to start their treatment with the compulsory-licensed generic drugs and other drugs that are on the National Essential Drug List. Expert medical professionals, who were doctors and pharmacists, considered these drugs and established the protocol guidelines, for example:

For AIDS patients, the protocol guidelines rely on the levels of symptoms and severity of the disease of the patients.

1) Naïve patients:

Efavirenz (compulsory-licensed generic drug) + drug B + drug C

2) Patients with drug resistance:

Lopinavir/Ritonavir (compulsory-licensed generic drug) +  
drug D + drug E

7.1.2.4 Lack of active campaigns for, and focus on, encouraging doctors to administer the first-priority drugs and the compulsory-licensed drugs

It was found that doctors' selection of drugs depended on different factors, such as doctors' diagnoses, patients' symptom levels, and patients' medical care rights. Although there were many generic drugs available, doctors often prescribed original drugs even for early-stage treatment. These original drugs were much cheaper and were produced because the patent protection of their original drugs expired. The reason why doctors administered original drugs was that they had more confidence and trust in the therapeutic efficiency and effectiveness of original drugs than generic drugs, especially original drugs that were on the National Essential Drug List. However, they also considered their patients' medical care rights because the budget monies to subsidize patients in different schemes were allocated by three different agencies, and the amount of monies budgeted was not the same. If doctors in a hospital used original drugs excessively, the MOPH and their hospital would be burdened with higher drug costs. Patients under the Universal Healthcare Coverage Scheme (30 baht Healthcare Scheme) were provided with generic drugs first, while patients under the other two schemes were more likely to be administered original drugs rather than generic drugs. The MOPH did not actively request cooperation from

doctors in administering generic drugs or the compulsory-licensed drugs as the first-priority drugs to reduce excessive drug use, drug costs, and disparity in treatment among patients under the different schemes.

## **7.2 Guidelines for the Policy Implementation at the Micro Stage**

This study also evaluated operating units' policy implementation to reveal their implementation guidelines for the adoption and compliance with the policy or work plans. It also assessed changes made to their traditional practices into new practices according to the policy and work plans, as well as their willingness to comply with the policy as part of their routine. It also evaluated problems and obstacles, as well as factors that influenced their policy implementation. The results are outlined as follows.

### **7.2.1 Characteristics of Operating Units**

#### **7.2.1.1 Operating Units' Implementation Guidelines**

1) The policy implementation guidelines among operating units depended on the roles of hospital directors and doctors. Before the implementation of the compulsory licensing policy, the MOPH held a meeting to clarify the reasons for, objective, and goals of the policy, and issued a ministerial notification that defined the target group, requirements, and royalties for the drug patentees. Furthermore, the MOPH provided clear protocol guidelines for the compulsory-licensed generic drugs. Nonetheless, implementation guidelines of the policy were not clear, so the MOPH- and university-affiliated hospitals formulated their practice guidelines and procedures according to the policy framework based on three main factors – roles of hospital directors and doctors, and preparedness of hospitals. Based on the interviews with the hospital directors, the hospitals can be divided into three groups according to their management structure:

(1) Group 1-The directors in the group of hospitals played a very significant role in the hospital. They shared a similar view that the compulsory licensing policy was a solution to the problem of patients' inaccessibility to drugs, and generic drugs should be focused on more than the original drugs.

The hospital directors had the direct power to administer and control budget monies of their hospital. They could define and clarify guidelines for administering the generic drugs to comply with the policy. They held a meeting with doctors treating diseases that were defined in the policy, i.e. AIDS, cardiovascular disease, and cancer for patients under the three public health care schemes. Accordingly, the doctors had to start with drugs defined in the protocol guidelines, and then evaluate and follow-up the treatment by these drugs. If they did not adopt the protocol guidelines, they had to submit a written report with attachments that provided treatment or empirical evidence to the hospital director for consideration. Similarly, if the doctors administered compulsory-licensed drugs under the protocol guidelines and judged that these drugs had no therapeutic effectiveness and believe that other generic drugs or original drugs either on or off the National Essential Drug List should be adopted, they had to submit a written report with the same attachments to the hospital director.

After studying the report and its attachments and judging that other generic drugs or even original drugs were needed to save the patients' lives, the hospital directors had the power to approve the change. If the drugs proposed by the doctors were on the National Essential Drug List and were generic drugs, the disbursement would have no problem and the calculation was based on the central price of the generic drugs. If any doctors prescribed drugs that were not in the protocol guidelines, the problem could be:

Case 1: If patients' eligibility for the drugs is valid, the hospitals have to allocate budget monies to subsidize the drugs.

Case 2: If patients' eligibility for drugs is not valid, the doctors have to talk to patients about the medical bills that the patients have to pay for.

The hospitals that had drug inventories left, both original drugs and generic drugs, had to administer all of them before procuring generic drugs on the National Essential Drug List and the compulsory-licensed generic drugs, particularly the ones used for treating life-threatening chronic diseases.

Accordingly, the hospital directors shared a similar view that they quite trusted the quality and effectiveness of generic drugs produced by the GPO and generic drugs imported through the bidding process via the GPO. What

hospitals had to do was to provide explanations for patients to generate their understanding about, and confidence in, the equivalence between the original drugs and generic drugs.

Our hospital has the considered details and the credibility of pharmaceutical companies that won the bidding for generic drugs to be imported by the GPO, under the policy. If we have any questions, we will invite experts from the pharmaceutical companies that won the bidding to provide clarification to boost our understanding and confidence. Our hospital trusts in the GPO's production of generic drugs. Similarly, if we have any questions about drugs produced by the GPO, we'll ask GPO officers for clarification for our better understanding and confidence." (Director of a government hospital, 3 July 2013)

(2) Group 2-The hospital directors and doctors played equally important roles. Although the hospital directors had the direct responsibility for administration and control of the hospital budget, the doctors had high self-confidence about their profession; both parties felt considerate towards each other as people in the same profession. Therefore, the policy implementation of this group mainly involved meetings between both parties to point out the importance of the policy in the form of the MOPH's Notification and what they needed to consider-For the Thai government's policy, despite not being issued as an order, government hospitals, including university hospitals, are supposed to comply with it. This is because doctors' code of ethics attaches great importance to patients' continual and thorough access to medicines to reduce their suffering and improve their quality of life, especially those with chronic diseases that require a lifelong use of medications.

Another important issue was that "drug costs" could have many impacts. For example, higher drug costs as a result of original drugs would obstruct the equal access to medicines, while lower drug costs would allow for the equal and thorough distribution of drugs. The hospital directors held a meeting with doctors treating the three diseases defined in the policy to find appropriate guidelines

for generic drugs and the compulsory-licensed generic drugs for patients under the three public health care schemes. Under the guidelines, the treatment started with generic drugs as specified in the MOPH's protocol guidelines, and this was followed by an assessment and follow-up.

Another difference from Group 1 is that if the doctors examined patients' levels of symptoms and empirical medical data, such as blood tests, X-Ray, ultrasound and others, and judged that it was necessary to administer original drugs or generic drugs that were not included in the MOPH's protocol guidelines, they were allowed to make the change. However, they had to submit a written report with attachments that provided treatment or empirical evidence to clarify the reason and need for this change to the hospital director. If any doctors who administered generic drugs under this policy and the MOPH's protocol guidelines found that these drugs had no therapeutic efficiency and they had to switch to other generic drugs or original drugs that appear or did not appear on the National Essential Drug List, they had to submit the report with the attachments as the same.

As for the existing inventory of original drugs and generic drugs in the hospitals, it had to be administered and ordered as requested by the doctors, as necessary. The hospitals should start purchasing generic drugs on the National Essential Drug List as a reserve, in the case of campaigns for the use of generic drugs, generic drugs that replaced original drugs, and the compulsory-licensed generic drugs, which treat life-threatening chronic diseases. The doctors were not certain if the generic drugs that the GPO produced or imported via the bidding process would have therapeutic equivalence to the original drugs, which led to rejection of generic drugs and the compulsory-licensed generic drugs. This resulted in hospital budgets being insufficient and non-thorough drug distribution to patients.

Accordingly, the hospital directors in this group shared a similar comment to those in the first group that it was necessary to build trust and confidence among medical personnel and patients in applying the drugs and adjust negative attitudes towards the poor therapeutic efficiency of generic drugs. Each of the hospitals acted differently to create trust and confidence in the compulsory-licensed generic drugs, which varied according to different factors, e.g. hospital directors' administration power and doctors' decision-making power.

(3) Group 3-The hospital directors in this group allowed their doctors to play a major role in choosing drugs for treating the patients. Thus, the policy implementation guidelines for this group of hospitals put an emphasis on the clarifications for doctors on duty about the necessity of this policy, costs that the hospitals had to absorb, as well as the campaigns for the use of generic drugs and the compulsory-licensed drugs according to the MOPH's guidelines. The directors also attended meetings with the hospital doctors.

As for the existing inventory of original drugs and generic drugs in the hospitals, it had to be administered and ordered as requested by the doctors, as necessary. The hospitals should start purchasing generic drugs on the National Essential Drug List as a reserve as options and the compulsory-licensed generic drugs, which treat life-threatening chronic diseases. The doctors were not certain if the generic drugs that the GPO produced or imported via the bidding process would have therapeutic equivalence to original drugs, which led to rejection of generic drugs and the compulsory-licensed generic drugs. This resulted in hospital budgets being insufficient and non-thorough drug distribution to patients, as was the case with Group 2.

## **7.2.2 Practitioners' Attitudes**

7.2.2.1 Lack of confidence in the therapeutic efficiency of the compulsory-licensed generic drugs-The interviews suggested that the doctors treating chronic diseases specified in the policy had a similar opinion that imposing compulsory licensing was one solution to improve patients' access to medicines, especially those who need a lifelong use of drugs to reduce their suffering and improve their quality of life.

On the contrary, an item in doctors' code of ethics is: "doctors are patients' last refuge; therefore, doctors must exercise their discretion carefully and have confidence in the therapeutic effectiveness that allows patients to recover from their suffering equally and thoroughly without discrimination." This conceptual framework resulted in different attitudes among doctors towards the guidelines for treatment and for administering drugs for the life-threatening chronic diseases-AIDS, cardiovascular disease, and cancer. Before, most doctors administered original drugs

as a result of clinical research and trials in humans in terms of their efficiency and safety, strong confidence in the production technology and process of original drugs, as well as empirical evidence about their therapeutic effectiveness.

In addition, doctors had no faith in the quality and effectiveness of the compulsory-licensed generic drugs. Also, some patients had no trust or confidence in the quality and effectiveness of generic drugs for substitution despite receiving some explanations from their doctors. As for cardiovascular and cancer patients eligible for the Social Security Scheme and the Social Security Scheme and the Medical Benefit Scheme for Civil Servants and State Enterprise Employees, they often rejected generic drugs and requested original drugs. This came from their fear that generic drugs would fail to cure them and be harmful to them or their relatives. Some were willing to pay for higher drug costs on their own.

When the policy was promulgated for the seven drugs, whereby generic drugs would be first-priority drugs, most doctors had concerns. They did not have faith in their quality, effectiveness or safety for treating these serious diseases. They believed “if any minor error occurs, it will immediately affect the patient’s life.” They also had concern about what explanations they should give to patients to build their acceptance of, and understanding about, the use of generic drugs in replace of the original drugs they had been prescribed earlier. Some hospital directors mentioned what doctors had said about this policy, as follows:

Doctors had concern about the treatment because of research about the differences in the quality and effectiveness between generic drugs and original drugs. Also, there was no clear supporting data on their equivalence in clinical trials on humans. Despite bioequivalence studies, they worried about the use of generic drugs, and they had concern and uncertainty about their impurities. There is a research work on the impurities in the generic drug Doxetaxel, which was one of 13 generic drugs available in 14 countries, in Asia, Africa, the Middle East and Latin America. Its active ingredients were found to have no standard and have excessive impurities (Vial et al., 2008). The doctors want an equivalence study in clinical trials on humans between

generic drugs and the original drugs to boost their confidence and allow them to answer patients' questions and reassure patients that generic drugs have the same quality and therapeutic effectiveness as the original drugs, based on empirical evidence. (Director of a government hospital, 16 May 2013)

The doctors treating cardiovascular disease had concern about the toxicology of generic drugs under the policy, so they requested the generic drug Plavix<sup>®</sup>, whose generic drug name is Clopidogrel, for patients with a coronary artery balloon for at least three months. For patients without a coronary artery balloon, they are prescribed generic drugs or Clopidogrel (if the right to medical care is not considered). This is because they are sure about the quality, effectiveness, and impurities of generic drugs, which will have really harmful effects on patients. (Director of a government hospital, 11 June 2013)

Doctors treating cardiovascular disease have not been sure if Clopidogrel will result in acute coronary syndrome. For patients wearing a stent in coronary arteries, if thrombosis occurs, it will be seriously harmful to them. This was why doctors didn't administer the generic drug Clopidogrel immediately. Instead, they were waiting for research results, especially the results of clinical research in humans that show their equivalence to original drugs. However, after the MOPH's policy promulgation, government hospitals under the MOPH had to comply with it. However, they asked the Permanent Secretary to the MOPH the question as to who would be responsible if any people sued for the occurrence of thrombosis in patients wearing a stent in coronary arteries. (Director of a government hospital, 19 June 2013)

7.2.2.2 Lack of trust in operations of the GPO, the government's representative to produce and import drugs for sale under the government use compulsory licensing policy



The interviews reflected why hospital directors, doctors, pharmacists and other medical personnel lacked confidence in the GPO's operations. The reasons can be divided into many issues, as follows:

1) The GPO's officers had inadequate technical data about the GPO's generic drugs, and they did not pay attention to doctors' feedback about the advantages or disadvantages of the generic drugs after they had been administered. Instead, they focused on providing information to hospital directors. The hospital directors shared the same view:

Providing information about the GPO's drugs only for the hospital directors was not a wrong thing, and this did not mean that the GPO's drugs are not good or have poor quality, but what they did was irrelevant. Most hospital directors are executives, and treatment is their secondary task, so their feedback about the GPO's drugs may not be correct or complete. If the GPO wants to receive acceptance, they need to reach the target group-doctors who administer the drugs-because doctors know about the properties, quality, effectiveness and advantages of the drugs. Also, the GPO needs to listen to suggestions and exchange information with the doctors about their advantages and their disadvantages that the GPO can improve. This is what private pharmaceutical companies have done, so they are able to produce and improve medicines that meet doctors' needs. This will build a good relationship and trust with doctors and improve the GPO's image mentioned several times for their drugs' poor quality and efficiency.

2) The GPO's management system was rather slow and involved different complicated procedures and their drugs were frequently insufficient for hospitals.

The GPO has introduced the Vendor Managed Inventory (VMI) system to solve the problem of delay of the management system, for receiving orders, prescriptions, transportation and distribution of drugs to hospitals that meet their needs. The VMI system is one concept for inventory management, whereby producers

or dealers manage the inventory for customers. In the system, producers or dealers manage stocks in the warehouse and are responsible for adding products for customers. By storing goods and planning for their delivery by themselves, producers are able to know their customers' product balance and decide to add products for their customers. This will reduce the problem of accumulated goods in stock for the producers and retailers' distribution center. The VMI system's main benefit is products regularly fed to customers, which helps to reduce accumulated items in stock in the warehouse for producers and customers' distribution centers, too. Also, this can reduce the number of staff and production costs. Furthermore, the VMI system reduces errors in data because it involves computer-to-computer communication, which has higher data transfer speeds.

The GPO's problem that could not be resolved was the inadequate capacity for drug production that meets hospitals' need. This was followed by the problem of amortization to the GPO and hospitals' ordering drugs from other pharmaceutical companies. As for the compulsory-licensed generic drugs, they were in a sufficient quantity, as a result of the VMI system and the focus on these drugs as first-priority drugs.

#### 7.2.2.3 Confusion of the diverse uses of generic drugs bid under the policy

After the policy was promulgated, individual MOPH and university-affiliated government hospitals had to establish the guidelines for solving problems in their organization. The MOPH's policy had a sound objective-to improve the access to essential drugs of patients in the MOPH and university-affiliated hospitals. The tool that the MOPH provided for these hospitals was only the guidelines for defining the target group of the drugs and budget provided for patients under each of the public health care schemes-the Universal Healthcare Coverage Scheme (30 baht Healthcare Scheme), Social Security Scheme, and the Medical Benefit Scheme for Civil Servants and State Enterprise Employees. Respective hospitals' internal management was their responsibility. Despite being clearly informed of the target group for these compulsory-licensed drugs and protocol guidelines and having the freedom to manage their own budget, the hospitals experienced many problems, such as patients' being unclear about their medical care rights, doctors' unacceptance of this policy, and the

amount of inventories of drugs that are not the compulsory-licensed drugs. The hospitals had to resolve issues all the time.

The most important common issue encountered by these hospitals in relation to the GPO's roles relates to two cases.

1) Case 1: The GPO as the drug producer-So far, the GPO has been able to produce two out of the seven drugs-Efavirenz and Lopinavir/Ritonavir, used for treating AIDS. In this case, no problem occurred because the trade name, pill forms, packaging, and producer name for these drugs were not different than before. The hospitals could put a code on the drugs and record the patients' history of drugs administered, which facilitated doctors' explanations to allow their patients to have a clear understanding about the medications and eased the follow-up of symptoms, therapeutic effectiveness, as well as adverse symptoms.

2) Case 2: The GPO as the agent for bidding to import generic drugs from pharmaceutical companies with a certified drug production process and drug quality-There were five medications imported-Clopidogrel (cardiovascular disease) and Imatinib, Letrozole, Doxorubicin and Erlotinib (cancer). In this case, problems were related to the hospitals' drug encoding and recording of patients' history of drugs administered. This was because the compulsory-licensed generic drugs were derived from the bidding process. A pharmaceutical company may win the bidding a few times successively, and the next bidding may be won by another pharmaceutical company that presents new drugs with the same active ingredients. Accordingly, generic drugs obtained from bidding come from many companies, which are different in trade name, pill forms, and packaging. This resulted in problems with drug encoding and recording of patients' history of drugs administered, and this was an obstacle to the follow-up of symptoms, therapeutic effectiveness, and undesirable symptoms. More importantly, it caused doctors to have difficulties in explaining the reasons for changing the drug form and drug use. This was because most patients remembered drugs by their appearance and packaging, especially elderly patients, which may result in their confusion about the medication they are taking.

### 7.2.3 Budget for the Policy

Budget monies were a key resource for implementing the policy to allow its objective and goals to be met. The public health budget for the seven generic drugs for patients under the public health care schemes was disbursed by the three agencies, as outlined in Table 7.2.

**Table 7.2** Agencies Responsible for Budget Disbursement to Government Hospitals

<b>Rights to medical care</b>	<b>Agency concerned</b>
Universal Healthcare Coverage Scheme (30 baht Healthcare Scheme)	The National Health Security Office
Social Security Scheme	The Social Security Office
Medical Benefit Scheme for Civil Servants and State Enterprise Employees	The Comptroller General's Department

The criterion for the budget disbursement is: Government hospitals have to inform the agencies about the number of patients entitled to the public health care scheme under their responsibility, and then these agencies will disburse the monies to the hospitals and leave the hospitals to manage the budget on their own.

Following the policy promulgation to improve the general public's access to essential drugs and to reduce drug costs, as well as the MOPH's campaigns and request for the use of generic drugs in replace of original drugs, it was found that drug costs and the volume of imported original drugs were still high (Bureau of Drug Control, 2009).

An officer from the National Health Security Office said:

The three agencies provide the hospitals with budget monies on the basis of the number of patients, and the hospitals are allowed to manage the budget without control. What the hospitals have to do is report where their spending goes to. Nonetheless, doctors' dispensing of drugs doesn't always comply with the MOPH's protocol guidelines under the policy. Drug prescriptions depend on several factors, such as

patients' symptoms, patients' unacceptance of generic drugs, and the doctor's discretion. Therefore, management of the budget may not meet the objective and guidelines in this policy. These agencies have to be stricter to ensure that the budget spending is appropriate and meets the policy's objective." (National Health Security Office, 30 July 2013)

The interview with the officer from the National Health Security Office revealed that in 2012, the budget allocation to government hospitals, especially for the compulsory-licensed generic drugs had been changed. The calculation on the basis of the number of patients remained the same, but the disbursement system changed. That is, these agencies would pay the government hospitals for the compulsory-licensed generic drugs provided that they complied with the MOPH's protocol guidelines. The hospitals had to submit a report on administering drugs to the agencies every quarter before they received that disbursement. If their drug administering for any patients did not comply with the protocol guidelines, the hospitals would not receive the subsidy for these patients and they or these patients had to take care of the drug costs. In addition, the notification concerning public health expenditures from the MOPH and the Ministry of Finance (MOF) was issued. In the notification, a new criterion for disbursement for the public health care schemes was defined-the disbursement is possible in the case of administering generic drugs and drugs on the National Essential Drug List. In addition, it stated that certain drugs were removed, such as Vilatril<sup>®</sup>, which increases lubrication in knee joints and is not an essential drug.

#### **7.2.4 Political Changes**

Three political changes occurred from the time the policy was first adopted until the start of policy implementation by government hospitals. The interviews with hospital directors showed that they had a similar view about this matter:

The compulsory licensing policy for these seven essential drugs is one method to definitely increase people's access to medicines. It is beneficial to patients, especially those under the

Universal Healthcare Coverage Scheme. This policy allows them to have significantly better access to essential drugs. This is also true for those under the Social Security Scheme and the Medical Benefit Scheme for Civil Servants and State Enterprise Employees, whose eligibility for the medical care is high-they can request original drugs to replace generic drugs. Under the policy, patients in the last two groups have also been found to have better access to essential drugs. In spite of political changes, the hospitals still complied with this policy, which was a benefit for patients. However, if political changes cause the cancellation of this policy, it must be discussed later about the new policy direction of the MOPH as the policy maker.

### **7.3 Results of the Policy Implementation in Thailand**

This study on the implementation of the compulsory licensing policy for seven essential drugs found that the policy achieved the objective to improve the general public's equal and thorough access to the drugs. It also helped to reduce drug costs.

The author collected data about patients' history for each drug administered and the drug costs in MOPH- and university-affiliated government hospitals that were the data collection fields. It was found that collecting the data in these hospitals was a real challenge as a result of unequal efficiency in their IT systems for data storage. Some hospitals had no IT system while others had just installed the IT system for collecting all patient information. This was why data obtained from them were very different-data could not be collected for every year and the IT system was not advanced enough to extract patients' data under each drug item. Some hospitals had started collecting patients' data in the IT system the year before, and the data before that were still on paper. Due to this limitation, data needed to be displayed as the indicators of the policy implementation as a whole, which were quite complete, from 2008 to 2010. The indicators included the number of new patients receiving the drugs from 2008 to 2010, which are outlined in Table 7.3 and Figure 7.1. The savings in costs resulting from the use of compulsory-licensed generic drugs, compared with the original drugs, are detailed in Table 7.4 and Figure 7.2.

**Table 7.3** Number of New Patients Receiving Respective Drugs, from 2008 to 2010

Drug	Number of new patients			Total
	2008	2009	2010	
<b>Efavirenz 200 mg</b>	5,030	7,080	11,675	23,785
<b>Efavirenz 600 mg</b>	20,120	25,980	37,220	83,320
<b>Lopinavir/Ritronavir</b>	14,600	24,500	26,100	65,200
<b>Clopidogrel</b>	40,200	61,300	87,800	189,300
<b>Doxetaxel 20 mg</b>	2,710	6,790	9,130	18,630
<b>Doxetaxel 80 mg</b>	3,321	6,570	8,920	18,811
<b>Letrozole</b>	0	1,572	2,307	3,879
<b>Total</b>	<b>85,981</b>	<b>133,792</b>	<b>183,152</b>	<b>402,925</b>

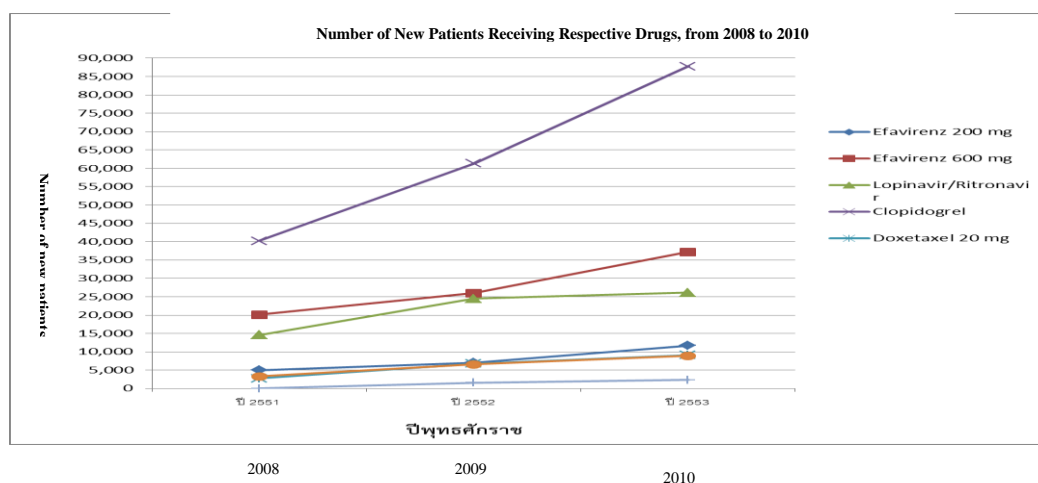
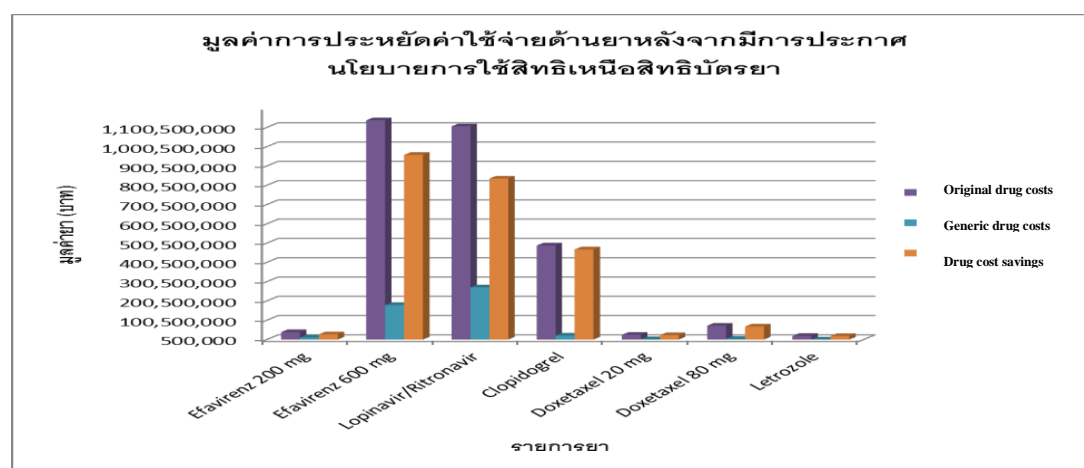
**Figure 7.1** Number of New Patients Receiving Respective Drugs, from 2008 to 2010

Table 7.3 and Figure 7.1 show the number of new patients receiving respective drugs from 2008 to 2010. It was found that after the policy promulgation, the number of new patients taking all the medicines administered under the policy for serious chronic diseases-AIDS, cardiovascular disease, and cancer-increased steadily from 2008 to 2010. This implied that patients had significantly better access to the medicines.

**Table 7.4** Drug Cost Savings after the Policy Promulgation, from Fiscal Year 2008 to 2010

Drug	Price of original drugs (baht)	Price of generic drugs under the policy (baht)	Purchase quantity	Drug cost savings (baht)
Efavirenz 200 mg	2,224.75	646.79	17,417	27,483,329
Efavirenz 600 mg	1,973.52	310.99	576,401	958,283,955
Lopinavir/Ritronavir	8,907.75	2,181.59	124,172	835,200,740
Clopidogrel	72.53	3.05	6,730,000	467,600,400
Doxetaxel 20 mg	7,811.00	557.22	3,200	23,212,096
Doxetaxel 80 mg	28,355.00	1,706.04	2,548	67,901,550
Letrozole	4,500.00	181.88	4,200	18,136,104
Drug cost savings (baht)				2,397,818,173



**Figure 7.2** Drug Cost Savings after the Policy Promulgation, from Fiscal Year 2008 to 2010

Table 7.4 and Figure 7.2 show the drug costs savings from 2008 to 2010. It was obvious that the costs of respective drugs to treat the three diseases reduced continually from 2008 to 2010 so that the government hospitals had enough budget monies for purchasing more medicines to improve their patients' access to other drugs. This was in line with the increase in the number of new patients from 2008 to 2010 after the policy promulgation.



## **CHAPTER 8**

### **CONCLUSION, DISCUSSION, AND RECOMMENADATION OF THE RESEARCH**

This chapter outlines findings from secondary data (e.g. articles) and primary data (interviews with stakeholders in the compulsory licensing policy), as well as the policy implementation indicators. Conclusions and discussions were developed from the research results-from the policy formation to the policy implementation. Also, recommendations for implementing this policy to achieve more efficiency are presented.

#### **8.1 Conclusion and Discussion**

The results of the research and evaluation of the policy implementation revealed that this policy was an important way to address the problem of the inaccessibility to drugs for people, particularly in underdeveloped and developing countries, including Thailand. The per-capita GDP in these countries is very low to moderate (WHO, 2004), which forces many patients to discontinue medical treatment due to unaffordable drugs. They choose to spend their money on their daily living and their family rather than on life saving drugs (Nusaraporn Kessomboon, 2002). This usually occurs among patients living with serious chronic diseases, such as AIDS, cardiovascular disease, and cancer; the death statistics from these diseases have risen steadily. Patients inflicted with diseases need a lifelong use of medications to allow them to be free from suffering and lead their lives normally (WHO, 2004). Nonetheless, drugs used for treating these diseases are original drugs, which are costly as a result of patent protection under patent law. The law protects the intellectual property of people who develop an invention or innovation that is beneficial to mankind. As for generic drugs, they have active ingredients that have equivalent

therapeutic efficiency to, and lower prices than, the original drugs. Generic drugs are available in the market when the original drugs' patent protection has expired. Originally, patent law in these countries dealt with process protection with a protection period of 15 years. Later, it was changed to a protection period of 20 years. Patent protection has resulted in monopoly in patented innovations, which include drugs. However, an exception appearing in many documents, such as the Doha Declaration, the TRIPs Agreement, and patent laws is that-In cases where a country experiences shortages of consumer goods or medicines, or epidemics of uncontrollable diseases, or war, any ministry, bureau or department of the government may impose compulsory licensing by themselves or through others, by producing or importing generic drugs with active ingredients and therapeutic effectiveness without delay. It shall notify the drug patentee company without delay and shall submit its offer setting forth the royalties to the company.

The secondary data showed that despite the exception for compulsory licensing, there were no developing or underdeveloped countries that solved their public health problems based on this exception for the sake of their population. The main reason was economic, trade and exportation pressure from superpower countries, e.g. the U.S.A., as well as other threats, including cutting of the Generalized System of Preferences (GSP) and other benefits.

For a period of time, most developed and underdeveloped countries had concern about the loss of a good relationship with superpower countries, which could lead to the loss of economic and trade privileges, revenues from imports and exports, and other assistance from these countries. None of them took actions following the exception for public health purposes. Amidst this concern among underdeveloped and developing countries, in 2004, the U.S.A. took advantage of this exception by imposing compulsory licensing on Ciprofloxacin, a drug patented by Germany's Bayer to cope with the uncontrollable spread of anthrax (WHO, 2004). This compulsory licensing allowed the U.S.A to improve their population's access to the drug and reduce drug shortages and costliness. No developing or underdeveloped countries imposed compulsory licensing immediately after the action taken by the U.S.A. As stated, this resulted from their fear for greater power, loss of aid, and economic losses.

Developing and underdeveloped countries did not weigh between the worthiness of the courage to solve public health issues and the potential consequences.

This situation did not change until 2006, when AIDS epidemics became severe and uncontrollable throughout the world, which resulted in increasing death rates. This mainly came from the fact that AIDS patients could not afford their essential medicines, which caused them to stop their medical treatment to spare their money for other needs and their family. This was a major ongoing public health problem, particularly in developing and underdeveloped countries. Although there were different foundations that offered free medicines to AIDS patients, the quantity of the medicines was not enough for all patients. Some foundations set many conditions, which made it difficult to implement in a timely manner during the emergency. Many developing and underdeveloped countries decided to impose compulsory licensing on AIDS drugs to improve their people's access to essential medicines, such as Africa (WHO, 2004), Brazil (Okie, 2006), Malaysia (Ling, 2006), Ghana (Avafia, 2006) and others. The imposition of compulsory licenses resulted in their population's improved drug access drugs and the significant decrease in mortality rates.

Thailand also experienced the same situation for AIDS, which spread extensively and could not be controlled; this resulted in a public health problem for the country. Therefore, the Ministry of Public Health (MOPH) held a meeting to seek the optimal solution to the problem of patients' inaccessibility to drugs in order to promulgate and implement it as a policy.

The secondary data showed that there were many issues that needed to be addressed to begin to solve the problem of patients' inaccessibility to drugs-increasing the public health budget, increasing the quantity of drugs on the National Essential Drug List, negotiating with the patent-owner companies over the prices of original drugs, as well as imposing compulsory licensing.

To achieve the most practical solution, many factors were taken into account. Despite negative impacts on the country's economy, image and so on, it was assessed that the imposition of the compulsory licensing policy would bring out benefits to the Thai population and Thailand as a whole. Compulsory licensing was the most suitable way given the circumstances in Thailand in 2006. The MOPH promulgated the compulsory licensing policy for seven essential drugs. Based on the primary and

secondary data, the reasons for formulating the compulsory licensing policy for the seven drugs from 2006 can be outlined as follows:

First-Thailand is a developing country where the average per-capita GDP is low to moderate, and the per-capita GDP is only high to very high for a small minority of the Thai population.

Second-Thailand is an agricultural country, not an industrial country, so its major exports are agricultural products for consumption. The value of these products is not high, if compared with oil or gold. Thailand has exported very few industrial products to compete with richer countries with more expertise. Many factories in industrial estates serve as the production base for foreign companies who rely on Thai labor working on low wages. Therefore, the major proportion of revenue that has nurtured the country comes from the agricultural sector, the value of which is not high. Thailand also exports non-agricultural products, but these products do not constitute enormous revenue that can serve as a budget to provide public welfare for the entire population equally and thoroughly. Although the budget that the government allocates to the MOPH has increased every year, it is very small, compared to the country's per-capita GDP and the number of old and new patients. For Thailand, solving the problem of patients' inaccessibility to drugs by means of increasing the public health budget and adding drugs onto the National Essential Drug List is not practical because it involves monies. Increasing the budget and drugs is compared to swimming in circle in a basin while trying to fill holes in it, whereby an actual solution cannot be found. As mentioned, this is because Thailand has a limited budget to allocate for its national development and security. Accordingly, a budget is compared a piece of cake that needs to be shared according to the priority of problems within and outside the country.

The number of patients in Thailand has increased every year, and the budget to subsidize patients has increased accordingly. In addition, new drugs have been added to the National Essential Drug List to cover patients eligible for medical care in the public health system. In this case, two methods are mentioned: 1) increasing monies to fill a void that is the failure to treat patients thoroughly; and 2) adding original and generic drugs to the National Essential Drug List, under which the drugs are subsidized. It is found that the prices of the added drugs remain unchanged,

but the number of patients has increased every year. The budget will never be sufficient because it is using the investment money to deal with the cost that is higher than the investment money. This situation is called “washing money in the river.” No matter how much budget is allocated by the government, it cannot allow the public to have better drug access, and it wastes the budget without getting any returns. This opinion is in line with the opinion of the National Health Security Board’s officer who had a role in formulating the compulsory licensing policy.

Third-Negotiation with the drug-patentee companies over the original drugs. Based on the primary and secondary data, the negotiation over the prices of patented original drugs is extremely difficult because drug-patent companies have an advantage when they claim their right to their drugs they have invented for mankind, with a huge investment of wisdom, knowledge, technology, and money. The companies have been granted patent protection under intellectual property law in relation to their rights to produce, import, and sell their invention. Pricing patented original drugs is exclusive for their patentee companies. When original drugs are produced, imported and registered after being checked by the Thai Food and Drug Administration (Thai FDA) of each country, if that country does not have a drug-pricing control mechanism, or has an inappropriate or an unclear drug-pricing control mechanism, the drug-patentee companies have legitimacy to price their patented original drugs.

The drug-pricing control mechanism is pharmaceutical companies’ strength, and it is Thailand’s major weakness because no mechanism for drug-pricing control exists in the country. However, this does not mean that drug companies can set any price for their patented original drugs in countries that have no proper or clear mechanism for drug-price control. This is because drugs are “merit goods,” which are not general goods, such as electronic devices or other commercial products. Drugs are necessary for the existence of life, which determines the survival or non-survival of patients, who have legitimacy to receive essential drugs to cure their disease, to free themselves from suffering, and to have a better quality of life.

The Ministry of Commerce (MOC) set up a committee on the consideration of the mechanism for screening categories of products and controlling prices of different categories of goods, which have different impacts on people and

the country. The Committee has considered which categories of goods should be scrutinized to avoid adverse impacts on people and yield great benefits to the country. To consider the mechanism for controlling prices of drugs, which affect the general public and can impact the country's public health problems, the Committee should consist of experts or academics equipped with medicinal knowledge. Pharmacists with expertise in clinical pharmacy and medical economics should be involved in the Committee.

Fourth-Compulsory licensing. The primary and secondary data showed that this was the optimal method to solve the problem of patients' inaccessibility to drugs during that time. Also, the method had the greatest impact on Thailand's external factors-patent-owner companies and international relationships-in terms of image, economy and so on. The compulsory licensing can be regarded as "wrist-wresting with global superpowers using legitimacy," on the basis of benefits defined in the Thai Patent Act, Doha Declaration, TRIPS Agreement, and righteousness rights of the WHO.

Compulsory licensing can be called "wrist-wresting with global superpowers using legitimacy" because the right to impose compulsory licensing is a legal right, in the case it is imposed with the strict compliance with relevant details, conditions, and requirements. Without the strict compliance, it is considered to be an infringement on the drug-patentee companies' intellectual property. In 2006, the AIDS epidemic was severe and uncontrollable, which resulted in high mortality rates. The medications used for treating AIDS had patent protection, which made them costly. The Thai government and MOPH could not add the medicines to the National Essential Drug List as a result of an important factor – inadequate budget to subsidize all AIDS patients. Also, the patients could not afford these medications. There were many foundations that offered complementary drugs for AIDS patients in underdeveloped and developing countries, e.g. the Clinton Foundation and Oxfam. However, the quantities of drugs were insufficient for all AIDS patients and newly-infected people. These foundations stated that if any patients needed more drugs after receiving the complementary drugs, they would be subject to conditions for buying the drugs.

The best solution for Thailand that time was the compulsory licensing policy promulgated by the MOPH. Actually, the problem of patients' inaccessibility to drugs was not restricted to AIDS patients, but also patients experiencing other chronic diseases, for example, cardiovascular disease and cancer.

The MOPH and government decided to impose compulsory licensing on the drugs through legal procedures, which included considering necessary medications for compulsory licensing, negotiating on the drug prices, promulgating the compulsory licensing policy, and setting royalties under international calculations. The government issued a notification to the drug-patentee companies without delay and assigned the GPO to be the representative to produce or import drugs under this policy for sale in Thailand. In total, the MOPH and the government promulgated the policy for seven drugs: two AIDS drugs and one cardiovascular drug in 2006 and four cancer drugs in 2008. The policy had many impacts on Thailand, including economic threats related to cutting the Generalized System of Preferences (GSP) and a bad global image for intellectual property infringement. It was found that economic threats related to GSP cutting affected the country's non-major exports because Thailand is an agricultural country. With respect to the country's bad image related to the infringement on intellectual property, Thailand adopted relevant conditions and requirements, clarified all procedures, and issued a notification to the patent-owner companies without delay-all these can improve the country's image about the intellectual property infringement. The MOPH studied secondary data on risk assessment and forecast potential outcomes of the policy. The in-depth interviews showed that this policy increased patients' access to the drugs.

The assessment between the adverse impacts or risks and good outcomes related to patients' increased drug access revealed that the positive impact related to a human's right to access medicines to cure their disease and liberate themselves from suffering outweighs negative impacts, which could be resolved easily at that time. This value led to the imposition of the compulsory licensing policy. The primary and secondary data showed that even though Thailand took proper actions in compliance with requirements, procedures, legal conditions, and international agreements (Doha Declaration and the TRIPS Agreement), notable issues arose (Thai FDA, 2007), which are described below:

1) The drug companies refused to negotiate with the Committee on the Negotiation on Prices of Patented Essential Drugs negotiation over the royalties, which ranged from 0.5 to 2%, based on international calculations. Instead, they submitted a proposal to reduce drug prices under the condition that if an agreement is reached, the policy must be waived. Actually, the MOPH assigned to the Committee to negotiate with the companies over the drug prices before the policy was promulgated, except for the cancer drug Imatinib, which was under the Glivec<sup>®</sup> International Patient Assistance Program (GIPAP). The response from the companies was always the same: “the drug prices cannot be lowered. We would like to keep the old prices, which are the minimum.” Actually, before the policy promulgation, the Committee negotiated with the drug companies over 7-8 times. As for cancer drugs, the price negotiation took place over 10 times. This showed that the government and MOPH tried hard to negotiate over the prices, but the companies’ response was rejection. These companies expressed their intent to negotiate over drug discounts after this policy was imposed, which was not a right time to do it. More importantly, the drug prices fixed by these companies were many hundred times higher than their cost. It was found that eventually, they offered a huge discount when they were pressured so that they fell into a disadvantageous position for their profits.

The government and MOPH deemed the policy promulgation to be completed and it was leading to desirable results, so they continued the policy. Since then, the negotiation over royalties has not been resumed, and the companies have not accepted the royalties offered by the GPO. As stated, the royalties represented 0.5-2% of the sales of the respective generic drugs under this policy. The MOPH is still keeping the royalties, and has not prepared any notification. Also, the MOPH has not received any order from the government to resume the negotiation with the companies over the royalties.

2) The drug patent system in Thailand was fairly lax and lacked expertise in patent protection to avoid disadvantages to the general public and country. This led to several loopholes in the system, which allowed evergreening patents. According to the Thai Patent Act, a patent is intended to protect an inventor’s or product designer’s exclusive right to their intellectual property. It is an important document issued by the government for the said protection. According to intellectual



property law, a patent may be granted only for an invention if the following conditions are satisfied (Patent Act, 1979):

(1) The invention is new, which is different from existing inventions and has never been widely used or sold within or outside a country.

(2) It involves advanced technology and cannot be easily developed by those with average knowledge in a field, or a technical solution to existing inventions of the same kind.

(3) It is capable of industrial application if it can be made or used in any kind of industry, including handicrafts, agriculture and commerce.

It is noted that a patent is intended to transfer invention methods that are useful for further development. It provides protection against copying inventions or innovations for a certain time period. During the legal protection period, the inventors can reap the benefits of their invention, for which they have invested a great deal of money, wisdom and knowledge- “the protection is comparable to a reward for their dedication and ideas about their invention and innovation.” This can be viewed in both positive and negative sides- 1) generation of incentives for researchers or individuals to invent things for the sake of humanity, and 2) a huge loophole for evergreening patents and the patent right as the right to a monopoly.

As stated, “drugs” are merit goods; they are different from most general goods, as they are vital to life. Therefore, rules for general goods cannot be applied to drugs equally. For drug products, moral and ethical dimensions must be first considered. To allow any drugs to be patented, it must be scrutinized if they are innovations. For example, Glaxo Smith Kline Co., Ltd. applied for the patent for Combivir<sup>®</sup>, used for treating AIDS, as a new drug (Sirirat, 2007). Combivir<sup>®</sup> is a combination of Lamivudine and Zidovudine, containing a lubricant that allows them to blend together well. Pharmaceutically, mixing drugs in this way is developing a basic formula. This is because even if they are not mixed together, each of them can treat AIDS individually. Accordingly, it was not considered to be an innovation. If Thailand had granted the patent to Combivir<sup>®</sup> without scrutiny, and if there had not been any objection from the general public, the company would have a monopoly on Combivir<sup>®</sup> and the process of mixing Lamivudine with Zidovudine-their patent would have been considered to be an evergreening patent. There are many strategies utilized

by pharmaceutical companies to get a so-called “an evergreening patent.” They include conducting rough verification for the newness of their invention, giving incomplete data, and requesting to keep their drug test data confidential.

Accordingly, it is necessary to review loopholes in the drug patent system in Thailand and correct them. The issues that should be improved are as follows:

1) Objection to patent issuance, which can be divided into two ways: pre-patent issuance objection and post-patent issuance objection. The second way has been applied in Thailand, although it is very difficult to process and the ability to file and win a lawsuit for waiving a patent is not easy. Many countries, such as Germany and Japan, are more likely to use pre-patent issuance objection (Sirirat, 2007) because they can consider relevant data to find reasons and arguments as to why the patent should not be issued. This method is easier and results in transparent and checkable control of patent issuance by the government sector and the general public.

2) Modern IT systems should be introduced for collecting data on drugs patented in Thailand, in order to facilitate checking data to avoid the following: evergreening patent strategies, infringement on patents due to unawareness of data from generic drug manufacturing companies, provision of incomplete data by companies that apply for patent registration, and so on.

## **8.2 Conclusion and Discussion of the Policy Implementation**

### **8.2.1 Conclusion and Discussion of the Policy Implementation**

Concerning the results of the policy implementation among operating units, MOPH- and university-affiliated governments, it was found that the number of patients that could access the seven compulsory-licensed drugs from 2008 to 2010 had a sharp rise. This excluded cancer drugs Imatinib and Erlotinib. The GPO had no capacity or adequately sophisticated technology to produce cancer drugs, so it has to import them. Now, the GPO is seeking companies for bidding for cancer drugs. Because there have been no companies that can produce cancer drugs with good properties and adequate efficiency to participate in the bidding, data on these two

drugs has not been presented. As for cost savings, after this compulsory licensing policy was imposed, the drug costs decreased significantly from 2008 to 2010, except for Imatinib and Erlotinib.

It can be said that the policy implementation achieved its objective and goals – improving patients’ access to drugs and saving budget monies for drugs. As a result, the MOPH and government hospitals could save some budget monies to improve patients’ access to other drugs or medical services.

Despite the achievement of the policy’s objective and goals, there was some feedback about problems and obstacles in the policy implementation. It can be concluded that: “although the policy implementation achieved the objective and goals, throughout the policy implementation period, there were many problems and obstacles experienced by the MOPH- and university-affiliated government hospitals. Each of the hospitals solved immediate problems and implemented the policy. As for problems and obstacles that the hospitals reported to the MOPH, some had been resolved but some had not; there were both direct and indirect impacts in the short and long term. For the short term, the problems and obstacles resulted in hospital personnel feeling discouraged, bored, and unmotivated to work, which caused delay and negligence in complying with the policy. In the long run, the problems and obstacles could lead to opposition and non-compliance with the policy. The short- and long-term effects could lead to the failure of the policy, as discussed below.

## **8.2.2 Conclusion and Discussion of the Policy Implementation at the Macro Stage**

The macro stage dealt with transformation of the policy from the MOPH, the central agency, into implementation plans for the operating units-MOPH-and university-affiliated hospitals. The results demonstrated that the factors that influenced the policy implementation at the macro stage included characteristics of the policy, the consistency of policy, political changes and, the communication of the policy, which are outlined below:

8.2.2.1 Characteristics of the policy-The policy was clear in details about its objective, basic criteria, and the target group

To succeed in implementing a policy efficiently, the policy must outline the objective, basic criteria (Sanger, 1999), and the target groups, and these details must be shared among all operating units (Coburn, 2006). The MOPH had a meeting with the directors of the MOPH- and university-affiliated government hospitals to clarify the reasons, needs, and objectives of this policy. This was intended to develop their understanding about the transformation of this policy into guidelines or work plans. Also, the policy was publicized periodically via different media, including television, newspapers and others to educate other medical personnel and the general public. After that, the MOPH issued “the MOPH’s Notification” for different drugs and sent it to all the operating units-the government hospitals and the GPO. Each notification specified basic details for the policy implementation-the objective, duration of the compulsory licensing, the target group, and percentage of the royalties for the drug patentees. This policy was well prepared by the MOPH, through meetings with executives and publicizing relevant information-the latter was good strategy to produce interest, awareness, and understanding about this policy. However, it took a long time before the MOPH’s Notification was sent to different hospitals and the GPO, as a result of bureaucracy, which involves operations and approval along a chain of command (hierarchy) in the MOPH (Tippawan Lorsuwannarat, 2008). This resulted in the delay in the policy implementation in government hospitals because the written MOPH’s Notification had to be utilized as the guidelines for converting the policy into work plans or implementation guidelines. The hospital executives needed to utilize the written MOPH’s Notification to develop trust of, belief in, and understanding about, this policy among medical personnel and other personnel to result in similar policy implementation as assigned by the MOPH. The MOPH’s Notification was only board guidelines for the policy implementation. As for other details, individual hospitals needed to study them, and they had to formulate implementation guidelines on their own. This is why the direction of the policy implementation among different hospitals was not the same-it depended on their preparedness, especially data about the patient’s rights to medical care.

The results of this study suggest that the MOPH’s preparation and operations need consistent, fast, and timely planning, especially for policies that are vital to solving the country’s public health problems that are life-threatening (Ripley

et al., 1973). “The MOPH offered the hospitals a good solution-formulating the compulsory licensing policy, to increase the accessibility to medicines for the general public. Nonetheless, the MOPH did not equip them with sufficient tools for the policy implementation.” There were only news releases and meetings with hospital executives; this made people who were and were not involved with the policy implementation uncertain whether or not the compulsory licensing policy was true and important and if it had to be implemented. This doubt led to many disputes over practices and made it very difficult to achieve the objective. Furthermore, the MOPH’s Notification was only broad guidelines for the policy implementation, but details for different hospitals could not be defined in a single direction. The details varied to respective hospitals, which are different in nature.

In the policy promulgation, the MOPH did not only serve as the policy maker, but also the “mentor” that provided advice, assistance, and work coordination. The MOPH should set up “the Coordination and Consultation Center for the Compulsory Licensing Policy.” The Center should provide advice and coordinate work to solve problems for hospitals during early stages of the policy implementation. When the implementation guidelines become more clearly developed, the MOPH should leave the working mechanisms to the government hospitals to function on their own.

The written MOPH’s Notification has clear details about the target groups-Patients under the Universal Healthcare Coverage Scheme (30 baht Healthcare Scheme), those under the Social Security Scheme, and those under the Medical Benefit Scheme for Civil Servants and State Enterprise Employees. However, it was found that details about the number of patients under each scheme in the government hospitals were not clear, and not all patients’ information could be checked. This reflected problems in the policy implementation, as follows:

First: Patients lacked knowledge and understanding about their own rights in the public health system, which was followed by several problems. For example, they did not exercise their rights; they did not notify the hospital of their eligibility for medical care. Some patients used two rights in the hospital, the costs of which the government sector had to pay. This case was related to the system of collecting patients’ information of the hospitals. With regard to this issue, the MOPH,

as the agency responsible for formulating the compulsory licensing policy and defining the target group of the policy, is supposed to boost people's knowledge and understanding about their rights in the public health system via publicizing this information. The MOPH needs to inform the Thai population entitled to a public health care scheme to register in the hospital where they are entitled to the scheme, in addition to a clear regulation that they are only eligible for one public health care scheme. This written information should be circulated to all government hospitals to prevent the duplicated use of rights to medical care.

Second-Many government hospitals did not have a good IT system to collect patients' information. The research results showed a huge disparity in the preparedness for the data collection system among the hospitals. Some hospitals used a hi-tech data collection system, but had just started collecting the data, so their data were scattered. This made it difficult for them to organize and classify the data. Some hospitals used old technology that could not process the overall data, but only some data items. Most importantly, some still stored their patients' data on paper, so searching for the data was very difficult. Although the MOPH defined the target group of the policy, the database system and data availability among the operating units was not equal. This was a major defect with respect to the policy implementation. The policy maker formulated and imposed a good policy, but did not survey data, or plan and prepare supporting factors to facilitate the policy implementation to achieve the established objective. Thus, the problem with patients' inaccessibility to drugs in equal and thorough manners may shift to the problem of with patients' inaccessibility to medical care in the public health system. It can be said that "the objective and goals to solve the problem are good, but there are no data or incomplete data about the goals to contribute to problem-solving."

8.2.2.2 Consistency of the policy-The policy and its objective were consistent with current situations and could solve the problem of patients' inaccessibility to drugs. In order to formulate a public policy to address a problem, it must be ensured that this problem is related to the needs and affects the lives of the general public. Also, the general public want the problem to be resolved (Page and Shapiro, 1983). The number of patients and deaths of patients in Thailand concurrently increased steadily. The statistics showed Thailand's failure to control the

morbidity and mortality rates, especially of chronic diseases, including AIDS, cardiovascular disease, and cancer. As mentioned, essential drugs for a lifelong use by patients with these diseases were costly because of their patent protection. The fact that the Thai government, the MOPH and patients could not afford the expensive drugs resulted in patients' inaccessibility to the drugs and, ultimately, death. The most practical, logical method was to find ways to reduce the drug costs to improve their drug access. As a result of the failure of the drug price negotiations with drug-patentee companies and limited budget monies to subsidize the drugs, authorities at the MOPH decided to impose the compulsory licensing policy to address the problem of drug access. The study results showed that hospital directors and other medical personnel concerned believed that this policy could definitely solve this problem. Nonetheless, there were many factors that could result in an inadequate understanding and doubts about-and finally, mistrust and lack of confidence in-the policy implementation. All these would have a great impact on the policy implementation. Therefore, the MOPH, as the central agency for the policy implementation, needs to clarify the reasons for implementing this policy and remove all doubts, in order to boost people's confidence in attaining the efficient policy implementation (Foster, 2011). Some of the doubts identified can be outlined as follows:

- 1) Are the quality and therapeutic effectiveness of the compulsory-licensed generic drugs equivalent to those of the original drugs? The question came from the concern that these drugs have a direct relationship with a patient's life.

An inadequate understanding of, and questions about, this policy would definitely result in mistrust and lack of confidence in the quality of generic drugs under the policy. According to doctors' code of ethics, doctors must provide the best treatment for patients, to free them from suffering and cure them effectively. Empirical evidence that original drugs have therapeutic efficiency and effectiveness to cure the diseases was followed by a question: "Can generic drugs be substituted for original drugs?" This question changed the attitudes and ideas of doctors, who are in the healing profession and adhere to their professional code of ethics. The MOPH with other two agencies-the Thai FDA, which is charge on drug quality, and GPO, the government's representative to produce or import drugs – need

to develop trust in generic drugs among doctors, medical personnel, and other stakeholders. The MOPH and Thai FDA should clarify that the procedure for inspecting the production or importation process for the compulsory-licensed generic drugs is the same of that for original drugs. Furthermore, they need to clarify that the quality and effectiveness of generic drugs and original drugs meet the same standards. These pieces of information should be given to the government hospital's executives, doctors, medical personnel, and other stakeholders. These people should be provided with empirical evidence and reliable data about the generic drugs. These people need to have faith in, without bias, the quality and effectiveness of the generic drugs examined by the Thai FDA, and accept that can be substituted for the original drugs.

Furthermore, the GPO needs to build the belief and confidence that its production of generic drugs is appropriate and meets established standards; the importation process of generic drugs is transparent; and the imported drugs' quality and effectiveness have been checked by the Thai FDA under a sound procedure and process to make sure that they can be substituted for the original drugs.

2) Has this compulsory licensing of Thailand complied with laws and supporting conditions and has it affected the country's image and economy?

An inadequate understanding about the policy and fear of a bad image and economic impacts can be possessed by any people, not only by doctors or medical personnel. This is because 'patents' are not a daily-life topic. For four basic necessities, people normally perceive that they have to work to collect money to buy a house, food, clothing and drugs. For people in general, if their essential drugs are too expensive to afford, they have to discontinue using them, and if they can afford them, they can continue using them. Nonetheless, they are not interested in the mortality rates and the epidemics of different diseases each year. Instead, they believe that the country's economy, trade, and image will affect the mental health and incomes or expenses of the majority of people. In order to cope with the fear of a bad image and economic impacts, the MOPH, the policy maker, can provide details about actions that the Thai government took before making the decision to impose this policy. Also, the MOPH can clarify how the policy implementation has affected the country's economy and how it has helped patients in the country. They can do this by means of mass media, such as television, free documents, symposia, and newspapers. As stated,



the MOPH should set up “the Coordination and Consultation Center for the Compulsory Licensing Policy,” equipped with experts to answer questions about this policy in a timely manner. This will bring about trust and confidence in the MOPH’s operation and lessen problems relating the policy implementation.

8.2.2.3 Communications of the policy-The MOPH’s communication to the government hospitals about the transformation of this policy. It was found that their communication was characterized as top-down and one-way communication. The MOPH formulated the policy and provided policy-related information in the form of the MOPH’s Notification, which included the objective and target group of this policy. The study reflected that the MOPH’s one-way communication resulted from the fact that this policy was a semi-command request for MOPH-affiliated agencies and other concerned agencies. Verification and evaluation of the data were conducted only by the policy maker (Tippawan Lorsuwannarat, 2007). Clarifying the needs and reasons for promulgating this policy, as well as broad guidelines for government hospitals and operating units, the MOPH did not communicate to collect feedback from these government hospitals. Additionally, the MOPH did not provide the information for other related bodies that could impact the policy implementation. Nor did it contact the government hospitals to learn about their preparedness and factors that could be obstacles or problems for the policy implementation. Coordination of work between organizations will provide input and feedback that will reveal limitations, problems, and obstacles for the implementation in order to plan problem-solving in line with actual situations (Ben-Ali, 2011), and this will allow the policy objective to be achieved.

Moreover, communication between the policy maker and policy implementers is necessary for linking details about the objective of the policy and guidelines for the policy implementation clearly. This is intended to achieve proper policy implementation consistently among the operating units under the established objective (Grizzle and Carole, 2002). Accordingly, the policy promulgation does not only involve MOPH’s announcement of the objective, target group, and the main guidelines for the policy implementation, but also communication and coordination of work to receive details relating to the implementation guidelines.

8.2.2.4 Political changes-Relating to the change in the government or political parties, this is a key factor to a public policy, including imposition, delay or cancellation. Politics has a significant influence on the formation of a public policy, which aims to appropriately and efficiently address issues of the general public in accordance with their needs, such as by allocating budget monies and defining sound laws in line with the public policy (Cook, 2010). The continuity of the formulation and cancellation of the public policy also relies on political changes (Hauge and Scott, 2009). With regard to the compulsory licensing policy, political changes-three different government administrations-had a direct effect on the continuity of the policy promulgation.

Under political change, if a policy is not waived, the MOPH will have government hospitals continue implementing the policy, as a result of the increasing number of patients accessing essential drugs and each administration's focus on reducing public health costs. This can be witnessed from the campaign for the use of generic drugs and the disbursement of medical care costs for patients under the three public health care schemes in the case that the generic drugs are first-priority drugs.

### **8.2.3 Conclusion and Discussion of the Policy Implementation at the Micro Stage**

At this stage, the policy implementation is introducing work plans to operating units-government hospitals. The results of the research demonstrated that factors that impacted the policy implementation at the micro level included the characteristics of the operating units, budgets, and political changes, which are outlined below:

8.2.3.1 Characteristics of the operating units-These characteristics were involved with the structure of the operating units, including the command, formality in working, and qualifications of personnel. These had direct and indirect impacts on the policy implementation (Sombat Thamrongthanyawong, 2003). The two key success factors to the policy implementation are the structure and qualifications of, personnel in the operating units. First, because the structure in operating units is not the same, the policy implementation needs management to be in line with each structure. Second, personnel's qualifications play an important role in the policy implementation. Achieving the policy's goals relies on personnel equipped with

adequate expertise in, and understanding about, their tasks in compliance with the policy (Reynold, 2010). Operational units need personnel with sound expertise in, and understanding about, the implementation of activities to achieve the policy's objective efficiently (Gkeredakis et al, 2011). Accordingly, the policy implementation must be tailored to the operating units' structure and involves personnel with good knowledge about the implementation. As for the compulsory licensing policy, the structure of the MOPH- and university-affiliated government hospitals, as operating units, was a professional structure under which personnel were similar in their expertise in the healing profession and equal in dignity. Respective hospitals were also different (Tippawan Lorsuwannarat, 2007).

The policy implementation by the government hospitals relied on three factors-hospital directors' roles, doctors' roles, and hospitals' preparedness. As a result, the management approach needs to be tailored to the organizational structure and personnel. The management in the organization must go in the same direction, on the basis of policy guidelines-patients eligible for the compulsory-licensed drugs are those with a medical care right under one of the public health care schemes-the Universal Healthcare Coverage Scheme (30 baht Healthcare Scheme), Social Security Scheme, and the Medical Benefit Scheme for Civil Servants and State Enterprise Employees. Doctors were assigned to follow the protocol guidelines, and if they wanted to use original drugs or generic drugs that were not in the protocol guidelines, they had to submit a report to their director. The right to reject doctors' requests and the degree of the impact on drug costs for a hospital varied to the roles of its director and its doctors.

8.2.3.2 Personnel's attitudes-This is a crucial factor to policy implementation, in terms of the response to, willingness to adopt, and dedication to activities under the policy. If personnel have positive attitudes towards a policy, they will be willing to respond to, and adopt, assigned activities. This, in turn, will lead to the desired goals being achieved (Sombat Thamrongthanyawong, 2003). For the compulsory licensing policy, a major problem to the mobilization of the implementation of the policy was the perception of generic drugs being substituted for the original drugs. Doctors and patients did not trust the generic drugs in all aspects, including their quality, effectiveness, sources, and toxicology (Reeta et al., 2007)

(Inge, Morten and Anne G., 2006). The lack of faith in the seven drugs under the policy can be outlined as follows:

- 1) Lacking confidence in the therapeutic effectiveness of the compulsory-licensed generic drugs to be substituted for the original drugs.
- 2) Lacking confidence in operations of the GPO as the government's representative to produce generic drugs and to import the generic drugs from pharmaceutical companies through the bidding process under the policy.
- 3) Confusion over the diverse uses of generic drugs bid under the policy.

Due to doctors' lacking faith in the quality, effectiveness, sources, and toxicology of the generic drug, the Thai FDA, in charge of considering data of generic drugs and inspecting their quality and efficiency, needs to clarify the therapeutic equivalence of generic drugs produced and imported by the GPO, by referring to the general drug inspection that demonstrates that they have the same standard as the original drugs. This aims to build doctors' confidence in describing reliable properties of the generic drugs to their patients. In addition, the MOPH and the Thai FDA need to actively run campaigns and public relations activities to boost patients' knowledge and understanding about this matter, and more importantly to convince them to accept the quality, effectiveness, and sources of generic drugs, especially the compulsory-licensed generic drugs. This will solve the problem of diverse uses of generic drugs that were bid under this policy. If doctors and patients have trust and confidence in generic drugs, especially those under this policy, their trust and confidence in the drugs will be sustained, no matter how diverse the drugs in the bidding process are.

Furthermore, the GPO needs to demonstrate that its manufacturing process meets GMP standards as approved by the Thai FDA; it has to make sure that the generic drugs that it has produced or imported have reliable technical data, quality and efficiency that meet pharmaceutical criteria and are supported by empirical evidence.

8.2.3.3 Budget for the policy-This important factor will ensure smooth policy implementation for operating units. To achieve the policy's objective and goals effectively and efficiently, adequate financial support is needed because money has

socio-economic impacts on operating units and people involved in activities under the policy. Proper, adequate and systematic financial support will allow the policy's goals to be achieved efficiently (Grizzle and Carole, 2002). The budget allocated to the compulsory licensing policy, for patients under the public health care schemes that are the target group of the seven compulsory-licensed generic drugs, was disbursed by three different agencies, which shared the same disbursement guidelines. In principle, individual government hospitals had to report the number of patients under respective public health care schemes to the agencies in charge. The respective agencies calculated the budget according to the number of patients eligible for the scheme they took charge of, and they would disburse the budget to the hospitals and leave them to manage the budget on their own. However, this could result in 'budget transfer,' which might lead to a failure to achieve the objective and goals of this policy. A certain period after this policy was implemented, the drug costs and the volume of imported original drugs were still high (Bureau of Drug Control, 2009). One reason was the inequality of drugs administered and drug cost disbursement for patients under the different public health care schemes. In the old disbursement system, doctors considered the best treatment method for their patients, and the patients expected to receive the best treatment and medications (Inge, Morten and Anne G., 2006). In addition, treatment guidelines were dependent on the requirements and criteria of respective public health care schemes. A comparative study on the medical benefits and patients' characteristics (National Health Security Office, 2011) manifested that disbursement for patients under the Medical Benefit Scheme for Civil Servants and State Enterprise Employees was the least strict among the schemes. Under this scheme, drugs administered were more likely to be original drugs than generic drugs; patients eligible for the scheme always requested, and negotiated with, their doctors to change generic drugs to original drugs, which resulted from their positive attitudes towards, and confidence in, the original drugs in terms of quality, effectiveness, and toxicity than generic drugs (Mohamed et al., 2007).

Thus, the agencies responsible for budget disbursement for the government hospitals issued new disbursement guidelines and criteria, stipulating that generic drugs and drugs on the National Essential Drug List are first-priority drugs. The calculation based on the number of patients remained the same, but the

disbursement system changed. That is, these agencies would pay the government hospitals for the compulsory-licensed generic drugs provided that they complied with the MOPH's protocol guidelines. The hospitals had to submit a report on administering drugs to the agencies every quarter before they received that disbursement. If their drug administering for any patients did not comply with the protocol guidelines, the hospitals would not receive the subsidy for these patients and they, or these patients, had to take care of the drug costs. In addition, the MOPH's and MOF's notification concerning public health expenditures was issued. In the notification, a new criterion for disbursement for the public health care schemes was defined-the disbursement is possible in the case of administering generic drugs and drugs on the National Essential Drug List.

Following the stricter disbursement rules, the government hospitals considered a drug cost management system to control their expenses, in addition to reducing their costs, so that they could allocate this budget efficiently. Thus, the new disbursement guidelines were a good way to ensure that the drugs would be administered equally to patients in all public health care schemes.

8.2.3.4 Political changes-As stated, this factor relates to the change in the government or political parties. This key factor affects a public policy, from the policy process until the policy implementation. Politics has a significant influence because it drives a public policy to solve problems, as needed by the general public. It is important to implement public policies to address public issues accordingly and efficiently, especially the policies towards budget allocation and formulation of practice guidelines and conditions for operating units in line with the needs of people in different groups (Cook, 2010). Also, delay or continuation of the policy implementation directly depends on political changes (Hauge and Scott, 2009). As for the implementation of the compulsory licensing policy in Thailand, three political changes occurred in Thailand, from the time the policy was formed until the start of policy implementation by government hospitals. Politics affected only small details in the implementation guidelines.

Under political change, if a policy is not waived, respective hospitals will continue implementing the policy, as a result of the increasing number of patients accessing essential drugs and each administration's focus on reducing public health

costs. This can be witnessed from the campaign for the use of generic drugs and the disbursement of medical care costs for patients under the three public health care schemes in the case where the generic drugs are designated as the first-priority drugs.

In conclusion, the compulsory licensing policy was a suitable and practical method for solving the problem of patients' inaccessibility to drugs given the circumstances in Thailand in 2006, especially given the limited budget monies and lack of a strict drug-price control mechanism. Unlike other goods, drugs are merit goods for which ethical and moral issues have to be considered; they determine the survival or non-survival of patients. The research results showed that after the compulsory licensing policy was imposed on the seven generic drugs-Efavirenz and Lopinavir/Ritonavir (AIDS drugs), Clopidogrel (cardiovascular drug), Letrozole, Doxetaxel, Imatinib and Erlotinib (cancer drugs), patients had improved access to the drugs steadily, and drug costs were reduced significantly. It found that from 2008 to 2010, patients had better access to these drugs, except for Erlotinib, which could not be produced or imported; the drug costs decreased by over two billion baht. It can be said that this policy had great success in solving the problem of patients' inaccessibility to drugs.

The study results showed that the compulsory licensing policy solved the said problem; however, they also showed that from the time when the policy was formulated to until the start of policy implementation, there were many drawbacks associated with the Thai public health system, which are described below:

#### 8.2.3.5 Environmental Drawbacks

- 1) Lack of a strict, clear drug-pricing control mechanism that differentiates drugs from other commercial goods.
- 2) Lack of knowledge about the evaluation of "innovative" drugs being applied for a patent before granting it to them.

#### 8.2.3.6 Policy Formulation Related Drawbacks

- 1) The MOPH did not launch a campaign for boosting knowledge and understanding about patients' rights in the public health system, the compulsory licensing policy, or for generic and original drugs in terms of their efficiency, effectiveness, costs, quality and toxicology for the general public, patients, doctors and medical personnel.

2) The MOPH did not survey government hospitals to determine how different they were with respect to preparedness, equipment, and equality in factors prior to the implementation of this policy.

3) The MOPH did not clarify legal mechanisms available to minimize the impacts from the allegations about intellectual property infringement by patent-owner companies that lost benefits from this policy. This lack of clarification resulted in a lack understanding about, and confidence in, this policy. This would lead to problems with the policy implementation.

#### 8.2.3.7 Policy Implementation Related Drawbacks

1) Lack of a coordination center to provide useful information and solve problems related to the compulsory licensing policy.

2) Lack of clear roles of the MOPH-The Thai FDA actively clarified the validity of the policy implementation and provided explanations for, and confirmation of, the equivalence of quality and therapeutic effectiveness between generic drugs and original drugs, in order to develop faith and confidence in generic drugs among the general public, patients, doctors, and medical personnel.

3) Unequal medical care benefits among patients in different public health care schemes

4) Lack of the development of trust in the GPO as the government's representative to produce or import the generic drugs under the policy for sale in the country. Issues related to its trust included: Capacity, standard production process, transparent drug importation, the quality of the produced and imported drugs, as well as the therapeutic equivalence between generic and original drugs. The GPO needs to prepare technical data and provide empirical evidence about the quality, therapeutic effectiveness, and therapeutic equivalence between generic and the original drugs.

These drawbacks can lead to other public health problems endlessly and problems in the policy implementation among operating units in the short and long term. Ultimately, it may result in the failure of the policy in the future.



### **8.3 Policy and Practical Recommendations**

As mentioned, although this policy could solve the problem of patients' inaccessibility to drugs, formulation of this policy involved many factors and impacts and this was only one among possible methods. Therefore, the Thai government needs to pay serious attention to the development of the country's public health system as a whole to solve the said problem on a sustainable basis. The issues that the government should focus on are as follows.

#### **8.3.1 Policy Recommendations**

8.3.1.1 The MOPH should allocate sufficient budget monies for developing IT systems for government hospitals in order to link data on patients from all of them. This will be highly useful for solving public health problems in an efficient manner and developing the country's public health system.

8.3.1.2 The Thai FDA, on behalf of the MOPH, needs to seriously promote and support the capacity of the country's pharmaceutical industry so that it has a world-class standard. This can develop the faith and confidence in locally-produced generic drugs among the general public, patients, doctors, and medical personnel. This has proved to be successful in many countries, such as Japan and Canada. Also, there should be campaigns for the application of generic drugs as first-priority drugs.

8.3.1.3 The MOF and MOPH should establish protocol guidelines and regulations on disbursements that are equal for patients under the three public health care schemes, which should also take into account doctors' treatment and discretion. This will also help to control the country's spending on drugs.

#### **8.3.2 Practical Recommendations**

8.3.2.1 Creation of a drug-price control mechanism and patent-issuance control systems that have clear principles, requirements and conditions and take into account ethical and moral aspects-This should involve personnel with expertise in different fields related to drugs, such as the characteristics of new drugs and pharmacoeconomics, in the working groups to bring utmost benefits to the country.

8.3.2.2 The Thai FDA, on behalf of the MOPH, needs to stress that the inspection of the pharmaceutical industry in Thailand has complied with international standards. Also, the Thai FDA needs to promote the data on the therapeutic effectiveness between generic drugs and original drugs in order to develop trust and confidence in generic drugs among the general public, patients, doctors and medical personnel.

### **8.3.3 Guidelines for Further Study**

8.3.3.1 Positive and negative impacts of the compulsory licensing policy.

8.3.3.2 Differences in the policy implementation by government agencies and private agencies.

8.3.3.3 Guidelines for establishing drug-price mechanisms and guidelines for evaluating the issuance of patents for new drugs, to be in line with current situations in Thailand.

8.3.3.4 Guidelines for developing the capacity of the domestic pharmaceutical industry to achieve equal cooperation in business in the drug markets; and developing knowledge, technology and collaborative learning among the GPO, private drug manufacturers and universities for research and development with the aims to improve the efficiency of generic drugs and develop new drugs to compete with drugs from other countries.

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## **APPENDICES**

**APPENDIX A**  
**IN-DEPTH INTERVIEW GUIDELINES**  
**FOR POLICY MAKING**

### **Participants in the Interviews**

- The National Health Security Board (2006)
- The Subcommittee on the Selection of Essential Drugs and Medical Supplies with the Access Problem
- The Committee on the Negotiation on Prices of Patented Essential Drugs
- The Committee on the Promotion of the Government Use Compulsory Licenses for Patents on Drugs and Medical Supplies

### **Policy and the Clarity of the Policy**

1. What were the major reasons for deciding to formulate this policy to solve the problem of patients' accessibility to drugs?
  - 1.1 Morbidity rates of the population
  - 1.2 Mortality rates of the population
  - 1.3 Drug costs in the public health system
  - 1.4 Inaccessibility to drugs of the population
2. Were there any other solutions to the problem of patients' access to drugs than compulsory licensing?
3. What were the key factors that influenced the decision to promulgate the compulsory licensing policy to solve the problem of patients' accessibility to drugs?
4. In your point of view, how can the promulgation of the compulsory licensing policy solve the problem of patients' accessibility to drugs? What are the implementation guidelines?
5. What are the criteria for defining the target group for solving the problem of patients' accessibility to drugs by means of the compulsory licensing policy?
6. What are the criteria for selecting drugs to impose compulsory licensing on?
7. Under the compulsory licensing policy, are there any laws, rules or regulations that have been formulated to support the compulsory licensing policy?
8. What are the expected benefits of the promulgation of the compulsory licensing policy?
9. What have been the effects of the promulgation of the compulsory licensing policy?



[illegible]

1. How have the budgets been allocated to support operating units in implementing the compulsory licensing policy?
2. Are there any budget-spending rules or regulations formulated to support the compulsory licensing policy?

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1. Did the change in government administrations affect the formulation of the compulsory licensing policy?
2. Did the change in MOPH Ministers within the same administration affect the imposition of the compulsory licensing policy?
3. Did coups and political violence affect the imposition of the compulsory licensing policy? If yes, how?
4. Did political parties have an influence over the formulation of the compulsory licensing policy? If yes, in which areas?
  - 4.1 Opposition
  - 4.2 Budget allocation
  - 4.3 Interference in, for example, law and mass communication

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1. Did the formulation of the compulsory licensing policy in Thailand depend on influential groups within the country that are stakeholders in the policy? If yes, how?

- 1.1 The people's sector, such as foundations
  - 1.2 The representatives from drug-patentee companies in Thailand
  - 1.3 The Thai Pharmaceutical Manufacturers Association (TPMA)
2. Did the formulation of the compulsory licensing policy in Thailand depend on influential groups outside the country that are stakeholders in the policy? If yes, how?
  - 2.1 Organizations, such as the WHO, UNDP and UNAIDS
  - 2.2 Drug-patentee companies
  - 2.3 The U.S. Trade Representative (USTR)
  - 2.4 The Pharmaceutical Research and Manufacturers of America (PhRMA)
3. What is the degree of the impacts of the compulsory licensing policy on these stakeholders inside the country?
4. What is the degree of the impacts of the compulsory licensing policy on these stakeholders outside the country?
5. Have there been any assessments of the impacts on these influential groups on the worthiness of the compulsory licensing policy?
6. What are the guidelines for managing the impacts of these influential groups on the organizations' internal management in the following issues?
  - 6.1 Negotiation
  - 6.2 Conditions relating to the benefits for both parties
  - 6.3 Compromise

[illegible]

**APPENDIX B**  
**IN-DEPTH INTERVIEW GUIDELINES FOR POLICY**  
**IMPLEMENTATION**

## Participants in the Interviews

### • Directors of Government Hospitals and Health Institutions

#### Clarity of the Policy

1. In your point of view, can the promulgation of the compulsory licensing policy solve the problem of patients' inaccessibility to drugs? Why do you think so?
2. In your point of view, in the compulsory licensing policy, were the objective and goals to solve the problem of patients' inaccessibility to drugs clearly defined? Why do you think so?
  - 2.1 How detailed is the information provided for the policy implementation?
3. Are the objective and goals of the compulsory licensing policy appropriate and consistent with current urgent problems?
4. With respect to the compulsory licensing policy, are there any laws, rules or regulations formulated to support the policy?
5. To manage the implementation of the compulsory licensing policy, have you defined any themes for your organization? If yes, what are they?
  - 5.1 Implementation guidelines that are consistent with the policy's objective and goals
  - 5.2 Appropriateness of the target group
  - 5.3 Patients' equality of medical services
  - 5.4 Patients' medical care rights and welfare
  - 5.5 Number of patients using the services
6. Have agencies above you created an understanding about, and support for, the implementation of the compulsory licensing policy? If yes, how?
  - 6.1 Coordination of work
  - 6.2 Incentives and compensation
7. What problems or obstacles have you encountered when implementing the compulsory licensing policy based on the guidelines provided for your organization?

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### **Resources for the Policy**

1. What are your organization's principles relating to budget allocation for organizational management in these areas?
  - 1.1 Medical treatment
    - 1.1.1 Adequate quantity of drug order
    - 1.1.2 Spending the budget for patients' medical care rights and welfare
    - 1.1.3 Budget allocation based on the number of patients
2. Is the budget for implementing the compulsory licensing policy in your organization sufficient? How?
3. Since the compulsory licensing policy started to be implemented in your organization, has the use of generic drugs in substitution for the original drugs affected the way the budget has been managed in the following areas? If yes, how?
  - 3.1 General management
  - 3.2 Cost of drug purchases
  - 3.3 Number of patients receiving the drugs
  - 3.4 Patients' doses of drugs

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### **Politics**

1. Did the change in government administrations affect the implementation of the compulsory licensing policy? If yes, how? Please consider these issues.
  - 1.1 Continuity of the policy implementation
  - 1.2 Loss of benefits in the case of interrupted implementation
  - 1.3 Negative impacts on patients
2. Did the change in MOPH Ministers within the same administration affect the implementation of the compulsory licensing policy? If yes, how? Please consider these issues.
  - 1.1 Continuity of the policy implementation
  - 1.2 Loss of benefits in the case of interrupted implementation
  - 1.3 Negative impacts on patients

•••••

1. Did the implementation of the compulsory licensing policy in Thailand depend on influential groups within the country that are stakeholders in the policy? If yes, how?
  - 1.1 The people's sector, such as foundations
  - 1.2 Representatives from drug-patentee companies in Thailand
2. Did the implementation of the compulsory licensing policy in Thailand depend on influential groups outside the country that are stakeholders in the policy? If yes, how?
3. What are your guidelines for managing the impacts of these influential groups on the implementation of the compulsory licensing policy?

## **BIOGRAPHY**

### **NAME**

Tapanee Phueksuwan

### **ACADEMIC BACKGROUND**

Master's Degree in Pharmacy from  
Chulalongkorn University in 2002  
Bachelor's Degree in Pharmacy  
Chulalongkorn University in 1997

### **WORK EXPERIENCE**

Pharmacist 7, Head of Tablet Production, the  
Government Pharmaceutical Organization  
(GPO) Bangkok, 10400, Thailand