A DECENTRALIZATION MODEL FOR THE BANGKOK METROPOLITAN ADMINISTRATION IN REGULATION OF THE RETAIL PHARMACY VIA HEALTH CENTERS' PARTICIPATION

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รูปแบบการกระจายอำนาจการควบคุมร้านยาสำหรับกรุงเทพมหานครโดยการมีส่วนร่วมของศูนย์บริการสาธารณสุข

นายเพียรพันธุ์ พิระภิญโญ

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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Thesis Title	A DECENTRALIZATION MODEL FOR THE BANGKOK METROPOLITAN ADMINISTRATION IN REGULATION OF THE RETAIL PHARMACY VIA HEALTH CENTERS' PARTICIPATION
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เพียรพันธุ์ พิระภิญโญ: รูปแบบการกระจายอำนาจการควบคุมร้านยาสำหรับกรุงเทพมหานคร โดยการมีส่วนร่วมของศูนย์บริการสาธารณสุข (A DECENTRALIZATION MODEL FOR THE BANGKOK METROPOLITAN ADMINISTRATION IN REGULATION OF THE RETAIL PHARMACY VIA HEALTH CENTERS' PARTICIPATION) อ.ที่ปรึกษาวิทยานิพนธ์หลัก: รศ.ภก.ดร. วิทยา กุลสมบูรณ์, อ. ที่ปรึกษาวิทยานิพนธ์ร่วม: ผศ.ภญ.ดร. วรรณา ศรีวิริยานุภาพ, 90 หน้า

การวิจัยครั้งนี้มีจุดมุ่งหมายเพื่อนำเสนอรูปแบบการกระจายอำนาจการควบคุมร้านยาสำหรับ กทม. มีขั้นตอนการวิจัยประกอบด้วย การวิจัยเชิงปริมาณดำเนินการโดยเก็บข้อมูลจากแบบสอบถาม กลุ่มประชากร คือ ผู้อำนวยการศูนย์บริการสาธารณสุขและเภสัชกรประจำศูนย์ ฯ และการวิจัยเชิงคุณภาพดำเนินการโดยการประชุมกลุ่มผู้เชี่ยวชาญจากหน่วยงานที่เกี่ยวข้อง ได้แก่ กรุงเทพมหานคร สำนักงานคณะกรรมการอาหารและยา สำนักงานสาธารณสุขจังหวัด ศูนย์วิทยาศาสตร์การแพทย์ และโรงพยาบาลชุมชน

ผลการวิจัยพบว่า ผู้อำนวยการศูนย์ ฯ เห็นว่า กทม. ควรมีบทบาทในการตรวจสอบร้านยา ร้อยละ 56.5 ในขณะที่เภสัชกรประจำศูนย์ฯ เห็นด้วย ร้อยละ 92.1 ส่วนบทบาทของ กทม. ในการออกใบอนุญาตร้านยา ผู้อำนวยการศูนย์ ฯ เห็นด้วย ร้อยละ 40.3 ขณะที่เภสัชกรประจำศูนย์ ฯ เห็นด้วย ร้อยละ 61.9 ข้อมูลจากการวิจัยพบว่า รูปแบบการกระจายอำนาจการควบคุมร้านยาสำหรับ กทม. ที่มีประสิทธิภาพมากที่สุด คือ การกระจายอำนาจเต็มรูปแบบ ประกอบด้วย การกระจายอำนาจการออกใบอนุญาตและการตรวจสอบร้านยา ครอบคลุมร้านยาทุกประเภท มีหน่วยงานที่เกี่ยวข้อง ดังนี้ 1) หน่วยงานในการออกใบอนุญาตควรเป็นกองเภสัชกรรม 2) หน่วยงานในการตรวจสอบร้านยาควรเป็นศูนย์บริการสาธารณสุขร่วมกับกองเภสัชกรรม โดยมีสำนักงานเขตเป็นหน่วยงานสนับสนุนการดำเนินงาน 3) หน่วยงานในการดำเนินคดีตามกฎหมายควรเป็นกองเภสัชกรรม 4) หน่วยงานรับเรื่องร้องเรียน ประกอบด้วยหลายช่องทาง เช่น สายด่วน 1555 สายด่วนสำนักอนามัย กองเภสัชกรรม ศูนย์บริการสาธารณสุขและ สำนักงานเขต

ข้อเสนอแนะเชิงนโยบายแก่ผู้บริหารของกรุงเทพมหานครเพื่อให้การควบคุมร้านยามีประสิทธิภาพ คือ การจัดสรรกรอบอัตรากำลังและงบประมาณที่เหมาะสมในการดำเนินงาน และการพิจารณาสายงานความก้าวหน้าในวิชาชีพรองรับบทบาทของเภสัชกรในกองเภสัชกรรมและศูนย์บริการสาธารณสุขตามความรับผิดชอบที่เพิ่มขึ้น

ภาควิชา เภสัชศาสตร์สังคมและบริหาร...ลายมือชื่อนิสิต.....

สาขาวิชา เภสัชศาสตร์สังคมและบริหาร...ลายมือชื่ออ.ที่ปรึกษาวิทยานิพนธ์หลัก.....

ปีการศึกษา 2552.....ลายมือชื่ออ.ที่ปรึกษาวิทยานิพนธ์ร่วม.....

##5076867833 : MAJOR SOCIAL AND ADMINISTRATIVE PHARMACY
KEYWORDS: DECENTRALIZATION / RETAIL PHARMACY REGULATION / BANGKOK METROPOLITAN ADMINISTRATION

PIANPAN PHIRAPHINYO : A DECENTRALIZATION MODEL FOR THE BANGKOK METROPOLITAN ADMINISTRATION IN REGULATION OF THE RETAIL PHARMACY VIA HEALTH CENTERS' PARTICIPATION. THESIS ADVISOR : ASSOC. PROF. VITHAYA KULSOMBOON, Ph.D., THESIS Co-ADVISOR : ASST. PROF. WANNA SRIVIRIYANUPAP, Ph.D., 90 pp.

The purpose of this research was to propose the decentralization model for the Bangkok Metropolitan Administration (BMA) in regulation of the retail pharmacy. This research was quantitative and qualitative methods. The quantitative method was to collect the questionnaire from directors and pharmacists of health centers. The qualitative method was to conduct a focus group discussion. The experts group from the BMA and Ministry of Public Health who had their work related with retail pharmacy regulation were selected to be in the focus group.

The research found that 56.5% of directors and 92.1% of pharmacists agreed that the BMA should be responsible for retail pharmacy inspection. In addition, 40.3% of directors and 61.9% of pharmacists thought that the BMA should be responsible for approving pharmacy license. The results of study showed that the appropriate decentralization model should completely include the tasks of retail pharmacy license and retail pharmacy inspection, and it should cover all types of retail pharmacy. There were several agencies of the BMA which should be responsible for regulating the retail pharmacy, as following: 1) Agency to approve retail pharmacy license was Pharmaceutical Division 2) Agencies to inspect retail pharmacy were Health Centers with Pharmaceutical Division, which were supported by District Offices. 3) Legal process agency was Pharmaceutical Division 4) Agencies to receive drug complaints such as Hotline 1555, Hotline of Health Department, Pharmaceutical Division, Health Centers, and District Offices.

The suggestion of this research to the executive of the BMA were allocating manpower and budget for this new task, and establishing the professional career for pharmacist in Pharmaceutical Division and Health Centers to be responsible for this new responsibilities.

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LIST OF ABBREVIATIONS

BMA	BANGKOK METROPOLITAN ADMINISTRATION
FDA	FOOD AND DRUG ADMINISTRATION
MOU	MEMORANDUM OF UNDERSTANDING
SAO	SUBDISTRICT ADMINISTRATION ORGANIZATION
PHARMACY TYPE 3	TRADITIONAL PHARMACY
PHARMACY TYPE 4	VETERINARY PHARMACY

CHAPTER I
INTRODUCTION

1.1 Rationale

The main role of the Thai Food and Drug Administration (Thai FDA) is to protect consumer's health, and to ensure safety, quality and efficacy of health products which are foods, drugs, psychotropic substances, narcotics, medical devices, volatile substances, cosmetics and hazardous substances available in Thailand. Besides, the Thai FDA is completely responsible for retail pharmacy regulation in Bangkok but delegate this responsibility to 75 provincial health offices to regulate retail pharmacy in their areas.

The Constitution of the Kingdom of Thailand B.E. 2550 mentions about local government administration and decentralization in section 281 to 290. **(1)** The Determining Plan and Process of Decentralization to Local Government Organizations Act B.E. 2542 (1999) indicates that central government must decentralize its tasks to local government according to the operational decentralization plan within 10 years after it was enforced. **(2)** The Thai FDA specified the 4 tasks related with health product protection to be transferred to the local governments under the operational decentralization plan, including:

1) Producing media of health product protection and distributing them to consumer

2) Developing the knowledge about health product protection for consumer and informing consumer about their consumer right

3) Creating and expanding consumer protection network in community

4) Inspecting food, drug, cosmetic, hazardous and medical device at place of sale

For the decentralization policy, the Thai FDA must promote and support the local governments' officers to solve their health product problems effectively such as training course, consultation, appointing them to be health product authority and etc. Besides, the roles of the Thai FDA and the provincial health office for promoting and supporting local governments are to give consultation about the knowledge of health

product protection, to monitor health product problems, and to evaluate the tasks concerning health product protection.

For the tasks number 1 to 3, local government could proceed immediately because they had the roles on promotion and support. The role on regulation is to complicate, and it is not easy to do. So, the decentralization of this task must use the time for promotion and support. The regulation of health product involved many factors such as chief executive's policy, manpower, budget, knowledge, and law enforcement. Thus, it will be the last task to be transferred to the local government.

Retail pharmacy inspection is in the task number 4. The Thai FDA must decentralize this task to the Bangkok Metropolitan Administration (BMA). The Thai FDA trained the BMA's officers on drug inspection course for 2 years (2003 – 2004) but it didn't appoint the BMA's officers to have regulation authority on pharmacy under the drug law. However, the Thai FDA signed MOUs with the BMA in order to decentralize health product (drug, cosmetic, medical device, and hazardous) inspection at place of sale in 28 November 2006. **(3)**

At present, data show that there are 18,729 retail pharmacies in Thailand. These are 4,788 retail pharmacies in Bangkok and 13,941 retail pharmacies in provincial part. These retail pharmacies in Bangkok comprise of 3,856 pharmacies type 1, 428 pharmacies type 2, 85 veterinary pharmacies, and 419 traditional pharmacies. **(4)** There are only 15 drug inspectors of the Thai FDA to regulate them. The lack of drug inspector is the main problem of the Thai FDA which leads to incomplete work on inspecting retail pharmacies. Consequently, in year 2007 – 2008, there were many drug complaints in Bangkok, data showed that there were 68 cases in year 2007, and there were 252 cases in year 2008. These drug complaints were expired drug, counterfeit drug, deteriorated drug, over claims of drug advertisement, and etc. So, if the BMA is responsible for retail pharmacy regulation by cooperating with the Thai FDA, the regulation of retail pharmacy in Bangkok will be much more effective.

When the Thai FDA decentralizes the regulation of the retail pharmacy to the BMA, this will be the new responsibility of the BMA. Therefore, the studying on "A decentralization model for the BMA in regulation of retail pharmacy via health

centers' participation" is important to the BMA in terms of restructuring its organization to regulate retail pharmacy effectively.

1.2 Objectives

1. To review roles, responsibilities, and structures of the Bangkok Metropolitan Administration, the Thai Food and Drug Administration, and the provincial health offices in regulating the retail pharmacy under decentralization policy

2. To study the opinion of health center leaders on the new role, responsibility, and structure of the BMA in regulating the retail pharmacy under decentralization policy

3. To propose the decentralization model for regulation of the retail pharmacy by the Bangkok Metropolitan Administration, based on the experts' opinion

1.3 Expected Benefit

An appropriate decentralization model for the BMA in regulation of the retail pharmacy will be developed.

1.4 Scope of the study

This study was to survey the directors and pharmacists' opinions of 68 health centers of the BMA**.** The information was used to develop decentralization model for the BMA in regulation of the retail pharmacy by the expert group.

1.5 Operational definition

1. Retail pharmacy regulation was defined as the tasks of pre-marketing control which were retail pharmacy license approval and post – marketing control which were pharmacy inspection.

2. Approval of retail pharmacy license was defined as the approval of the licenses to sell modern medicine, traditional medicine, and veterinary medicine of pharmacy type I, pharmacy type II, traditional pharmacy, and veterinary pharmacy including to change, edit, and extend theses licenses.

3. Retail pharmacy inspection was defined as inspection of drug dispensing, drug label, list of special control drug, counterfeit drug, expired drug, retail pharmacy

license and etc. at pharmacy type I, pharmacy type II, traditional pharmacy, veterinary pharmacy, and grocery store based on the Drug act B.E. 2510.

4. Pharmacy type I was defined as modern pharmacy with at least one registered pharmacist on duty. All types of drugs were allowed to be sold in these drug stores including dangerous drugs, controlled substances, and psychological drugs.

5. Pharmacy type II was defined as modern pharmacy which do not need registered pharmacist on duty. They were allowed to sell only non-dangerous, pre-package medications (as known as over-the-counter medications such as house-hold remedies).

6. Traditional pharmacy was defined as old-fashioned pharmacy with at least a registered traditional pharmacist on duty. All types of drugs were traditional medicine not modern medicine.

7. Veterinary pharmacy was defined as pharmacy which sold pre-package medications for animals.

8. Provincial health office was defined as provincial organization which was responsible for the tasks of public health administration in their provinces.

9. District health office was defined as health organization which was under provincial heath office, and was responsible for the tasks of public health administration in its district.

10. Community hospital was defined as government hospitals in district level which had 10 – 120 hospital beds, and pharmacists of community hospitals were responsible for retail pharmacy inspection in their districts.

1.6 Conceptual Framework

Preliminary model was established by the literature review including the roles, the responsibilities, the structures, and the models of retail pharmacy regulation of the Thai FDA and the provincial health offices. Then, preliminary model was tested by the opinion of health center leaders in order to form a model of retail pharmacy regulation. The preliminary and proposed models were delivered to the experts panel discussion. The process to develop a proper the models of retail pharmacy regulation under the decentralization policy appeared in Figure 1.1 .

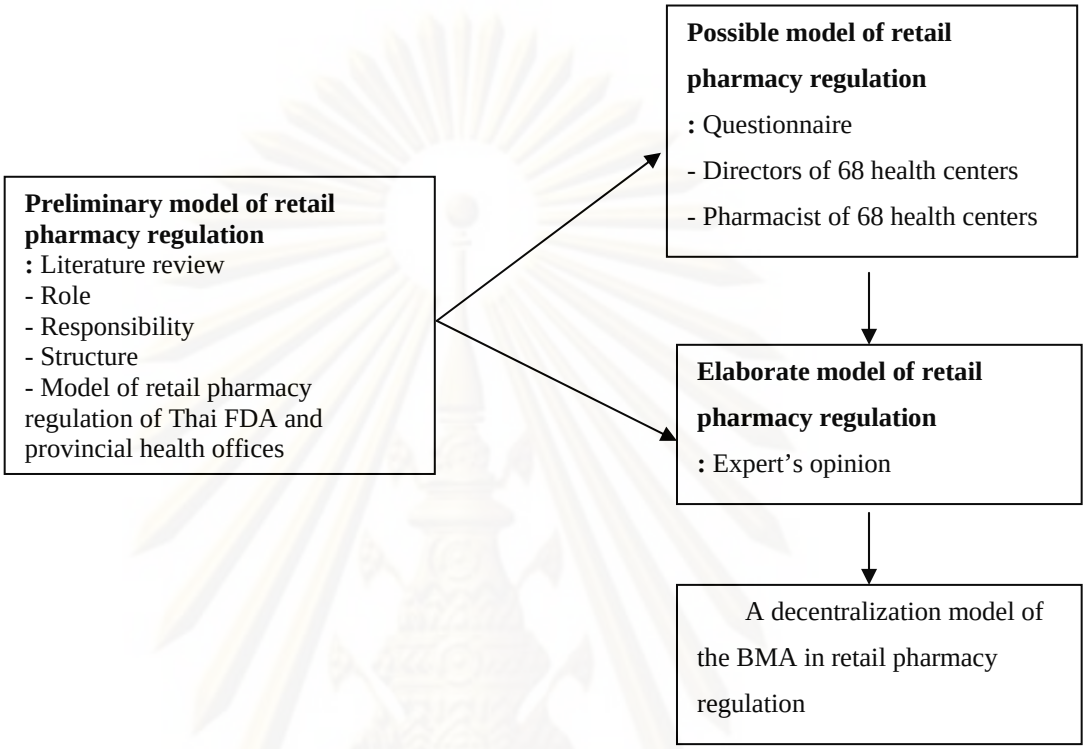


Figure 1.1 Conceptual framework of the study

CHAPTER II
LITERATURE REVIEW

This study applied concepts, theories and researches which were related to decentralization including decentralization concept, law related to decentralization, roles and responsibility of the Thai FDA, retail pharmacy regulation under the Drug Act, B.E. 2510, the Bangkok Metropolitan Administration, and decentralization to local government in Thailand.

2.1 Decentralization Concept

The administration of Thailand has the important policy on decentralization which is legislated by the Constitution of the Kingdom of Thailand, B.E. 2550 (2007). Besides, the Determining Plan and Process of Decentralization to Local Government Organizations Act B.E. 2542 (1999) indicates that central government must decentralize its tasks to local government according to the operational decentralization plan within 10 years after it was enforced.

2.1.1 Meaning of decentralization

Decentralization is central government transferring the decision making about the administration or governance to the local government organizations in order to provide the public services such as engineering, economics, education, art and culture, and environment management. It doesn't include the tasks of military and foreign affairs. Besides, there are 3 aspects of decentralization, as following.

1) Transferring the responsibilities of central and provincial governments to local government organizations

2) Local government organizations have to freedom to specify their policies and administration

3) Efficiency of local government organizations was related with people's demands

2.1.2 Governance decentralization

Governance decentralization can divide into 4 types that are political decentralization, administrative decentralization, fiscal decentralization, and economic

decentralization. Each types of decentralization have different characteristics, as following.

2.1.2.1 Political decentralization

Political decentralization means the central government organization transferring the decision-making to many representative governments in each area. These representative organizations will not be interfered by central government or they will be interfered in the limit.

2.1.2.2 Administrative decentralization

Administrative decentralization is to transfer the authority, responsibility and financial resources for providing public services from central government or regional government to local government. There are three major forms of administrative decentralization that are deconcentration, delegation, and devolution.

1) Deconcentration

Deconcentration is the weakest form of decentralization and is used most frequently in unitary countries which transfers decision making authority and financial and management responsibilities among different levels of the national government. It can shift responsibilities from central government officials to those working in regions, provinces or district organizations.

2) Delegation

Delegation is a more extensive form of decentralization. Central governments transfer their responsibilities for decision-making and administration of public functions to semi-autonomous organizations which are controlled partially by the central government. Central governments can establish these organizations by law and they delegate their responsibilities when they create public projects, transportation authorities, special service districts, semi-autonomous school districts, or special project implementation units.

3) Devolution

Devolution is the most extensive form of decentralization. When governments devolve functions, they transfer authority for decision-making, finance, and management to quasi-autonomous organizations which are not controlled by central government. Devolution usually transfers responsibilities

for services to local governments. These organizations can raise their own revenues, and have independent authority to make investment decisions.

2.1.2.3 Fiscal decentralization

Dispersal of financial responsibility is a main component of decentralization. If local governments are to carry out decentralized functions effectively, they must have an adequate level of revenues as well as the authority to make decisions about expenditures. Fiscal decentralization can take many forms, including:

- Self-financing or cost recovery through user charges
- Co-financing or co-production arrangements through which the users participate in providing services and infrastructure through monetary or labor contributions
- Expansion of local revenues through property or sales taxes, or indirect charges
- Intergovernmental transfers that shift general revenues from taxes collected by the central government to local governments for general or specific uses
- Authorization of municipal borrowing and the mobilization of either national or local government resources through loan guarantees.

2.1.2.4 Economic decentralization

Privatization and deregulation are to transfer the responsibility for functions from the public to the private sector. The functions have been primarily or exclusively the responsibility of government to be carried out by businesses, community groups, cooperatives, private voluntary associations, and other non-government organizations.

1) Privatization

Privatization is to provide goods and services entirely to the public-private partnerships. It can include:

- Allowing private enterprises to perform functions that had previously been monopolized by government

- Contracting out the provision or management of public services or facilities to commercial enterprises

- Financing public sector programs through the capital market and allowing private organizations to participate

- Transferring responsibility for providing services from the public to the private sector through the divestiture of state-owned enterprises.

2) Deregulation

Deregulation is to reduce the legal constraints on private participation in service provision or allows competition among private suppliers for services that in the past had been provided by the government or by regulated monopolies.

2.1.3 The strengthens and weakness of decentralization

Decentralization has many strengthens, on the other hand, it also has many weaknesses, as following. **(6)**

2.1.3.1 The strengthens of decentralization

1) Local government organizations will be able to response to people's demand in local area. Local government administrators must know problems and people's demand in their area better than the central government. They could solve the problems quickly because they have the authority to make decision without any control by central government

2) Local government organization can share the responsibility with the central government. Central government can be responsible for country's projects, while local government organizations take care their tasks in local area.

3) Decentralization enhances people to be responsible for interesting in self administration more than the central government. People may be more likely to the local government administrators to solve their problems.

2.1.3.2 The weaknesses of decentralization

1) Decentralization may threaten the administration unity and the stability of country. Competition among local government organizations may increase the gap between big and small local government organizations in each area.

2) Local government administrators may use their power to defame their opponents.

3) Local government organization may concern on their specific benefit more than overall benefit.

4) Local government organizations have to spend their budget for manpower, and instruments to improve their ability.

2.2 Law related to decentralization

Constitution of The kingdom of Thailand, B.E. 2550, and Determining Plan and Process of Decentralization to Local Government Organizations Act, B.E. 2542 mention that central government must decentralize their tasks to local government organizations, as following. **(1), (2)**

2.2.1 Constitution of The kingdom of Thailand, B.E. 2550

Section 78. The State shall act in compliance with the following State administration policies:

(3) to decentralize powers to local government organisations in order to promote self-dependency and self-determination of local affairs, to promote local government organisation participation in the implementation of directive principles of fundamental State policies, to develop local economies, public utilities and assistances as well as a comprehensive and nationally uniform information infrastructure in the localities, including to develop a competent *Changwat* into a large-sized local government organisation after having due regard
to the will of the people in that *Changwat*

Section 281. Subject to section 1, the State shall give independence to local government organizations under the principle of self government according to the will of the people in a locality and shall encourage local government organizations to become the principal public services provider and to participate in rendering solutions to any problem occurs within its area.

Any locality exhibiting a competence to self-govern shall have the right to be formed as a local government organization as provided by law.

Section 282. The supervision of local government organizations shall be exercised in so far as was necessary under the rules, procedures and conditions which were clear, consistent and appropriate for each type of local government organization as provided by law with a view to protecting local interest or the interests of the country as a whole, provided that it shall not substantially affect the principle of

self-government according to the will of the people in the locality or otherwise than as provided by law.

In the conduct of supervision under paragraph one, there shall be a supervision standard as a guideline which shall be applied by the local government organizations, upon their own selection, with regard to the appropriateness and difference of level of development and efficiency in the administration of each type of local government organization without prejudice to the capability of making decisions for the performance with regard to the needs of local
government organizations and there shall be a mechanism for the examination of performance thereof which is executed mainly by the people.

Section 283. Local government organizations have the powers and duties to maintain and provide, in general, public services for the benefit of the people in localities and shall enjoy autonomy in laying down policies, administration, provision of public services, personnel administration, finance and shall have powers and duties particularly on their own part with regard to the compliance with the development of *Changwat* and the country as a whole.

Local government organizations shall be promoted and encouraged to strengthen their independent administration and their capability to meet the demands of the people in the localities efficiently, the ability to develop local financial systems so as to provide all public services under their powers and duties and to establish or jointly establish organizations to provide public services under their powers and duties with a view to comprehensively provide good value and beneficial services to public.

There shall be a law determining plans and processes for decentralization prescribing the delineation of powers and duties and the allocation of revenues between central and provincial administrations and local government organization and between local government organizations themselves with due regard to the increased decentralization of powers pursuant to the capability levels of each form of local government organization, including an examination and evaluation system. There shall be a committee consisting of representatives of the relevant government agencies, representatives of local government organizations and qualified persons in an equal number responsible for carrying out acts as

provided by law.

There shall be a law on local revenues prescribing powers and duties for the collection of taxes and other revenues of local government organizations, wherein there shall be rules which were suitable to the nature of each type of taxes, the allocation of resources in public sector and the balance of revenues and expenditures according to the functions of local government organizations. In such case, regard shall be had to level of economic development of localities, financial status of local government organizations and financial sustainability of the State.

In the case where the delineation of powers and duties and the distribution of revenue to local government organizations has already been made, the committee under paragraph three shall review such matter every five years in order to consider the suitability of the delineation of powers and duties and the allocation of revenues previously made, having particular regard to the promotion of decentralization.

The proceeding under paragraph five shall be effective when the approval of the Council of Ministers has been obtained and the National Assembly has been notified thereof.

Section 284. A local government organization shall have a local assembly and local administrative committee or local administrators.

Members of a local assembly shall be elected.

A local administrative committee or local administrators shall be directly elected by the people or shall be from the approval of a local assembly.

An election of members of a local assembly and local administrative committee or local administrators who must be directly elected by the people shall be made by direct suffrage and secret ballot.

Members of a local assembly, local administrative committee or local administrators shall hold office for the period of four years.

A member of a local administrative committee or local administrator shall not be a government official holding a permanent position or receiving a salary or an official or employee of a government agency, State agency, State enterprise or local government organization and shall not have any conflict of interest in the holding of position as provided by law.

The qualifications of the person having the right to vote and the person having the right to apply for candidacy in an election, rules and procedures for the election of members of a local assembly, members of a local administrative committee and local administrators shall be in accordance with the provisions of the law.

In the case where a local administrative committee has vacated office *en masse* or local administrators vacate office and a local administrative committee or local administrators must be provisionally appointed, the provisions of paragraph three and paragraph six shall not apply, as provided by law.

The establishment of a special local government organization having a different organizational structure from the provisions in this section shall be as provided by law; provided that a local administrative committee or local administrators thereof shall be elected.

The provisions of section 265, section 266, section 267 and section 268 shall apply *mutatis mutandis* to members of local assembly and local administrative committee or local administrators, as the case may be.

2.2.2 Determining Plan and Process of Decentralization to Local Government Organizations Act, B.E. 2542

Section 30 Decentralization Plans to local Government Organization shall be proceeded as follows:

(1) Proceed the transferred missions relating to the public services managed by the State on the date of enforcement of this Act to local government organization with the period of time as follows:

(a) The overlap missions between the State and local government organization or the mission provided by the State in the area of local government organization, the proceeding shall be complete within four years.

(b) The missions provided by the State in the area of local government organization which impacted to other local government organizations, the proceeding shall be complete within four years.

(c) The missions proceeded under the government policy, the proceeding shall be complete within four years.

(2) Determine the area of responsibility in delivery of public services by the state and local government organization and between local government

organizations themselves according to powers and duties clearly determined in this Act. In the initial period, the missions of local government organization may be different in accordance with the readiness of each local government organization considered from the income and personnel of that local government organization, number of population, expenses in proceeding including the quality of delivery public services to the public. Thus, this shall not exceed the period of ten years.

2.2.3 Decentralization of health product protection

The main roles of the Thai FDA was to protect consumer's health, and to ensure safety, quality and efficacy of health products which were foods, drugs, psychotropic substances, narcotics, medical devices, volatile substances, cosmetics and hazardous substances available in Thailand.

According to Constitution of the Kingdom of Thailand, B.E. 2550, and Determining Plan and Process of Decentralization to Local Government Organizations Act, B.E. 2542, central governments must decentralize their tasks to local government organizations, so the Thai FDA assigned 4 missions for them, as following.

1) Producing media of health product protection and publicize to consumer

2) Developing the knowledge about health product protection to consumer and inform consumer about their consumer right

3) Creating and expanding consumer protection network in community

4) Inspecting food, drug, cosmetic, hazardous and medical device at place of sale

The Thai FDA had trained the BMA's officers in drug inspection course for 2 years (2003 – 2004), and only appointed the BMA's officers to food authority based on food law. Additionally, Secretary general of the Thai FDA had the policy of decentralizing health product to the BMA, and signed the first MOUs with the BMA in the topic of decentralizing drinking water and ice plants inspection at 4 September 2006. Then, the second MOUs was decentralization of health product (drug, cosmetic, medical device, and hazardous) inspection at place of sale at 28 November 2006.

After signing the first MOUs, the Thai FDA has trained the BMA to inspect drinking water and ice plants since 2007, and there were many the BMA's problems which impacted to inspection of drinking water and ice plants, as following **(3).**

1) Data base and linkage system of drinking water and ice plants inspection weren't complete.

2) The BMA's officers weren't readiness for inspecting drinking water and ice plants because they lacked of manpower and knowledge.

3) The BMA wasn't interested in the tasks of drinking water and ice plants inspection.

4) The BMA's structure wasn't appropriate for inspection of drinking water and ice plant.

2.3 Retail pharmacy regulation under the Drug Act, B.E. 2510

At present, there were 4 types of pharmacies in Thailand, which were pharmacy type 1, pharmacy type 2, veterinary pharmacy, and traditional pharmacy. **(7)** In the year 2010, there were 18,729 retail pharmacies which were 11,923 pharmacies type 1, 3990 pharmacies type 2, 696 veterinary pharmacies, and 2,120 traditional pharmacies. These retail pharmacies could divide in 4,788 retail pharmacies in Bangkok and 13,941 retail pharmacies in provincial part, as showed in Table 2.1. **(4)**

Table 2.1 Number of retail pharmacy in Thailand in the year 2010

Type of pharmacy	Bangkok	Provincial part	Total
Pharmacy type 1	3,856	8,067	11,923
Pharmacy type 2	428	3,562	3,990
Veterinary pharmacy	85	611	696
Traditional pharmacy	419	1,701	2,120
Total	4,788	13,941	18,729

Accordingly, systems of retail pharmacy regulation were divided into 2 parts, the first was pre-marketing control (approving retail pharmacy licenses), and the second was post-marketing control (inspection of retail pharmacy).

The Thai FDA was a main organization to regulate retail pharmacy in Thailand, especially in Bangkok, and it delegated the power of pre-marketing control and post-marketing control to 75 provincial health offices in order to regulate them in their provinces. Furthermore, it still delegated only the power of retail pharmacy inspection to district public health offices, and community hospitals.

2.3.1 Retail pharmacy regulation in Bangkok

Drug control division of the Thai FDA was the main organization for regulation of retail pharmacy. Pharmacy licenses unit of Drug control division was responsible for the task of approving pharmacy licenses. Besides, Drug inspectorate unit of Drug control division was responsible for the task of retail pharmacy inspection and drug complains inspection which were informed by Public and consumer affairs division. Furthermore, if drug inspectors checked illegal drug products which violated the Drug Act of B.E. 2510, Food and Drug Legal group would prosecute them, as showed in Figure 2.1 .

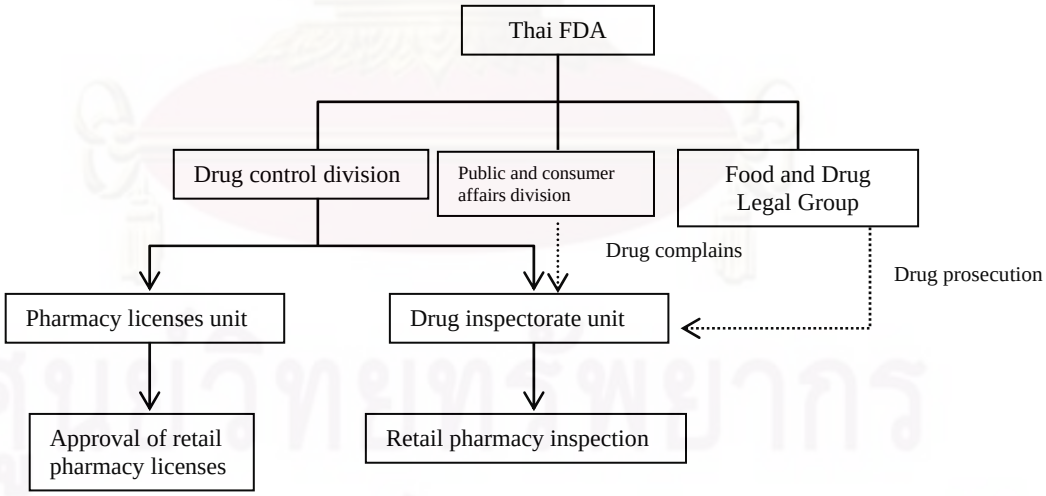


Figure 2.1 Retail pharmacy regulation of the Thai FDA

For pre-marketing control especially in approving pharmacy licenses by the Thai FDA, there were three characteristics of approving them which were approving new licenses, editing licenses, and extending licenses. Additionally, the Thai FDA used approximately 5 officers for these activities. They were two

pharmacists and three FDA staff at One Stop Service Center of the Thai FDA. The processes of approving retail pharmacy licenses was demonstrated in Figure 2.2, 2.3 and 2.4. **(8),(9)**

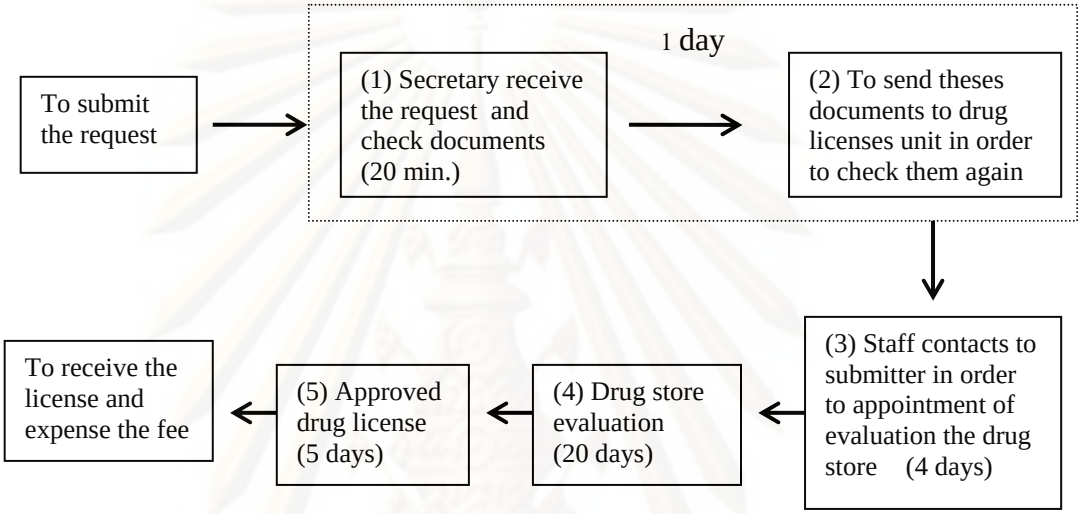


Figure 2.2 Processes of approving the new license to sell modern medicine (30 days)

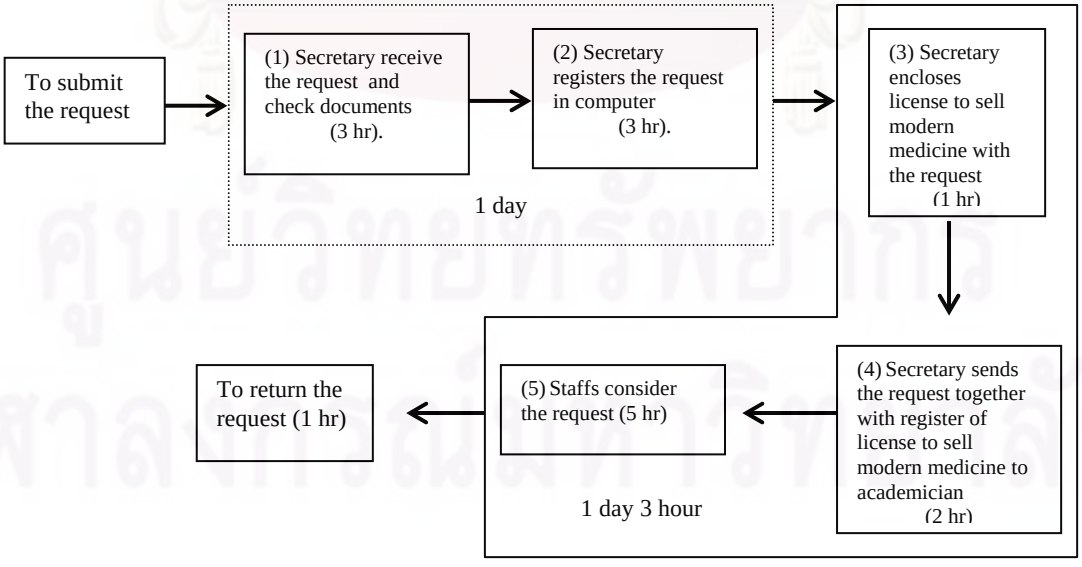


Figure 2.3 Processes of editing the license to sell modern medicine (2 days 3 hours)

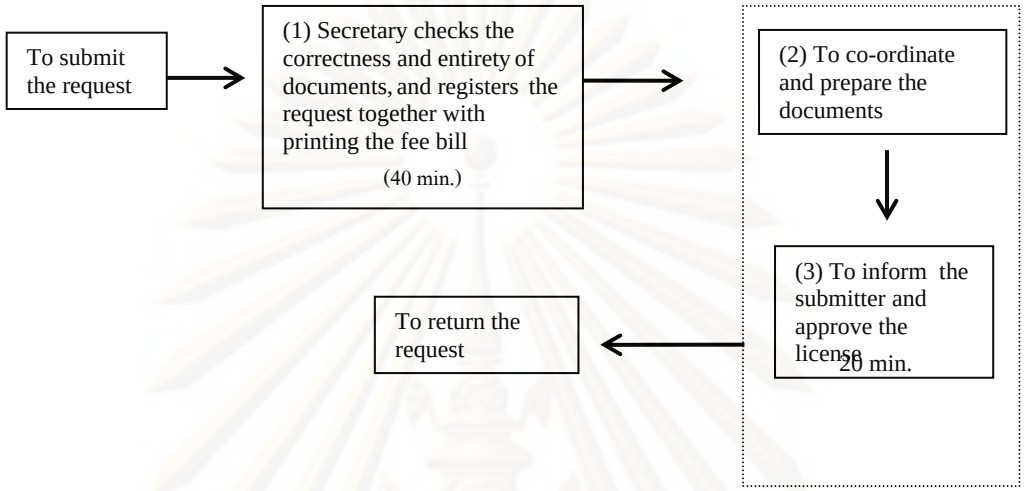


Figure 2.4 Processes of extending license to sell modern medicine (1 hour)

For retail pharmacy inspection in Bangkok, in the year 2008, there were only 15 drug inspectors to regulate 3,798 pharmacy type 1. Moreover, they still had the other tasks for routine job such as GMP regulation and drug complains inspection. Meanwhile, in year 1995, they had 24 drug inspectors to regulate 2,997 drugstores, but they also inspected the other health products such as food, cosmetic, hazardous, medical device, and narcotic. Accordingly, there still were many illegal activities, drug complaints and drug products which violated the Drug Act, B.E. 2510, as showed in Table 2.2 **(10)**, and drug complaints in Table 2.3. **(11)** Besides, the data showed that a number of retail pharmacy had still increased since 1999 to 2008. In the year 2008, there were 4,722 retail pharmacies (pharmacy type 1 = 3,798, pharmacy type 2 = 462, veterinary pharmacy = 83, and traditional pharmacy = 401) as showed in Table 2.4 **(12)**, and the number of retail pharmacy in each district of the BMA showed in Appendix D.

Table 2.2 Number of cases violating the Drug Act, B.E. 2510 in Bangkok in the year 2007

Cases violating the Drug Act, B.E. 2510	**Cases**
1. Did not make the list of special controlled drug	97
2. Did not control the drug label in accordance with register	23
3. Did not control the production of drug conforms to the formulae registration or GMP	10
4. Over claims drug advertisement	37
5. Did not control on the dangerous and special controlled drug	7
6. Pharmacists weren't on the duty for the duration of business hours	7
7. Did not extend pharmacy licenses	66
8. Did not keep imported drug sample	4
9. Did not control the importation of pharmaceutical chemicals	1
Total	252

Table 2.3 Number of drug complaints in Bangkok in the year 2005 - 2007

Drug complaints	**Year 2005 (cases)**	**Year 2006 (cases)**	**Year 2007 (cases)**
1. Pharmacists weren't on the duty for the duration of business hours	31	33	28
2. Did not have pharmacy license	49	25	21
3. Did not register drug	13	27	12
4. Prescribing psychotropic substances	7	2	5
5. Sold expired drug	5	5	2
Total	108	92	68

Table 2.4 Number of retail pharmacy in Bangkok in the year 1999 - 2008

Retail pharmacy	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
1. Pharmacy type 1	2,973	2,973	3,047	3,200	3,393	3,563	3,615	3,672	3,765	3,798
2. Pharmacy type 2	638	638	620	577	565	528	497	479	462	444
3. Veterinary pharmacy	34	34	43	67	81	83	84	87	83	79
4. Traditional pharmacy	411	411	409	412	420	401	400	406	418	401
Total	4,051	4,051	4,119	4,256	4,459	4,575	4,596	4,644	4,728	4,722

2.3.2 Retail pharmacy regulation in provincial part

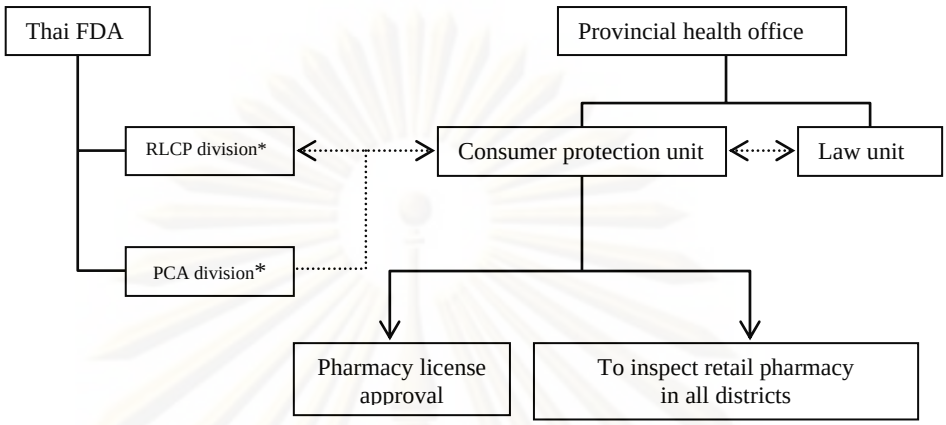
Consumer protection unit of provincial health offices was responsible for the tasks of retail pharmacy licenses, and retail pharmacy inspection. When the Thai FDA delegated the task of retail pharmacy inspection to the officers at district public health offices and pharmacists of community hospital, some provinces assigned this task to these organizations proceeding completely.

Besides, for solving drug complains in provincial part, when consumers complains about drug problems to Public and consumer affairs division, it will inform to consumer protection unit in order to solve these problems. Then, law unit of provincial health offices were responsible for prosecuting drug problems which break the Drug Act, B.E. 2510. Additionally, Rural and local consumer health products protection promotion division was the main organization which coordinated, promoted, and supported consumer protection unit for proceeding these tasks effectively.

Accordingly, there were 5 main models of retail pharmacy inspection variously, and there were many factors which specify the model of retail pharmacy in provincial part that were a number of pharmacists in consumer protection unit, a number of retail pharmacies, provincial size, network strength, and administrative policy of provincial health offices.

The first model of retail pharmacy inspection was the pharmacists of consumer protection unit in provincial health office inspecting all retail pharmacies in their provinces such as Phetchaburi, Samut Songkhram, Samut Sakhon, Suphanburi

and Chumporn provinces, and the factors of this model were a few retail pharmacies and small provinces, as showed in figure 2.5.

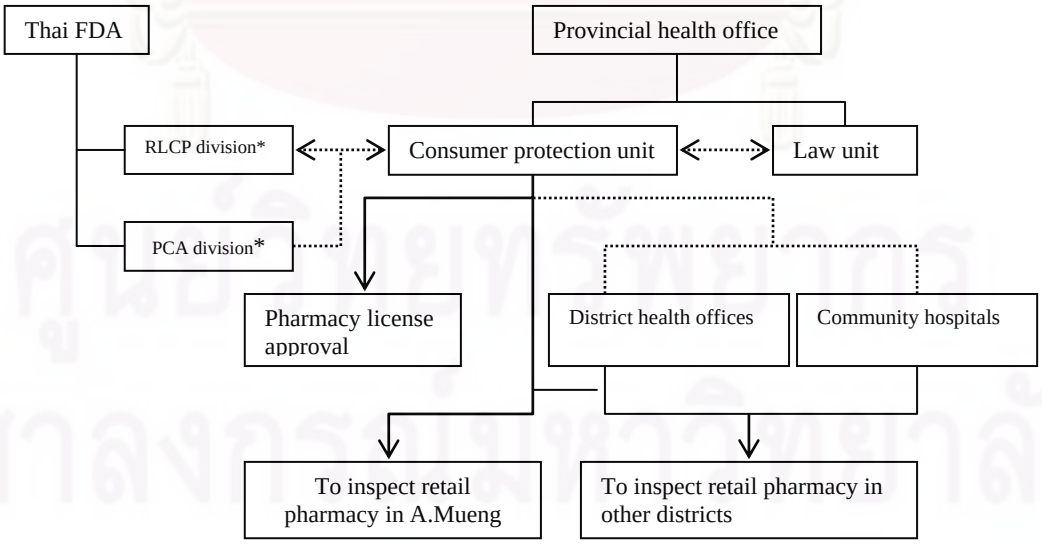


* RLCP division = Rural and local consumer health products protection promotion division

***** PCA division = Public and consumer affairs division

Figure 2.5 Model 1 of retail pharmacy inspection in provincial part

The second model was the pharmacists of consumer protection unit in provincial health offices inspecting retail pharmacy with the officers of Mueng district health offices in Mueng district, and they assigned the duty of retail pharmacy inspection to officers of district health offices and the pharmacists of community hospitals in other districts such as Prachuap Khiri Khan province. Then, the factors of this model were lack of pharmacists of consumer protection unit, large province, a lot of retail pharmacies, and network strength, as showed in Figure 2.6 .

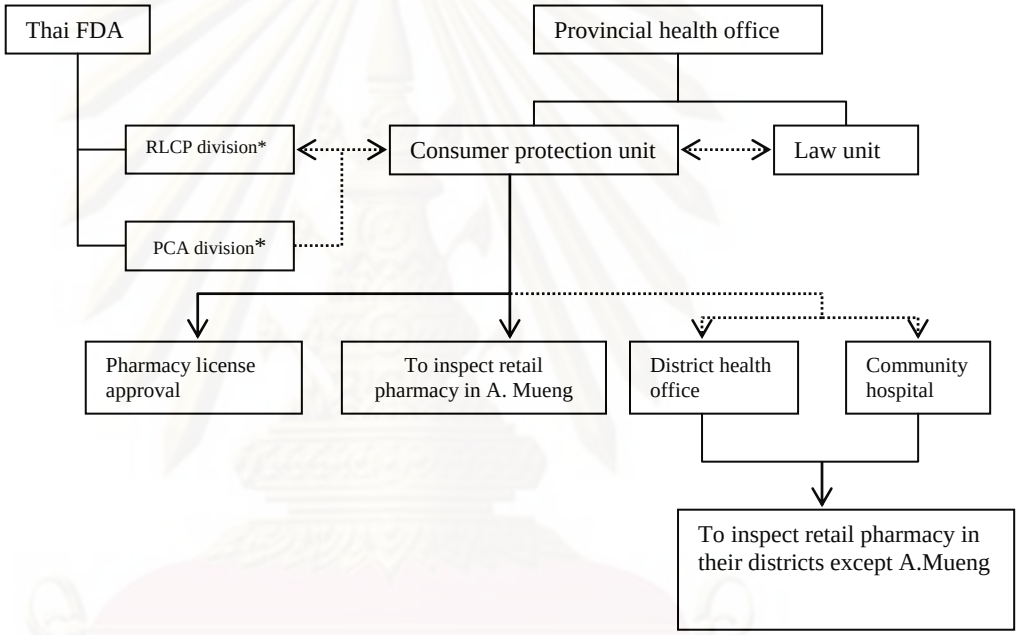


* RLCP division = Rural and local consumer health products protection promotion division

***** PCA division = Public and consumer affairs division

Figure 2.6 Model 2 of retail pharmacy inspection in provincial part

The third model was the pharmacists of consumer protection unit in provincial health offices inspecting retail pharmacies especially in Aumpur Mueng, and they assigned the duty of retail pharmacy inspection to the officers of district health offices and the pharmacists of community hospitals in the other districts such as Chonburi, Udon Thani, Nong Bue Lumphu, Nong Khai, Loei, Khon kaen, Maha Sarakham and Nakhon Ratchasima province. Then, the factors of this model were lack of pharmacist of consumer protection unit, large province, a lot of retail pharmacies, and network strength, as showed in Figure 2.7 .

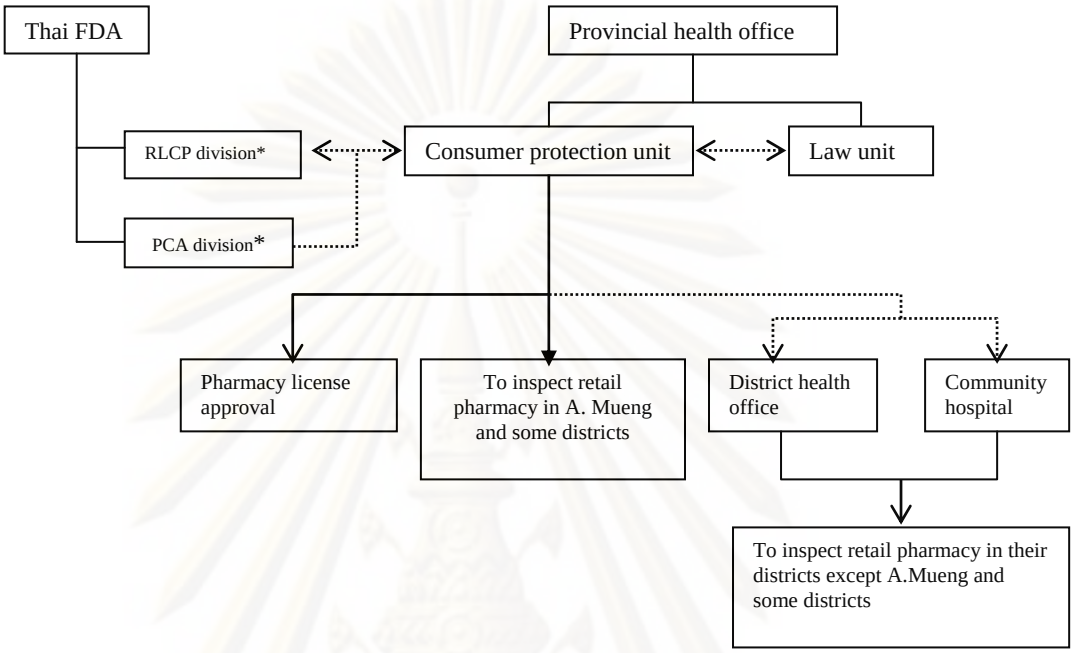


* RLCP division = Rural and local consumer health products protection promotion division

***** PCA division = Public and consumer affairs division

Figure 2.7 Model 3 of retail pharmacy inspection in provincial part

The fourth model was the pharmacists of consumer protection unit in provincial health offices inspecting retail pharmacies especially in Aumpur Mueng and some districts, and they assigned the duty of retail pharmacy inspection to the officers of district health offices and the pharmacists of community hospitals in the other districts such as Nakhon Pathom province. Then, the factors of this model were network weakness in some districts, a lot of retail pharmacy, as showed in Figure 2.8 .

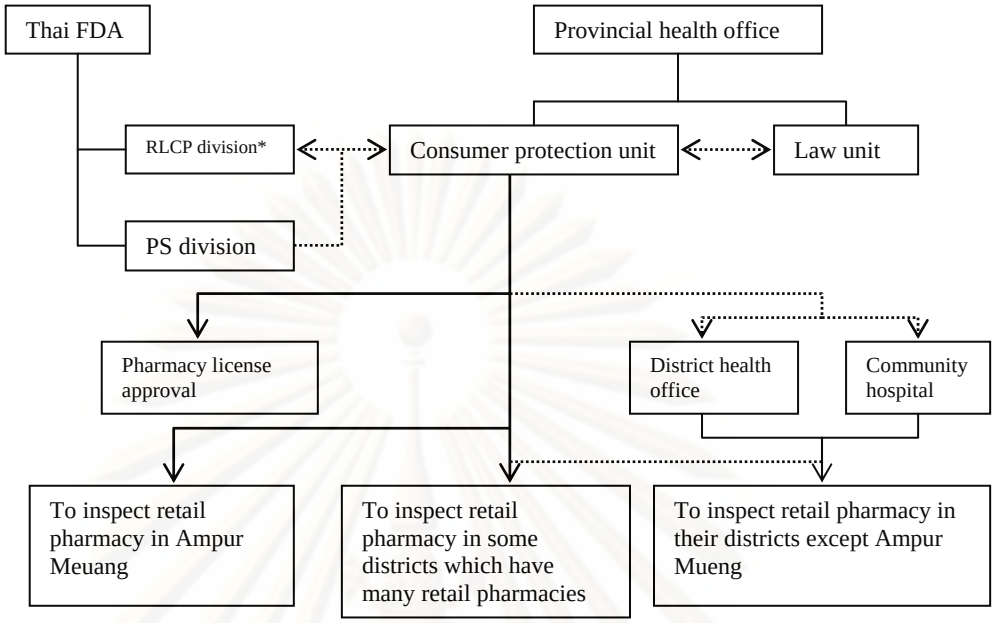


* RLCP division = Rural and local consumer health products protection promotion division

* PCA division = Public and consumer affairs division

Figure 2.8 Model 4 of retail pharmacy inspection in provincial part

The last model was the pharmacists of consumer protection unit in provincial health office inspecting retail pharmacies especially in Aumpur Mueng and some districts which had many retail pharmacies such as Kao samui district together with officers of district health office and pharmacists of community hospital. Moreover, they still assigned the duty of retail pharmacy inspection to the officers of district health offices and the pharmacists of community hospitals in other districts such as Surat Thani province. Accordingly, Then, the factors of this model were a lot of pharmacists of consumer protection unit (15 persons), a lot of retail pharmacies in some district (Ampur kaosamui), large province, and network strength, as showed in Figure 2.9 .



* RLCP division = Rural and local consumer health products protection promotion division

***** PCA division = Public and consumer affairs division

Figure 2.9 Model 5 of retail pharmacy inspection in provincial part

2.4 The Bangkok Metropolitan Administration

In Thailand, there were 5 types of local government organizations that were the BMA, Pattaya city, provincial administrative organization, municipality and subdistrict administrative organizations. The BMA was the biggest local government organizations, and had the roles, duties, and responsibilities to administer in Bangkok area.

2.4.1 Government sector of the BMA

The structure of the BMA comprised of 19 departments and 50 district offices. **(13)**

1) The Bangkok Governor Secretariat
2) BMA Council Secretariat
3) Office of the Bangkok Metropolitan Administration Civil Service Commission
4) Office of the permanent Secretary
5) Strategy and Evaluation Department
6) Public Works Department
7) Drainage and Sewerage Department
10) Education Department
11) Budget Department
12) City Law Enforcement Department
13) City Planning Department
14) Environment Department
15) Fire and Rescue Department
16) Finance Department
17) Medical Service Department

8) Traffic and Transportation Department
9) City Law Enforcement Department
18) Health Department
19) 50 District Offices

2.4.2 Health Department

The structures of Health Department comprised of 13 divisions, and Pharmaceutical division was the main agency to be responsible for the task of drug protections. **(14)**

1) Secretary office
2) 68 Health centers
3) Public health system development division
4) Dental health division
5) Environmental sanitation division
6) Veterinary public health division
7) Health promotion division
8) Public health nursing division
9) Aids control division
10) Drug abuse prevention and treatment division
11) Pharmaceutical division
12) Food sanitation division
13) Health laboratory division

2.4.3 Pharmaceutical division

The structure of Pharmaceutical division comprised of 4 units that were medical supplies unit, drug manufacture unit, academic unit, and secretary unit. Then, there were 14 pharmacists in this division divided in 5 pharmacists in medical supplies unit, 4 pharmacists in drug manufacture unit, and 5 pharmacists in academic unit as show in Figure 2.10 . **(15)**

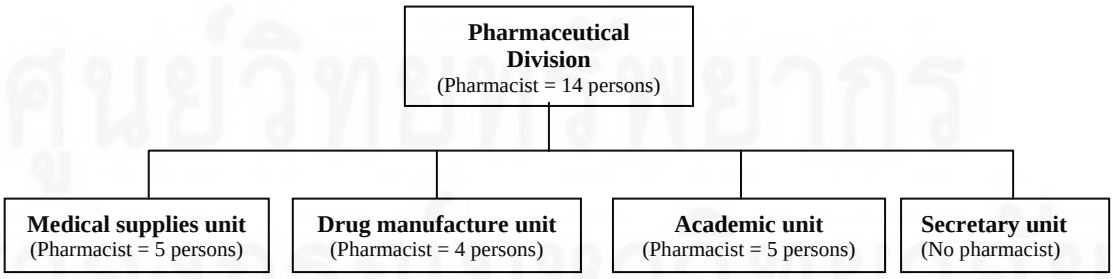


Figure 2.10 Structure of Pharmaceutical division

2.4.3.1 The responsibilities of Pharmaceutical division

1) To plan, control, develop the pharmacy services, and to support medicine, medical supplies, chemical, and medical devices to health centers and related organization.

2) To provide medicine, medical supplies, medical, and public health instrument, and to manufacture the medicines to the organizations within Health Department.

3) To study and research about pharmacy services

4) To develop the knowledge of pharmacists

5) To produce and publicize about the pharmaceutical documents.

6) The other tasks which were assigned

2.4.4. Health center

There were 68 health centers which were under Health department, and each health center comprised of 7 units which were medical care unit, dentistry unit, pharmacy unit, narcotic prevention unit, social work unit, financial unit, and secretary unit, as showed in Figure 2.11. At the present, there was only one pharmacist in each health center, and the responsibilities of pharmacy division were pharmacy services such as drug dispensing and consultant not involved drug inspection.

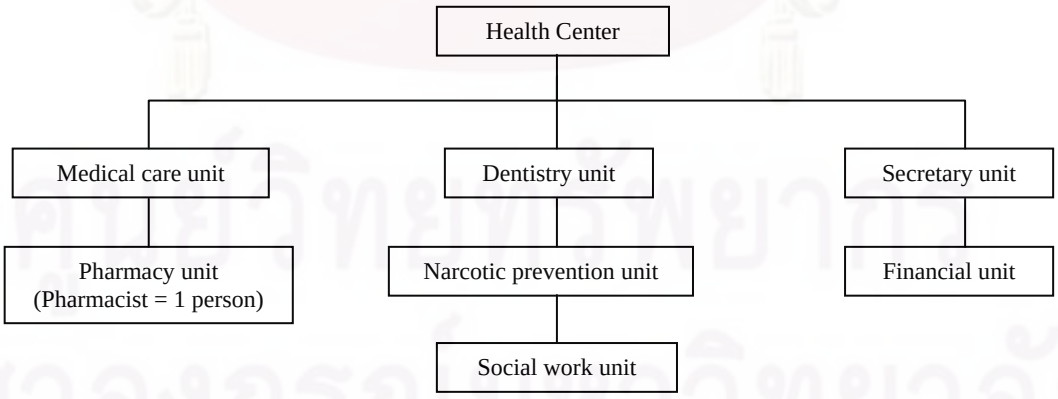


Figure 2.11 Structure of health center

2.4.5 District office

The BMA delegated the administration of central organizations to 50 district offices. Its structure comprised of 12 units and primary schools that were administrative unit, registration unit, Income unit, Education unit, Finance unit, Public work unit, Environment and sanitation unit, Cleansing and park unit, City law enforcement unit and Community development, Welfare unit, Registrar unit, and Revenue unit, as showed in Figure 2.12 . **(16)**

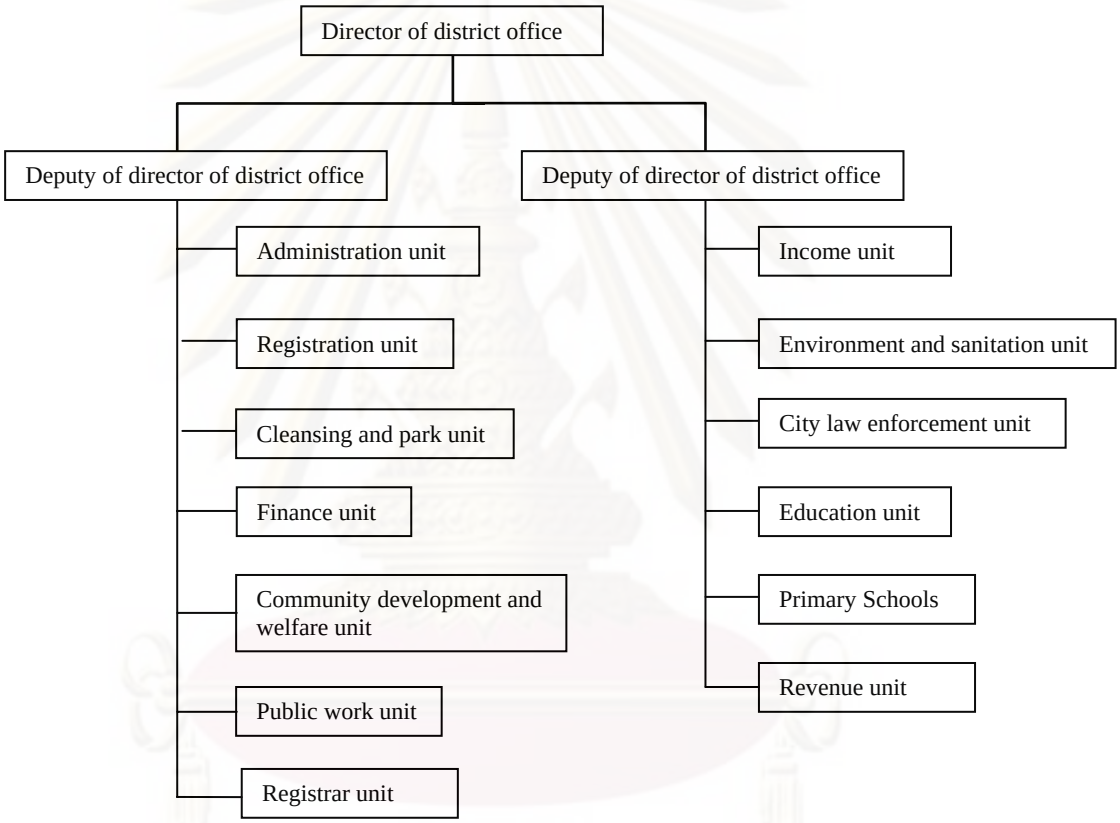


Figure 2.12 Structure of district office

2.4.6 The Administration of the BMA

The administration of the BMA were divided in 50 districts, and these districts were formed into 6 groups according to social, economic, population and culture, as following : **(17)**

2.4.6.1 Central Bangkok group

1) Pranakorn district, Dusit district, Pom Prap Sattu Phai district, and Samphantawong district

2) Din Daeng district, Huai Khwang district, Phaya Thai district, Ratchathewi district, and Wangthonglang district

2.4.6.2 Southern Bangkok group

1) Pathum Wan district, Sathon district, Bang Rak district, Bang Kho Laem district, Yan Nawa district, and Klongtaoe district

2) Vadhana district, Phra Khanong district, Suan Luang district, Bang Na district, and Prawet district

2.4.6.3 Northern Bangkok group

1) Jatujak district, Bang Su district, Lat Phrao district, and Lak Si district

2) Don Mueng district, Sai Mai district, and Bangkhen district

2.4.6.4 Eastern Bangkok group

1) Bangkapi district, Saphan Sung district, Bung Kum district, and Kannayao district

2) Lat Krabang district, Nong Chok district, Min Buri district, and Khong Sam Wa district

2.4.6.5 Northern Krungthon

1) Thon Buri district, Khlong San district, Chom Thong district, and Bangkok Yai district

2) Bangkok Noi district, Bang Phlad district, Taling Chan district,and Taweewattana district

2.4.6.6 Sounthern Krungthon

1) Phasi Charoen district, Bang Khae district, and Nong Khaem district

2) Bang Khun Thian district, Bang Bon district, Rat Burana district, and Thung-Khru district

2.5 Decentralization to local government in Thailand

The researches on decentralization in Thailand were summarized in two topics. The results showed that local government still had many problem in its organization, as presented following:

2.5.1 Decentralization to the BMA

The readiness of the BMA for transferring duty under the process of decentralization was moderate. It also found that the 1997 Constitution influenced the readiness of the transfer but several components did not. These included staffs' gender, age, education status, monthly income, working period, level, and knowledge about decentralization process, knowledge about the 1999 Decentralization Bill. **(18)** In addition, The BMA had many problems on public service including budget allocation didn't response to people's demand. Most of the budget was allocated for education and solving problems of waste water. **(19)** Central government didn't transfer manpower, budget and task under the action plan on decentralization. **(20)** Additionally, central government extremely controlled the BMA. Researcher also mentioned that decentralization policy was unclear. **(21)**

For decentralizing the food product regulation to the BMA, the officers of the BMA thought that the BMA was ready to carrying-out the 3 authorities which were pre-marketing control, post-marketing control, and legal process in drinking water product, ice product, and the other food products. They agreed that there should be co-operation in working between the BMA and the Thai FDA.**(22)** Consequently, for food product regulation, they thought that the Thai FDA should delegate the tasks of pre-marketing control and post-marketing control to director of Environment and sanitation unit of district office, and the public health officers. The Thai FDA should delegate the legal process to the chief executive of the BMA such as director of Health Department, director of district office, and deputy of director of district office. **(23)** However, if the Thai FDA delegate these partial authorities to the BMA, there will be more problems of the BMA's regulation. **(24)** At present, there were many problems in the decentralization of food product regulation. For example, processes of food inspection were unclear. The BMA had the problems of resource management such as lack of manpower, budget, and instrument. Information system of the BMA should be improved. **(25)**

2.5.2 Decentralization to provincial local government administration

The readiness of the budget of Nakornratchasima provincial administrative organization was high level, whereas, the readiness of planning, management, and command were normal level. **(26)** Besides, the researches showed that Subdistrict Administrative Organizations (SAOs) still had many problems in their organizations. These problems were SAOs still lacked of manpower, budget, and high technology instrument. **(27)** SAOs had low capability of small SAOs was lower than that of the big ones. Both big and small SAOs showed the weak supporting systems, ranging from high to low deficiency in five respects : 1) training 2) fiscal management 3) personnel management 4) Supervising and 5) information technology management. In comparison, three management functions namely, 1) planning 2) logistics management and 3) community preparation surpassed the minimum acceptable level. **(28)** In addition, the executives of all the SAOs had low management capability **(29),** and the decentralization policy in public health was ambiguous, and was not continuously implemented. Therefore, they just transferred only the mission to local government unit. **(30)** Accordingly, there was a lack of cooperation of government services from different organizations **(31).** Many public health officers did not have confidence on the public health decentralization. **(32)**

For the decentralization of health product protection to municipalities, the results of study showed that :

1) The roles in health product protection of municipality should be promotion role and supporting role more than punishment role. If municipality had the organization structure for health product protection, it will support the municipality to regulate health products in its areas effectively.

2) The major problems of municipality in health product protection were that chief executive wasn't interested in the task. These problems had effected to which impact to budget allocation, and the planning of the regulation. Besides, municipality did not have the structure for health product protection leading to the problem of co-ordination between provincial health office and municipality. **(33)**

CHAPTER III
METHODOLOGY

Quantitative research and qualitative research were used in the research methodology. The results of study were applied to provide the decentralization model for the BMA in regulation of the retail pharmacy. The Ethics Committee of The Faculty of Pharmaceutical Sciences, Chulalongkorn University, Bangkok, Thailand approved this study in June 12, 2009.

3.1 Study design

This study used mixed methods including quantitative research which collected data from questionnaire for directors of health center and questionnaire for pharmacists of health center, and qualitative research which was expert panel discussion. The objective of expert panel discussion was to discuss the primary data receiving form the results of questionnaires, and to propose the decentralization model for the BMA in regulation of the retail pharmacy.

3.2 Study population

3.2.1 Questionnaire

This study collected the data from health center leaders of Health Department of the BMA who were 68 directors and 68 pharmacists.

3.2.2 Expert panel discussion

There were eleven experts in expert panel discussion. They were form selected organizations which were the BMA, the Thai FDA, Medical science center provincial health office, and community hospital.

3.2.2.1 Inclusion criteria

1) Pharmacists in organizations of Ministry of public health who related to regulation of the retail pharmacy, and had the experience in retail pharmacy inspection more than 10 years.

2) Pharmacists in Pharmaceutical division and health center who had the knowledge about structure of the BMA and retail pharmacy regulation.

3) Officer of Environmental sanitation division, the BMA who had the experience more than 2 years in the decentralization in inspection of the drinking water and ice plan which the Thai FDA decentralized them to the BMA.

3.2.2.2 Experts selected for panel discussion

1) Department of Health, the BMA

- Pharmaceutical division 1 person
- Health center 2 persons
- Environmental sanitation division 1 person

2) The Thai FDA

- Rural and local consumer health products protection promotion division 1 person
- Drug control division 1 person

3) Ubonratchathani medical science center 1 person

4) Provincial health office

- Samut Prakan provincial health office 1 person
- Nakhon Phanom provincial health office 1 person

5) Community hospital

- Bangbo hospital, Samut Prakan province 1 person
- Pakret hospital, Nonthaburi province 1 person

3.3 Research Instruments

This study used two research instruments which were questionnaires and series of question guidelines to be discussed, and there were several processes to develop questionnaires, as following:

1) Reviewing documents and relating data about retail pharmacy regulation in Thailand in order to form questionnaires covering the objective of the study, and proposed them to advisors. After that, to adjust the questionnaires according to advisors' recommendation.

2) Asking for the recommendation these questionnaires from the experts of provincial health office and community hospital.

3) Testing these questionnaires with 2 directors of health centers and 2 pharmacists of health centers

4) Adjusting these questionnaires completely and approved by advisors

3.3.1 Questionnaire for directors of health centers (Appendix A)

This questionnaire had 18 questions, and it divided in 2 parts, as following:

Part 1: The opinions concerning retail pharmacy regulation for the BMA
(13 questions)

1) The opinions about the decentralizing retail pharmacy regulation

2) The BMA's agencies to be responsible for approving pharmacy license, retail pharmacy inspection, legal process, and receiving drug complaints

3) Roles and responsibilities

Part 2: Demographic data which were sex, age, position, education, and working period in health center (5 questions)

3.3.2 Questionnaire for pharmacists of health centers (Appendix B)

This questionnaire had 24 questions, and it divided in 2 parts, as following:

Part 1: The opinions concerning retail pharmacy regulation for the BMA (14 questions)

1) The opinions about the decentralizing retail pharmacy regulation

2) The BMA's agencies to be responsible for approving pharmacy license, retail pharmacy inspection, legal process, and receiving drug complaints

3) Roles and responsibilities

Part 2: Open-ended questions (2 questions)

1) Problems, obstacles, and recommendations

2) Requirement for developing retail pharmacy inspection

Part 3: Demographic data which were sex, age, position, education, working period in health center, experience in retail pharmacy inspection, and etc. (8 questions)

3.3.3 The question guidelines in expert panel discussion

There were 11 question guidelines in expert panel discussion such as agency to inspect retail pharmacy, agency to approve pharmacy licenses, legal process agency, agency to receive drug complaints, and etc., as showed in Appendix C.

3.4 Data collection

3.4.1 Data from directors of health centers

Questionnaires and covering letter were sent to 66 subjects by official mailing in the first time, and 56 respondents sent them back. Then, the other 10 questionnaires were resent administered to the directors who did not respond. Six respondents were sent the questionnaires back. Finally, the total was 62 questionnaires (93.9%).

3.4.2 Data form pharmacists of health centers

Questionnaires for 66 pharmacists of health center were provided to the pharmacists in the meeting on 31 August, 2009, and 58 questionnaires were responded. The second time, researcher sent the questionnaires to the other responders, and 5 questionnaires were sent back. Finally, the total was 63 questionnaires (95.5%).

3.4.3 Expert panel discussion

After collecting and evaluating the data of directors' questionnaires and pharmacists' questionnaires, the expert group discussion was organized to discuss data about decentralization model for the BMA in regulation of the retail pharmacy in 11 topics related to the obtained data at the Thai FDA. Finally, complete decentralization model was proposed.

3.5 Data analysis

The data of returned questionnaires were coded in a database, and analyzed by using the Statistical Package for Social Sciences (SPSS) window software version 13. Descriptive statistic was applied in this study such as means and percentage. Besides, content analysis was applied in the process of expert panel discussion in order to conclude the experts' concept.

CHAPTER IV
RESULTS

The results of this study were divided into two phases. Phase I was the results of questionnaire collected from the directors and pharmacists of the BMA health centers, and phase II was the results from expert panel discussion. These results were presented, as following.

4.1 Results of questionnaire

4.1.1 Questionnaires collected from the directors of health centers

The total of 66 questionnaires for directors of the BMA health centers were distributed. There were 62 questionnaires which were sent back from the directors (93.9 % response rate).

4.1.1.1 Demographic data

Most of the directors were female (59.7%). Their average age was 41.8 years. Most of their positions were Doctor level 8 (67.8 %). The others were Doctor level 7 (16.1%) and Doctor level 9 (8.1%). Most of them had highest education in Doctor of Medicine (62.9%). The others had Master degree or the certification of Medical Specialist (37.1%). The average working period in health centers was 11.3 years, as showed in Table 4.1.

Table 4.1 Demographic data of the directors

Demographic data	**Number (N = 62)**	**Percentage (%)**
1. Sex		
- Male	25	40.3
- Female	37	59.7

Table 4.1 (Cont.)

Demographic data	Number (N = 62)	Percentage (%)
2. Age		
- 21 – 30 years	1	1.6
- 31 – 40 years	27	43.6
- 41 – 50 years	24	38.7
- 51 – 60 years	10	16.1
3. Position		
- Doctor level 5	3	4.8
- Doctor level 6	2	3.2
- Doctor level 7	10	16.1
- Doctor level 8	42	67.8
- Doctor level 9	5	8.1
4. Education		
- Bachelor's degree in Doctor of Medicine	39	62.9
- Master degree/ the certification of Medical Specialist	23	37.1
5. Working period in health center		
- < 10 years	32	51.6
- 11 – 20 years	26	41.9
- > 20 years	4	6.5

4.1.1.2 The opinions concerning retail pharmacy inspection

The results of directors' opinion concerning retail pharmacy inspection showed that the BMA should be responsible for retail pharmacy inspection (56.5%). Agencies of the BMA to inspect retail pharmacies were health center with Pharmaceutical division (56.5%). The other agencies to inspect retail pharmacies were health centers with district offices (27.4%), and health centers with Pharmaceutical division and district offices (9.7%). Additionally, units of district office which were

responsible for retail pharmacy inspection were Environment and sanitation unit (80.6%) and City law enforcement unit (19.4%).

Beside pharmacy type 1 and pharmacy type 2, the BMA should inspect grocery store (67.7 %), traditional pharmacy (64.5%), and veterinary pharmacy (58.1%), and types of retail pharmacy inspection were action plan inspection (88.7%), drug complaint inspection (79.0%), and special case inspection (75.8%), as showed in Table 4.2.

Table 4.2 Number and percentage of the director concerning the opinions on retail pharmacy inspection

Opinions on retail pharmacy inspection	**Number (N = 62)**	**Percentage (%)**
1. The BMA should be responsible for retail pharmacy inspection		
1.1 Yes	35	56.5
1.2 No	27	43.5
2. If the BMA has the role on retail pharmacy inspection, agency of the BMA should inspect retail pharmacies		
2.1 Health centers	2	3.2
2.2 Health centers with Pharmaceutical division	35	56.5
2.3 Health centers with district offices	17	27.4
2.4 Health centers with Pharmaceutical division and district offices	6	9.7
2.5 Others : Health centers with the Thai FDA	2	3.2
3. Unit of district office should be responsible for retail pharmacy inspection		
3.1 Environment and sanitation unit	50	80.6
3.2 City law enforcement unit	12	19.4

Table 4.2 (Cont.)

Opinions on retail pharmacy inspection	Number (N = 62)	Percentage (%)
4. Beside pharmacy type 1 and type 2, the types of retail pharmacy were inspected by the BMA (Respondent could answer more than one choice)		
4.1 Grocery store	42	67.7
4.2 Traditional pharmacy	40	64.5
4.3 Veterinary pharmacy	36	58.1
5. Types of retail pharmacy inspection for the BMA (Respondent could answer more than one choice)		
5.1 Action plan inspection	55	88.7
5.2 Drug complains inspection	49	79.0
5.3 Special case inspection	47	75.8

4.1.1.3 The opinions concerning pharmacy license approval

The results of directors' opinion concerning pharmacy license approval showed that the BMA should be responsible for approving pharmacy license (40.3%). Agencies of the BMA to approve pharmacy license were Pharmaceutical division (77.4%), and district offices (14.5%), appeared in Table 4.3.

Table 4.3 Number and percentage of the director concerning the opinions on pharmacy license approval

Opinions on pharmacy license approval	Number (N = 62)	Percentage (%)
1. The BMA should be responsible for approving pharmacy license		
1.1 Yes	25	40.3
1.2 No	37	59.7

Table 4.3 (Cont.)

Opinions on pharmacy license approval	Number (N = 62)	Percentage (%)
2. If the BMA has the role on approving the license, agency of the BMA to be responsible for approving retail pharmacy licenses		
2.1 Pharmaceutical division	48	77.4
2.2 District office	9	14.5
2.3 Others : Health centers, Department of Health, and the Thai FDA	5	8.1

4.1.1.4 The opinions concerning legal process and drug complaints

The results of directors' opinion concerning legal process and drug complaints showed that agencies of the BMA to be responsible for legal process were Health Department (58.1%), and district office (25.8%). Besides, agencies of the BMA to be responsible for receiving drug complains were Hotline of Health Department (71.70%), Hotline 1555 (58.1%), and Pharmaceutical division (50.0%), as showed in Table 4.4.

Table 4.4 Number and percentage of the director concerning the opinions on legal process and complaints

Opinions on legal process and complaints	Number (N = 62)	Percentage (%)
1. Agency of the BMA to be responsible for legal process.		
1.1 Health Department	36	58.1
1.2 District office	16	25.8
1.3 Health center	4	6.4
1.4 Others : The Thai FDA, Law office of the BMA, and police	6	9.7

Table 4.4 (Cont.)

Opinions on legal process and complaints	Number (N = 62)	Percentage (%)
2. Agency of the BMA to receive drug complains form consumer (Respondent could answer more than one choice)	44	71.0
2.1 Hotline of Health Department	36	58.1
2.2 Hotline 1555	31	50.0
2.3 Pharmaceutical division	22	35.5
2.4 Health center	13	21.0
2.5 District office		

4.1.1.5 The opinions concerning the roles of retail pharmacy regulation

The results of directors' opinion concerning the roles of retail pharmacy regulation showed that the roles in retail pharmacy regulation were 1) to create and expand the consumer protection network in community (83.9%), 2) to developing the knowledge about health products protection to consumer and inform consumer about their consumer right (75.8%), and 3) to producing media of health product protection and inform to consumer (64.8%). Additionally, the BMA should develop retail pharmacy in the project of adverse drug reaction network, knowledge development, and accredited pharmacy and at 93.6%, 69.4%, and 61.3% respectively. Besides, the Thai FDA should decentralize the tasks of retail pharmacy regulation to the BMA within 5 years (30.6%), within 10 years (25.8%), and within 3 years (24.2%) as showed in Table 4.5.

Table 4.5 Number and percentage of the director concerning the opinions on the roles of retail pharmacy regulation

Opinions on the roles of retail pharmacy regulation	**Number (N = 62)**	**Percentage (%)**
1. The roles of the BMA in retail pharmacy regulation (Respondent could answer more than one choice)		
1.1 Creating and expanding the consumer protection network in community	52	83.9
1.2 Developing the knowledge about health products protection to consumer and inform consumer about their consumer right	47	75.8
1.3 Producing media of health product protection and inform to consumer	40	64.8
2. The BMA should have the roles of retail pharmacy development in knowledge improvement (Respondent could answer more than one choice)		
2.1 Project of adverse drug reaction network	58	93.6
2.2 Knowledge development	43	69.4
2.3 Program of community pharmacy accreditation	38	61.3
3. The Thai FDA should decentralize the task of retail pharmacy inspection to the BMA		
3.1 Immediately	7	11.3
3.2 within 1 year	5	8.1
3.3 within 3 years	15	24.2
3.4 within 5 years	19	30.6
3.5 within 10 years	16	25.8

4.1.2 Questionnaire collected from the pharmacists of health centers

Total of 66 questionnaires for pharmacists of health centers were distributed. There were 63 questionnaires returned in the survey for an overall 95.5 % response rate.

4.1.2.1 Demographic data

Most of pharmacists were female (68.3 %), and their average age were 39.5 years. Most of their positions were Pharmacist level 5 (25.4 %). The others were Pharmacist level 6, and level 7 at 23.8% equally. Most of the highest education were bachelor's degree in Pharmaceutical science (58.7%). The others were master's degree (41.3%). The average of working period in health centers was 11.9 years. Most of them had no experience on retail pharmacy inspection (93.1%), most of health centers had pharmacists part time (58.7%), as showed in Table 4.6.

Table 4.6 Demographic data of pharmacists

Demographic data	**Number (N = 63)**	**Percentage (%)**
1. Sex		
- Male	20	31.7
- Female	43	68.3
2. Age		
- 21 – 30 years	8	12.7
- 31 – 40 years	33	52.4
- 41 – 50 years	10	15.9
- 51 – 60 years	12	19.0
3. Position		
- Pharmacist level 3	2	3.2
- Pharmacist level 4	2	3.2
- Pharmacist level 5	16	25.4
- Pharmacist level 6	15	23.8
- Pharmacist level 7	15	23.8
- Pharmacist level 8	13	20.6

Table 4.6 (Cont.)

Demographic data	Number (N = 63)	Percentage (%)
4. Education		
- Bachelor's degree	37	58.7
- Master's degree	26	41.3
5. Working period in health center		
- < 10 years	28	44.4
- 11 – 20 years	23	36.5
- > 20 years	12	19.1
6. Experience in retail pharmacy inspection before working at health center		
- Yes	4	6.3
- No	59	93.7
7. Training the courses of retail pharmacy inspection with the Thai FDA		
- Yes	47	74.6
- No	16	25.4
8. Part time pharmacist in health centers		
- Yes	37	58.7
- No	26	41.3

4.1.2.2 The opinions concerning retail pharmacy inspection

The results of pharmacists' opinion concerning retail pharmacy inspection showed that the BMA should be responsible for retail pharmacy inspection (92.1%). Agencies of the BMA to inspect retail pharmacies were health centers with Pharmaceutical division (66.6%). The other models were health centers with district offices, and health centers with Pharmaceutical division and district offices at 9.5% equally. Additionally, units of district offices which were responsible for retail

pharmacy inspection were Environment and sanitation unit (90.5%) and City law enforcement unit (7.9%).

Beside pharmacy type 1 and pharmacy type 2, the BMA should inspected traditional pharmacy (82.5%), grocery store (76.2%), and veterinary pharmacy (52.4%), and types of retail pharmacy inspection were action plan inspection (95.2%), drug complaint inspection (92.1%), and special case inspection (85.7%), as showed in Table 4.7.

Table 4.7 Number and percentage of the pharmacist concerning the opinions on retail pharmacy inspection

Opinions on retail pharmacy inspection	**Number (N = 63)**	**Percentage (%)**
1. The BMA should be responsible for retail pharmacy inspection		
1.1 Yes	58	92.1
1.2 No	5	7.9
2. Agency of the BMA should inspect retail pharmacies		
2.1 Health centers	3	4.8
2.2 Health centers with Pharmaceutical division	42	66.6
2.3 Health centers with nearby health centers	3	4.8
2.4 Health centers with district offices	6	9.5
2.5 Health centers with Pharmaceutical division and district offices	6	9.5
2.5 Others : Health centers with the Thai FDA	3	4.8
3. Unit of district office should be responsible for retail pharmacy inspection		
3.1 Environment and sanitation unit	57	90.5
3.2 City law enforcement unit	5	7.9
3.3 Others : Social development unit	1	1.6

Table 4.7 (Cont.)

Opinions on retail pharmacy inspection	Number (N = 63)	Percentage (%)
4. Beside pharmacy type 1 and type 2, the types of retail pharmacy were inspected by the BMA (Respondent could answer more than one choice)		
4.1 Traditional pharmacy	52	82.5
4.2 Grocery store	48	76.2
4.3 Veterinary pharmacy	33	52.4
5. Types of retail pharmacy inspection for the BMA (Respondent could answer more than one choice)		
5.1 Action plan inspection	60	95.2
5.2 Drug complaint inspection	58	92.1
5.3 Special case inspection	54	85.7

4.1.2.3 The opinions concerning pharmacy license approval

The results of pharmacists' opinion concerning pharmacy license approval showed that the BMA should be responsible for approving pharmacy license (61.9%). Agencies of the BMA to approve pharmacy license were Pharmaceutical division (85.7%), and district offices (9.5%), as showed in Table 4.8.

Table 4.8 Number and percentage of the pharmacist concerning the opinions on pharmacy license approval

Opinions on pharmacy license approval	Number (N = 63)	Percentage (%)
1. The BMA should be responsible for approving retail pharmacy license		
1.1 Yes	39	61.9
1.2 No	23	38.1

Table 4.8 (Cont.)

Opinions on pharmacy license approval	Number (N = 63)	Percentage (%)
2. If the BMA has the role in approving the license, agency of the BMA should be responsible for approving retail pharmacy licenses		
2.1 Pharmaceutical division	54	85.7
2.2 District office	6	9.5
2.3 Others : the Thai FDA	3	4.8

4.1.2.4 The opinions concerning the issues related retail pharmacy inspection

The results of pharmacists' opinion concerning the issues related retail pharmacy inspection showed that the interesting issues of retail pharmacy inspection in high level were expired drug (88.9%), deteriorate drug (87.3%), counterfeit drug (81.0%), pharmacies on the duration of their business hour (60.3%), and drug advertisement (57.1%), whereas list of special control drug inspection was in medium level (49.2%), as showed in Table 4.9 .

Table 4.9 Number and percentage of the pharmacist by the level of the opinions concerning the issues related retail pharmacy inspection

Opinions on the issues related retail pharmacy inspection	Level of inspection		
	High (n/%)	Medium (n/%)	Low (n/%)
1. Pharmacists on the duration of their business hour	38 (60.3)	19 (30.2)	6 (9.5)
2. Physical drug inspection			
2.1 expired drug	56 (88.9)	6 (9.5)	1 (1.6)
2.2 deteriorate drug	55 (87.3)	8 (12.7)	0
2.3 counterfeit drug	51 (81.0)	9 (14.3)	3 (4.7)
3. List of special controlled drug	25 (39.7)	31 (49.2)	7 (11.1)
4. Drug advertisement	36 (57.1)	17 (27.0)	10 (15.9)

4.1.2.5 The opinions concerning legal process and drug complaints

The results of pharmacists' opinion concerning legal process and drug complaints showed that agencies of the BMA to be responsible for legal process were Health Department (69.8%), and district office (28.6%). Besides, agencies of the BMA to be responsible for receiving drug complains were Pharmaceutical division (71.4%), Hotline of Health Department (68.3%), and health centers (61.9%), as showed in Table 4.10.

Table 4.10 Number and percentage of the pharmacist concerning the opinions on legal process and complaints

Opinions on legal process and complaints	**Number (N = 63)**	**Percentage (%)**
1. Agency of the BMA to be responsible for legal process.		
1.1 Health Department	44	69.8
1.2 District office	18	28.6
1.3 Others: The Thai FDA	1	1.6
2. Agency of the BMA to receive drug complains form consumer (Respondent could answer more than one choice)	45	71.4
2.1 Pharmaceutical division	43	68.3
2.2 Hotline of Health Department	39	61.9
2.3 Health center	31	49.2
2.4 Hotline 1555	5	7.9
2.5 District office		

4.1.2.6 The opinions concerning the roles of retail pharmacy regulation

The results of pharmacists' opinion concerning the roles of retail pharmacy regulation showed that the roles in retail pharmacy regulation were 1) to create and expand the consumer protection network in community (96.8%), 2) to be surveillance the health product problems (82.5%), 3) to develop the knowledge about health products protection to consumer and inform consumer about their consumer

right (76.2%). Additionally, the BMA should develop retail pharmacy in the project of adverse drug reaction network, accredited pharmacy, and knowledge development at 88.9%, 81.0%, and 73.0% respectively. Accordingly, the main roles of the Thai FDA to promote and support the BMA in retail pharmacy regulation that were consultants (100%), training center (98.4%), and couching (92.1%), as showed in Table 4.11.

Table 4.11 Number and percentage of the pharmacist concerning the opinions on the roles of retail pharmacy regulation

Opinions on the roles of retail pharmacy regulation	**Number (N = 63)**	**Percentage (%)**
1. The roles of the BMA in retail pharmacy regulation (Respondent could answer more than one choice)		
1.1 Creating and expanding the consumer protection network in community	61	96.8
1.2 Developing the knowledge about health products protection to consumer and inform consumer about their consumer right	52	82.5
1.3 Producing media of health product protection and inform to consumer	48	76.2
2. The BMA should have the roles of retail pharmacy development in knowledge improvement (Respondent could answer more than one choice)		
2.1 Project of adverse drug reaction network	56	88.9
2.2 Program of community pharmacy accreditation	51	81.0
2.3 Knowledge development	46	73.0

Table 4.11 (Cont.)

Opinions on the roles of retail pharmacy regulation	Number (N = 63)	Percentage (%)
3. Roles of the Thai FDA to promote and support the BMA in retail pharmacy regulation (Respondent could answer more than one choice)		
3.1 Academic advisor	63	100
3.2 Training center	62	98.4
3.3 Coaching	58	92.1
3.4 Support media	57	90.5
3.5 Support drug special project	54	85.7
3.6 Inspect retail pharmacy when the BMA request	54	88.5
3.7 Others : Inspecting with the BMA, Supporting budget/manpower, Backing up the BMA's officers	5	7.9

4.1.2.7 Problems, obstacles, and recommendations

The results of open-ended questions about problems, obstacles, and recommendations in retail pharmacy regulation for the BMA showed that the main problems of the BMA were lack of manpower, budget, and vehicle. Additionally, the recommendations were to appoint the BMA's officers to be drug authority, to make the guideline of retail pharmacy inspection, and to backup the BMA's officers. Besides, The Thai FDA should train the BMA's officers in the course of experience in retail pharmacy inspection, on the job training, and legal process

4.2 Results of expert panel discussion

In order to consider the proper and effectiveness of the decentralization in retail pharmacy regulation for the BMA, members of the meeting were provided the information, as in the following.

4.2.1 Structure and manpower of the BMA

Pharmaceutical division of Health Department was divided into four units which were drug manufacturing unit, medical supply unit, academic unit, and general affairs. Also, Pharmaceutical division had opened four new positions, which

specially will deal with consumer protection of which one was already occupied and only three available.

Additionally, health centers included the position of one pharmacist and one pharmaceutical assistant. They had a similar purpose as a community hospital, but without Inpatient department and other obligations like a mobile medical unit and a health care volunteer meeting. They also have their role on community health care. Also, the information showed that the distribution of 68 health centers did not cover in every districts of Bangkok. Each district didn't have the same number of health centers, because the land of health centers was donated.

4.2.2 Decentralization model for the BMA in regulation of retail pharmacy

Principle for considering in regulation of retail pharmacy for the BMA had to be done in order to gain a proper and efficient management. The experts considered different concepts discussed in the meeting which could be concluded, as in the following:

1) Thinking about the citizens' benefit at the first such as convenient service, easy to reach and low cost

2) Emphazing on decentralization policy except at the circumstance which centralization of authority is needed

3) Achieving the best work on the retail pharmacy regulation

4.2.2.1 Agency to inspect retail pharmacy

There were five models for inspecting retail pharmacies which were considered and discussed by the experts.

Model 1: Pharmaceutical division was only agency to inspect retail pharmacy

The inspection of retail pharmacy should involve more than one agency, and it was not only the Pharmaceutical division. It would make the inspection more efficient, and the BMA would be able to cover a larger area during the inspection.

The following quotes from the discussion that supported the above statement:

"…The best way would be to involve more agencies in the process …"

"…If there were around four thousand pharmacies, the BMA should not have only one agency dealing with the inspection. So, Model 1 and Model 2 will not be the best solution."

Therefore, the model 1 was not appropriate based on the discussion because Pharmaceutical division had only 4 pharmacists who were responsible to inspect 4,788 retail pharmacies in Bangkok. It could not inspect them effectively by one agency.

Model 2: Health center was only agency to inspect retail pharmacies

Health centers had only one pharmacist in its organization. If health centers would be the only organization involved in this process, it would have the effect that their might be not enough personal dealing with this task. So, it would be better to involve other agencies which would cooperate with health centers in this process.

The following quotes from the discussion that supported the above statement:

"…The second model also might have problems in first five years. More than one agency should be involved in this process because health centers were not stable enough to do such task on its own…"

Therefore, the model 2 was not appropriate based on the discussion. Because the inspection of the retail pharmacy must has more than one inspector who was pharmacist, while health center had only one pharmacist to inspect retail pharmacies.

Model 3: Health center inspecting with Pharmaceutical division

Health center inspecting with Pharmaceutical division was the most appropriate structure for the present in Bangkok because the decentralization created a close relationship between the people and health centers in those areas. The inspection between Pharmaceutical division and health center would provide a balance of authority. Additionally, this model could solve the staff problems when inspects retail pharmacies.

The following quotes from the discussion that supported the above statement:

"…The structure of Pharmaceutical division and health center were separated. Therefore, the decentralization to these agencies would create a great balance…"

"Model 3…Decentralizing to the pharmacists in pharmaceutical division and health center would create a connection between both agencies in order to maintain the balance of these agencies."

"Pharmaceutical division had to be the main agency, but health center should join in with because it was the local agency. So, these agencies had to work together."

Therefore, when using those principles considering the data from experts, the appropriate decentralization model for the BMA should be the cooperation between Pharmaceutical division and health center.

Model 4: Health center inspecting with nearby health center

When considering officers of the provincial organizations like provincial health office, district health office, and community hospital, there were many points to be aware of. authority limitations. The decentralization should be given to the officers in their responsibility areas because

they were closer to the people living there, and they known the problems of health product in their areas.

The following quotes from the discussion that supported the above statement:

"…There would only be limitations of authority in the third model…if a connection between the centers occurred…authority problems might occur as well...each health center should only have authority within their responsibility area. So, pharmacists of each health center should be responsible for their own area.

Therefore, the model 4 was not appropriate based on the discussion because the decentralization in retail pharmacy inspection should have limit in each district. Then, pharmacist of health center could not inspect retail pharmacies in the other districts.

Model 5: Health center inspecting with district office

The BMA decentralized its tasks to district offices, because they were local offices. Additionally, the environmental and sanitation unit of district office was responsible for the tasks of public health, and it had not pharmacist in its structure. It had only the position of a sanitation technician officer and health officer. It might cause a problem during the inspection which had to use specific pharmaceutical knowledge. The cooperation was a very important problem during inspection, and the timetable of each district office differed from each health center. These problems lead to be inconvenience when doing this process.

The following quotes from the discussion that supported the above statement:

"…In the future, the inspection of pharmacies would include a more technical process which would focus on good pharmacy practice. So, officers must have a good understanding about pharmacy practice…"

"…District office had not pharmacist, this might cause problems in the future…"

"…In the case of connection, office hours, and other factors which differ between health center and district office, the inspection won't be able to gain the target…"

The roles of district office in retail pharmacy inspection might be to support health center such as by taking heath center officers to inspect in local areas, inspecting the complaints with health center, and providing information of the local pharmacies.

The following quotes from the discussion that supported the above statement:

"…The roles of the district offices were the supporter such as inspecting some special cases and drug complaints. District office couldn't inspect every pharmacy one by one because it was impossible to cover all of them…"

"…Environment and sanitation unit hadn't the duties about retail pharmacy inspection. However, the district offices could support the investigation by inspecting with pharmacist of health center."

Therefore, the model 5 was not appropriate based on the discussion because district office had not any pharmacist in its organization to inspect retail pharmacies. However, district office should relate to the task of retail pharmacy inspection such as special case inspection, and supporting budget because it was the agency to regulate all problems in its area.

In conclusion, the best model in retail pharmacy inspection for the BMA was health center inspecting with Pharmaceutical division, which was supported by the district office. This conclusion was based upon the following reasons:

1. The inspectors of retail pharmacies were pharmacists of Pharmaceutical division and health center who had knowledge and experience in this field.

2. The decentralizing to the health center would have a close relationship with the people.

3. The inspection covered the Bangkok's area.

4. This model created an authority balance during the inspection between health center and Pharmacy division.

5. District office would support the health center and Pharmaceutical division to inspect retail pharmacies effectively.

4.2.2.2 Agency to approve retail pharmacy license

If the Thai FDA decentralized the inspection of retail pharmacy to the BMA, it should transfer the task of pharmacy license as well. Because approving pharmacy license was the great importance for inspecting pharmacies. The inspection agencies would be able to know that what pharmacies were high risks to violate the drug law.

The following quotes from the discussion that supported the above statement:

"…Approving pharmacy licenses and inspection were related because the inspector had to know that what retail pharmacy was approved…"

"…The pharmacy license related with the post - marketing. The BMA would know that what retail pharmacies were high risks to violate the drug law. Post- marketing work had to follow…."

Therefore, the BMA should have the authority of pre-marketing and post-marking control within its area in order to provide regulation of retail pharmacies effectively.

Agencies which had the authority to approve license should be involved in the inspection process like the Pharmaceutical division because it was the main agency which involved in the pharmacy regulation. Besides, when considering the convenience of Bangkok's citizens in requesting a pharmacy license, the BMA should create a more efficient management system. It should have many agencies which involved in the processes of approving pharmacy licenses. For example; the 50

district offices of the BMA received the requests of pharmacy licenses, and send them to the Pharmaceutical division in order to approve or reject them later.

The following quotes from the discussion that supported the above statement:

"…The BMA should have one place to approve pharmacy licenses but it should have many places to receive those requests from citizens…"

"…The BMA should have more places to receive the requests, and sent them to the Pharmaceutical division in order to approve or reject pharmacy licenses."

Therefore, in the processes of pharmacy license approval, Pharmaceutical division was the main organization to approve pharmacy license. Besides, the BMA should have many agencies to receive the requests such as 50 district offices and Pharmaceutical division.

4.2.3.3 Legal process agency.

Health Department included the position of a lawyer in its structure, and this lawyer was responsible for legal issues in purchasing goods or employing. Pharmaceutical division hadn't any lawyer, so it should have a lawyer in order to have full authority in both regulating the pharmacies in its area that were pharmacy license approval, pharmacy inspection, and legal process in only one agency.

The following quotes from the discussion that supported the above statement:

"…If the Thai FDA decentralizes the regulation of retail pharmacy, it must decentralize the legal process as well. The Thai FDA should do not let the BMA to inspect retail pharmacy without the legal authority…"

"…When considering the whole system, the BMA will be able to deal with everything in the regulation of retail pharmacy including legal authority…"

"The agency which should be involved in this process was Pharmaceutical division because from its structure, it was responsible for inspecting and approving pharmacy license. If Pharmaceutical division was able to handle legal issues, the workflow would be more convenient within only one agency."

Consequently, health center should not be responsible for legal issues because it was only a local agency which hard to punish the local citizens who violate the drug law. If Health Department dealt with legal issues, the process might not be efficient because it hasn't any pharmacist who was able to evaluate, conclude and give an experts opinion.

The following quotes from the discussion that supported the above statement:

"…If health centers was responsible for legal process. It would bring a lot of problems because they were local agencies which couldn't afford to fine or prosecute."

"…Health centers shouldn't be involved in the legal process because the inspector wouldn't feel uncomfortable. The inspection would be proceeded under cooperation between health centers and Pharmaceutical division. Pharmaceutical division should be involved in the legal process directly…"

"…If Health Department was responsible for legal process, it might be uncomfortable. Because it was no pharmacist, this problem would make a lot of trouble…"

"…In the first stages, Pharmaceutical division would deal with legal issues because it covered the regulation of retail pharmacies and it had not a close relationship between the people and its organization…"

"…If Pharmaceutical division had a lawyer, the legal process would be easy for its organization to deal with these issues. Pharmaceutical division would be able to handle those problems because it had an advisor within its organization …"

Therefore, Pharmaceutical division should be legal process agency because it would have complete authority to regulate retail pharmacies in Bangkok area.

4.2.3.4 Agency to receive drug complaints.

The BMA should have many ways to receive drug complaints such as Hotline 1555, Hotline Department of Health, Pharmaceutical division, district offices, and health centers. However, if complaints were received, they would be sent to Pharmaceutical division because it was the main agency to regulate retail pharmacies.

The following quotes from the discussion that supported the above statement:

"…In the case of receiving drug complaints, it must be made easy for each citizen to complain. Drug complaints could be done by open different ways."

"…District office should be involved in the complaints receiving process because people were more likely to contact those places first…"

"…Drug complaints should have many ways such as health centers, and the focal point should be the Pharmaceutical division…"

Therefore, agency to receive drug complaints for the BMA should have many ways in order to be easy for people to complain that are Hotline 1555, Hotline of Health Department, Pharmaceutical division, district offices, health centers, and etc.

4.2.3.5 Type of retail pharmacy inspection

The BMA had to consider the risk management to inspect retail pharmacies, and there were three types of inspection as specified by the Thai FDA which were action plan inspection, special case and complaint inspection, and following inspection. If the types of inspection were separated, it would not be able to evaluate the whole process.

The following quotes from the discussion that supported the above statement:

"…There was a concept of risk management. If the types of pharmacy inspection would be separated in each part, The BMA would not be able to solve drug problems effectively."

"…The BMA might be able to inspect pharmacy on action plan inspection, drug complaint inspection, and following inspection. These types of inspection were specified by the flow chart of the Thai FDA."

Therefore, there were 3 types of inspection for the BMA in order to inspect retail pharmacy effectively that were action plan inspection, special case and complaint inspection, and following inspection.

4.2.3.6 Types of retail pharmacies to be regulated

Retail pharmacies were divided into four types that were pharmacy type 1, pharmacy type 2, traditional pharmacy, and veterinary pharmacy. When planning the inspection of each type of pharmacy, the BMA had to consider its policy and the risk factors of each types of retail pharmacy. The risk factors differed in each area, and in some areas, traditional pharmacy might have higher risk than pharmacy type 1.

The following quotes from the discussion that supported the above statement:

"…Before planning the inspection, there were 2 different types of information used which were the risk factor and the policy. The BMA should be concerned in each part equally. The types of pharmacy to be regulated should be composed of 2 parts which were local area information and annual policy in each year…"

"…If the BMA wanted to plan the inspection, it must know the condition of each area in the first. The BMA had to study the whole area, and classify each place by its risk factor. For example, traditional pharmacy might not be any risk, while pharmacy type 1 had many risks.

"The BMA would categorize the regulating each types of retail pharmacy hardly because in some places, pharmacy type 1 had a higher risk factor than pharmacy type 2. While in the other areas, pharmacy type 1 hadn't any problem…"

"…The inspection would also include grocery stores and supermarkets. If drug complaints occurred in grocery store, the BMA would inspect them."

In conclusion, because of the BMA's policy and risk factor of retail pharmacy, the BMA should inspect covering all types of retail pharmacy including grocery stores that sell medicine without a license.

4.2.3.7 Main issues during inspection of retail pharmacy

When inspecting retail pharmacy in the main issues, the BMA had to consider the BMA's policy, and the drug problems which occurred very often in each area. For example; traditional pharmacy and grocery store sold hazardous drugs or special controlled drug, and pharmacy type 1 dispensed hazardous drugs or special controlled drug without pharmacist.

The following quotes from the discussion that supported the above statement:

"…The BMA couldn't specify the inspecting issues of drug problem obviously because the policy changed every year. These issues were involved in the BMA's policy and local problems…"

"…For example, the BMA found the problem of no pharmacist or illegal medicine sold in the pharmacy type 1 but it didn't have to focus on those issues alone. It should consider the risk problems in each area…"

Therefore, the BMA should inspect retail pharmacies depended the BMA's policy and the drug problems in each area in order to solve drug problems effectively.

4.2.3.8 Development of retail pharmacy in knowledge improvement

The pharmacy development in knowledge improvement had to cover all types of pharmacy. It should provide the knowledge and media of retail pharmacy regulation, for example, medicine were withdrawn from the pharmacopoeia register. Besides, Pharmacy Community Association of Thailand trained pharmacy owners on the knowledge of drug dispensing to pharmacists every month. Therefore, the roles of the BMA would not be involved in the training but its roles might be involved in inviting the pharmacies to participate in the Program of community pharmacy accreditation.

The following quotes from the discussion that supported the above statement:

"…The Community Pharmacy Association of Thailand provided monthly training and updates knowledge on drug dispensing to pharmacists, and Program of community pharmacy accreditation was not involved in the education process but the BMA should introduce the importance of these projects…"

"…The other types of retail pharmacies which were traditional pharmacy, veterinary pharmacy, and pharmacy type 2 should not be neglected. The whole system should be developed."

Therefore, for development of retail pharmacy in knowledge improvement, there were 2 main roles of the BMA. The first was to support the update knowledge of drug issues for the retail pharmacy, and the second was to invite the retail pharmacy to participate in the Program of community pharmacy accreditation.

4.2.3.9 Roles and responsibilities

The conclusion on expert panel discussion showed that the BMA should have the roles and responsibilities on promoting and supporting the retail pharmacies, as in the following:

1) Producing media of health product protection and inform to consumer

2) Developing the knowledge about health product protection to consumer and inform consumer about their consumer right

3) Creating and expanding consumer protection network in community

The following quotes from the discussion that supported the above statement:

"…The producing media education following to laws by the Thai FDA had included four missions in its decentralization plan…"

"…The BMA was able to proceed in the roles and responsibility on promotion and support because it did not use any power to regulate retail pharmacy."

Therefore, besides the roles and responsibilities on the regulation of retail pharmacy, the roles and responsibilities of the BMA should include the three roles on promotion and support which were mentioned above.

4.2.3.10 Promotion and support by the Thai FDA

For decentralizing the regulation of retail pharmacy, the Thai FDA should promote and support the BMA in many issues such as providing the update information, giving academic consultation, training, providing the instruments, and etc.

The following quotes from the discussion that supported the above statement:

"…The Thai FDA should support the BMA in the issues of providing the update information and instruments, academic advisor, training, motivation, and budget."

"Motivation was very important for the regulating retail pharmacies successfully…"

"A very important factor was to have a good backup form the Thai FDA…"

In conclusion, the Thai FDA should promote and support the BMA, as in the following.

1) Academic advisor

2) Training

3) Providing the update information and instrument

4) Supporting the budget and explaining to the BMA's executive for allocating the higher budget of consumer protection

5) Supporting academic meetings or other motivation conference

6) Backing up the BMA's officers in retail pharmacy regulation

4.2.3.11 Problems, obstacles and recommendations

The main problems of the decentralization for the BMA in retail pharmacy regulation could be concluded into 2 topics. The first was unclear policy, and the second was misunderstanding.

The following quotes from the discussion that supported the above statement:

"…The decentralization policy of the Thai FDA and the BMA had to make clear and it should cover the whole system…"

"…The Communication within the agencies of the Thai FDA and the BMA was very important for the decentralization because some their officers might be not understand that why the Thai FDA must decentralize the task of retail pharmacy regulation to the BMA…"

Therefore, to solve these problems, the Thai FDA and the BMA should proceed, as following:

1) The decentralization policy of the Thai FDA and the BMA had to be well established.

2) The officers of Thai FDA and the BMA had to work together to understand process in the decentralization of retail pharmacy regulation correctly.

CHAPTER V
DISCUSSIONS AND CONCLUSIONS

The results from questionnaires and expert panel discussion were discussed in order to propose an appropriate decentralization model for the BMA in the regulation of the retail pharmacy. Besides, this chapter provided the conclusions and the recommendations.

5.1 Discussions

5.1.1 Agency to inspect retail pharmacy

The data form questionnaires showed that 56.5% of directors and 92.1% of pharmacists should have the role and responsibility on retail pharmacy inspection. It could conclude that pharmacists of health centers were interested in the task of retail pharmacy inspection more than the directors of health centers. It might explain that this task would transfer to pharmacists of health center directly, so they might think that it was their responsibility. Besides, most of pharmacists perceived already about decentralizing the tasks of retail pharmacy inspection because they had been involved in the course of retail pharmacy inspection between year 2003 and 2004 which were trained by the Thai FDA. On the other hand, the director had not ever known about this project.

In the pharmacy inspection issue, the directors, the pharmacists and the expert meeting had the same opinion that the Pharmaceutical division should cooperates with health center. However, the expert meeting suggested that the district office should support this process as the local officials by giving the local pharmacy information and involving in complaint investigation.

When considering about the human resource of the pharmacist of the BMA, we could see that nowadays the Pharmaceutical division had increased 4 pharmacist positions for working only in consumer protection. The health centers had only 1 pharmacist in each center with the total of 68 positions. Therefore, there was a possibility that the Pharmaceutical division will cooperate with health center, and there are many advantages, as following.

1) The pharmacy inspection had the same standard.

2) The transportation problems in pharmacy inspection process were solved. Pharmaceutical division would have the responsibility in this issue.

3) There was the balance of the administrative power between Pharmaceutical division and health center in pharmacy inspection

This inspection process had an issue to be discussed which was the flexibility of the process and cooperation. Because the inspection would be done by two agencies, Pharmaceutical division and health centers had to decide clearly about of their role, function and responsibility which included the period of the inspection.

For the pharmacy inspection process by the coordination between two health centers, this process could help solving the lack of human resource when inspecting the areas which need 2 staffs in each inspection process, and it used less budget and time than the above inspection. When considering about standard, administrative area, and transportation, this model was suitable for the areas which had near 2 or 3 health centers in districts of the BMA.

In the decision that the officers of Environment and sanitation unit in district offices should be involved in this process, when considering about the staff position in sanitation and environment unit of the district office, it had not any pharmacist. There were only the positions of sanitation technician officers and health officers about 7 – 8 persons who were responsible for many works such as food sanitation, unhealthful workplace sanitation, market sanitation, environmental sanitation, developing and protecting the environment according to the laws by the Ministry of Public Health, taking care of and stopping the annoying situations in the public or personal place and amplifier using allowance. It would be hard for the district offices to participate in pharmacy inspection because of the reasons above.

In brief, the pharmacy inspection agencies of the BMA were Pharmaceutical division and health centers. However, in the future, if the manpower structure of the BMA and the resources were changed such as an increasing of the BMA’s staffs, the pharmacy inspection process of the BMA would be adapted to suit for each area like retail pharmacy inspection in the provincial part.

5.1.2 Agency to approve retail pharmacy license

Most of the directors and pharmacists of health center suggested that if there was the decentralization in pharmacy inspection, the Thai FDA should decentralize the pharmacy license. It would make the pharmacy regulation in Bangkok to be more effective because this process started the regulating from the pharmacy license and inspection which were managed by one agency. If the Thai FDA didn't decentralize the pharmacy license authority, the problem about the database and the connection of the information between two agencies which were the licenser and the inspector would occur.

The pharmacy license agency of the BMA should be Pharmaceutical division of Health Department which had the role on pharmacy inspection. Therefore, the role on licensing and inspecting will be in the same organization. However, if the BMA transferred the pharmacy license authority to the district offices, the pharmacy owner who owned the pharmacy located near the district office would be more comfortable to get pharmacy license from the district office. The problem was the connection of the information between district office and Pharmaceutical division. The expert discussion suggested that the district offices should receive the requests of the pharmacy licenses agency and they would send the information to Pharmaceutical division for approving pharmacy licenses.

5.1.3 Legal process agency

The directors and pharmacists of the health center suggested that the agency of the BMA which should be the legal process agency was Pharmaceutical division. However, the experts in the discussion proposed that if Health Department had the role in legal process, it would have the problems on communication and coordination between Pharmaceutical division which was the inspection agency and Health Department which was the legal process agency. Therefore, they suggested that Pharmaceutical division should have the role in legal process. It would be the most effective way in regulating pharmacy because Pharmaceutical division was the only agency that had the complete role in approving pharmacy licenses, inspecting retail pharmacies and prosecuting illegal drug products.

5.1.4 Agency to receive drug complaints

The complaint receiving should have many choices for the people to complain comfortably such as Hotline 1555, Hotline of Health Department, Pharmaceutical division, health center, and district office. The most two comfortable ways to complain the problem were Hotline 1555 and district office because they were easy to remember. Due to this, when the complaints were received, they had to report them to Pharmaceutical division which was the complaint receiving center.

5.1.5 Roles and responsibilities

The BMA should have the roles in regulation and implementation of retail pharmacies, as following.

1) Approval, Inspection, and prosecution of the retail pharmacy

2) Producing media of health product protection and publicize to consumer

3) Developing the knowledge about health product protection to consumer and inform consumer about their consumer right

4) Creating and expanding consumer protection network in community

5) Academic developing of the pharmacy such as developing the pharmacy to be the network of bad response of using medicine or the quality pharmacy project

In the roles of pharmacy regulation processes, there were the retail pharmacy inspection, pharmacy license approval and legal process. All of them should cover all places included shop, stall and super market which sold medicine without license. The pharmacy inspection should be done under the policy of the Thai FDA and the BMA.

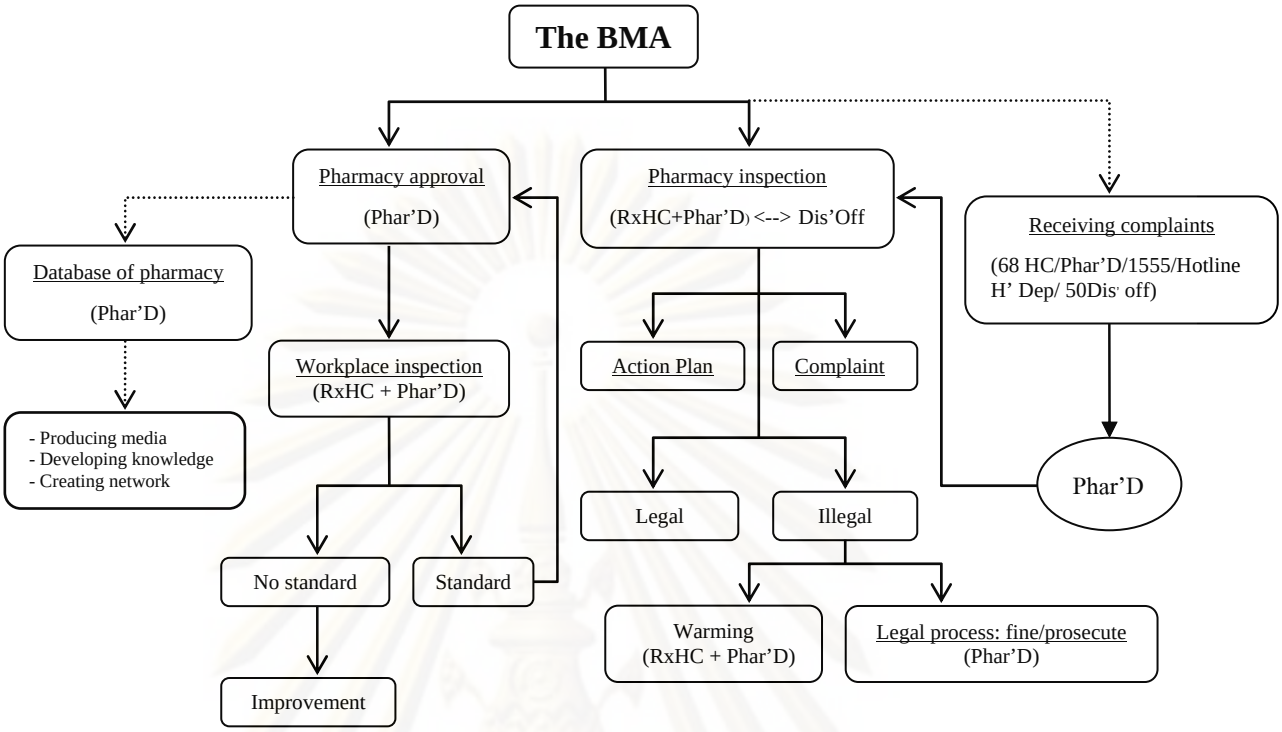
The BMA could make the pharmacy inspection plan covering the steps of the inspection including the annual inspection plan, special cases / complaints inspection and following up the results of the processes according to the drug safety policy of the Thai FDA, indicated in “Drug Compliance Policy, 2552 B.E.” This process had the important issues about pharmacy inspection, as showed in Table 5.1.

Table 5.1 The important contents to focus on pharmacy inspection

Example case situation	Drug Act 2510 B.E.	
	Content	**Punishment**
1. Shops/ traditional medicine pharmacies/ or private health care center selling medicine without license	Section 12	Section 101
2. Pharmacies selling hazardous drugs or special controlled drug	Section 19 (2) and 19 (3)	Section 102
3. No pharmacists in the duration of their business hour.	Section 39	Section 109
4. Making the list of hazardous and special controlled drug	Section 26 (6)	Section 109
5. Counterfeit drug, deteriorate drug, non standard drug, and non registered drug	Section 72	Section 121 and 122
6. Manufacturing and selling traditional medicine which mixed steroids.	Section 12	Section 101
7. Advertising without permission and illegal advertisement	Section 88 bis	Section124
8. Selling the medicine which was set by the pharmacy owner	Section 75 bis	Section 122 bis

5.2 Conclusions

The study of opinion given by the directors and pharmacists of the health center from the questionnaires, and the result of the expert panel discussion could be concluded in Figure 5.1.



* Phar'D = Pharmaceutical Division * Dis'off = District office

* H' Dep = Health Department * RxHC = Pharmacist of health center

Figure 5.1 Decentralization model for the BMA in regulation of retail pharmacy

The decentralization model for the BMA in regulation of the retail pharmacy via health centers' participation comprised of 5 dimensions that were 1) The tasks of retail pharmacy regulation for the BMA 2) Agency to regulate retail pharmacy 3) Legal process Agency 4) Agency to receive drug complaints 5) Roles and responsibilities.

This research found that the appropriate decentralization model should be completely including the tasks of retail pharmacy license and retail pharmacy inspection. The management of the regulation should be effective when it is established single organization. Agency to approve retail pharmacy license was Pharmaceutical division because it was the main agency to be responsible for retail pharmacy regulation. Before approving pharmacy licenses, both pharmacist in health center and pharmacists in should work together to inspect the pharmacy. Once the pharmacy complies with the drug law, the pharmacy license will be approved by the Pharmaceutical division. Additionally, Pharmaceutical division should set up the

database of retail pharmacy in Bangkok that were linked to the Thai FDA such as the name of pharmacists, address, telephone number and etc. In the near future, to solve the problems that a pharmacist doesn't show up during working time, database may be available in the internet in order to allow a consumer to check the appearance of a pharmacist.

Agencies to inspect retail pharmacy were health center with Pharmaceutical division, and district office was to support these agencies such as to join in drug complains inspection, to support information, etc. Additionally, the types of pharmacy inspection can divided into 2 parts, the first part was action plan inspection in accordance with the Thai FDA and the BMA' policy and risk problem in each area, the second was complaint inspection including follow up inspection. When the inspectors inspected illegal drug in pharmacies that were pharmacy type 1, pharmacy type 2, traditional pharmacy, veterinary pharmacy, and grocery store, they could solve these problems in 2 ways, which were warning and legal process such as fine and prosecution. Legal process agency was Pharmaceutical division because it was responsible for the tasks of approving pharmacy license and pharmacy inspection, so the legal process such as fine and prosecution should be the same agency to approve and inspect retail pharmacy. Besides, agencies to receive drug complaints comprised of many channels such as Hotline 1555, Hotline Department of Health, Pharmaceutical division, health centers, and district offices in order to complain easily, and Pharmaceutical division was the focal point to compile the drug complaints.

Roles and responsibilities of retail pharmacy regulation should cover the tasks of regulation, promotion and support that were:

1) License approval, inspection, and legal process

2) Creating and expanding the consumer protection network in community

3) Developing the knowledge about health products protection to consumer and inform consumer about their consumer right

4) Producing media of health product protection and publicize to consumer

5) Developing retail pharmacy in academic issues

5.3 Recommendations

5.3.1 Recommendations relating to research results

5.3.1.1 To inform and explain the tasks of retail pharmacy regulation to directors of health centers

The results of directors' opinions from questionnaires showed that directors agreed that the BMA should be responsible for retail pharmacy inspection at only 56.5%, while the opinions of pharmacists were 92.1%. According to the model of retail pharmacy inspection, pharmacists of health centers were to inspect with Pharmacist of pharmaceutical division. So, the Thai FDA and Pharmaceutical division should in form and explain to directors of health centers about decentralization of retail pharmacy regulation that pharmacists in their offices were responsible for retail pharmacy inspection.

5.3.1.2 To decentralize retail pharmacy regulation within 3 – 5 years

The results of directors' opinions from questionnaires showed the Thai FDA should decentralize the tasks of retail pharmacy regulation to the BMA in the next 3 years at 80.6% divided in within 5 years at 29.0%, within 10 years at 25.8%, and within 3 years at 24.2%. So, it could conclude that health centers weren't ready to proceed or this task wasn't interest. Therefore, the decentralization of retail pharmacy regulation within 1 – 3 years was to prepare the readiness of each organization, such as structure, budget, and manpower. After that, the BMA should proceed this task based on co-operation plan with the Thai FDA on the next 3 years.

5.3.2 Recommendations relating to the organizations being responsible for retail pharmacy regulation

5.3.2.1 The Thai FDA

1) Making the strategy and action plan of the decentralization in retail pharmacy regulation to the BMA

2) Meeting with the BMA's executive in order to implement the decentralization policy

3) Training the BMA's officers and appointing them to be the officers of the Drug act, B.E. 2510

4) Creating the communication channels between the Thai FDA and the BMA via e-mail, website, and web-board

5) Making the guideline for the BMA in retail pharmacy inspection

6) Communicating and making the understanding to manpower within organization and the BMA about decentralization in regulation of retail pharmacy

7) Publicizing the decentralization to pharmacy owner and consumer

5.3.2.2 Executive of the BMA

1) Implementing the policy to operate in related agencies such as Pharmaceutical division, health centers, and district offices

2) Allocating the budget in retail pharmacy regulation

3) Considering an appropriate manpower structure on pharmacist position in retail pharmacy regulation

4) Considering the career path progression such as specifying the position of pharmacist level 8 covering 68 health centers, or specifying the position of pharmacist level 9 in its organization

5.3.2.3 Pharmaceutical division of Health Department

1) Changing the structure organization, structure of manpower, and allocate budget for regulation of retail pharmacy

2) Making the operation plan to regulation of retail pharmacy, specifying the ways to proceed, and specifying the roles of related agencies of the BMA obviously

3) Meeting and explain the ways to regulate retail pharmacy to related agency such as health centers and district offices

4) Creating the channel of communication and reporting system between Pharmaceutical division and health centers such as E-mail and website

5.3.2.4 Health center of Health Department

1) Supporting pharmacists of health center to inspect retail pharmacy such as budget, and instrument

2) Making the database of retail pharmacy in each area

3) Coordinating with district offices and consumer network in regulation of retail pharmacy

5.3.2.5 District office

1) Specifying the roles and the ways to regulation of retail pharmacy obviously with pharmaceutical division, and health center

2) Supporting budget to solve drug problems

5.3.3 Suggestion for further study

Further study should test and evaluate this decentralization model, and should collect the data about problems and obstacles to be used in modifying the model. After that, the modified decentralization model should be developed and implemented to regulate retail pharmacy by the BMA completely.

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APPENDICES

Appendix A: Questionnaire for directors of health centers

Part 1: The opinions concerning retail pharmacy regulation for the BMA

1. Whether the BMA should be responsible for retail pharmacy inspection?

( ) Yes ( ) No

2. Whether the BMA should be responsible for approving pharmacy licenses?

( ) Yes ( ) No

3. If the BMA was responsible for approving pharmacy licenses in question (2), what was agency of the BMA to be responsible for?

( ) Pharmaceutical division

( ) District office

( ) Others …….

4. If the BMA was responsible for inspection of the retail pharmacy in question (1), do you agree that health centers should be only one agency of the BMA to inspect retail pharmacy in their areas ?

( ) Yes: Please answer question 7 ( ) No

5. If health centers weren't only one agency to inspect retail pharmacies, what was agency of the BMA should inspect with?

( ) Pharmaceutical division

( ) District office

( ) Others ……...

6. If district offices were responsible for retail pharmacy inspection, what was unit of district office should proceed?

( ) Environment and sanitation unit

( ) City law enforcement unit

( ) Others ……

7. What was agency of the BMA to be responsible for legal process?

( ) Health department ( ) District office

( ) Others ……

8. What were agency of the BMA should receive drug complains? (Respondent could answer more than one choice)

( ) Hotline 1555 ( ) Hotline of Health Department

( ) Pharmaceutical division ( ) Health center

( ) District office ( ) Others……

9. Beside pharmacy type 1 and pharmacy type 2, what were the types of retail pharmacy should be inspected by the BMA?

	Yes	No
9.1 Traditional pharmacy	( )	( )
9.2 Veterinary pharmacy	( )	( )
9.3 Grocery store	( )	( )

10. The types of retail pharmacy inspection for the BMA

	Yes	No
10.1 Action plan inspection	( )	( )
10.2 Drug complains inspection	( )	( )
10.3 Special case inspection	( )	( )

11. When the Thai FDA should decentralize retail pharmacy regulation to the BMA?

( ) Immediately ( ) Within 1 year ( ) Within 3 years

( ) Within 5 years ( ) Within 10 years

12. If the BMA was responsible for retail pharmacy regulation, the BMA should have the roles of retail pharmacy development in knowledge improvement.

	Yes	No
12.1 Program of community pharmacy accreditation	( )	( )
12.2 Project of adverse drug reaction network	( )	( )
12.3 Knowledge development	( )	( )
12.4 Others …….		

13. The roles of the BMA on promoting and supporting the drug products protection

	Yes	No
13.1 Producing media of health product protection and inform to consumer	( )	( )
13.2 Developing the knowledge about health product protection to consumer and inform consumer about their consumer right	( )	( )
13.3 Creating and expanding consumer protection network in community	( )	( )
13.4 Others …….		

<u>Part 2</u>: Demographic data

1. Sex ( ) Male ( ) Female
2. Age . ..... years
3. Position Doctor level .....
4. Level of education
   1) Bachelor's degree of …..medicine…… Institution ……
   2) Master's degree of …… Institution ……...……
   3) Doctor's degree of…… Institution …….……
5. Working period in health center ……. Years

Appendix B: Questionnaire for pharmacists of health centers

Part 1: The opinions concerning retail pharmacy regulation for the BMA

1. Whether the BMA should be responsible for retail pharmacy inspection?

( ) Yes ( ) No

2. Whether the BMA should be responsible for approving pharmacy licenses?

( ) Yes ( ) No

3. If the BMA was responsible for approving retail pharmacy licenses in question (2), what was agency of the BMA should be responsible for this task?

( ) Pharmaceutical division

( ) District office

( ) Others …….

4. If the BMA was responsible for inspection of the retail pharmacy in question (1), did you agree that health centers were only one agency of the BMA to inspect retail pharmacies in their areas?

( ) Yes: Please answer question 7 ( ) No

5. If health centers weren't only one agency to inspect retail pharmacies, what was agency of the BMA should inspect together with?

( ) Pharmaceutical division

( ) District office

( ) Others ……...

6. If district offices were responsible for retail pharmacy inspection, what was unit of district office should proceed?

( ) Environment and sanitation unit

( ) City law enforcement unit

( ) Others ……

7. What was agency of the BMA to be responsible for legal process?

( ) Health department ( ) District office

( ) Health center ( ) Others ……

8. What were agencies of the BMA should receive drug complaints?
(Respondent could answer more than one choice)

( ) Hotline 1555 ( ) Hotline of Health Department
( ) Pharmaceutical division ( ) Health center
( ) District office ( ) Others……..

9. The BMA should inspect retail pharmacies, beside pharmacy type 1 and pharmacy type 2, as following.

	Yes	No
9.1 Traditional pharmacy	( )	( )
9.2 Veterinary pharmacy	( )	( )
9.3 Grocery store	( )	( )

10. The types of retail pharmacy inspection for the BMA

	Yes	No
10.1 Action plan inspection	( )	( )
10.2 Drug complains inspection	( )	( )
10.3 Special case inspection	( )	( )

11. The BMA should inspect retail pharmacy issues based on the Drug act B.E. 2510.

	High	Medium	Low
11.1 Pharmacists weren't on the duty for the duration of business hour	( )	( )	( )
11.2 Physical drug inspection			
1) Expired drug	( )	( )	( )
2) Deteriorate drug	( )	( )	( )
3) Counterfeit drug	( )	( )	( )
11.3 To make drug list	( )	( )	( )
11.4 To inspect drug advertisement	( )	( )	( )

12. If the BMA was responsible for retail pharmacy regulation, the BMA should have the roles of retail pharmacy development in knowledge improvement.

	Yes	No
12.1 Program of community pharmacy accreditation	( )	( )
12.2 Project of adverse drug reaction network	( )	( )
12.3 Knowledge development	( )	( )
12.4 Others …….		

13. The roles of the BMA on promoting and supporting the drug products protection

	Yes	No
13.1 Producing media of health product protection and inform to consumer	( )	( )
13.2 Developing the knowledge about health product protection to consumer and inform consumer about their consumer right	( )	( )
13.3 Creating and expanding consumer protection network in community	( )	( )

14. The roles of the Thai FDA to support the BMA in retail pharmacy regulation (Respondent could answer more than one choice)

( ) Academic advisor
( ) Training center
( ) Couching
( ) Support media
( ) Support drug special project
( ) Inspect retail pharmacy when the BMA request
( ) Others ……

15. If the BMA was responsible for retail pharmacy regulation, did you have any suggestions to solve some problems when the Thai FDA decentralized this task to the BMA?

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……..……..

16. What were your requirements for knowledge development in retail pharmacy regulation?

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<u>Part 2</u> : Demographic data

1. Sex ( ) Male ( ) Female
2. Age ..... years
3. Position Pharmacist level.....
4. Level of education
    1) Bachelor's degree of pharmaceutical science Institution ……..……
    2) Master's degree of …… Institution ……...……
    3) Doctor's degree of…… Institution ……...…..……
5. Working period in health center ……. years
6. Did you have any experience in retail pharmacy inspection before working at health center?
    ( ) Yes from …… ( ) No
7. Had you ever been to train the courses of retail pharmacy inspection with the Thai FDA?
    ( ) Yes ( ) No
8. Did you have any part time pharmacist in your office?
    ( ) Yes ( ) No

Appendix C: Question guideline in expert panel discussion

1. Agency to inspect retail pharmacy
    - 1.1 Pharmaceutical division
    - 1.2 Health center
    - 1.3 Health center with Pharmaceutical division
    - 1.4 Health center with nearby health center
    - 1.5 Health center with district office
    - 1.6 Others
2. Agency to approve pharmacy licenses
    - 2.1 Pharmaceutical division
    - 2.2 District office
    - 2.3 Others
3. Legal process agency
    - 3.1 Pharmaceutical division
    - 3.2 Health Department
    - 3.3 Health center
    - 3.4 District office
4. Agency to receive drug complaints
    - 4.1 Hotline 1555
    - 4.2 Hotline of Health Department
    - 4.3 Pharmaceutical division
    - 4.4 Health Department
    - 4.5 Health center
    - 4.6 District office
5. Types of retail pharmacy inspection
6. Types of retail pharmacy to be regulated
7. Main issues during inspection of retail pharmacy
8. Retail pharmacy development sides of academics
9. Roles and responsibilities
10. Promotion and support done by the Thai FDA
11. Problems, obstacles, and recommendations

Appendix D: A number of retail pharmacies in 50 districts of Bangkok, year 2008

Districts of Bangkok	Health centers	Types of retail pharmacy				Total
		1	2	3	4	
1. Bangkapi	35 Huamark	220	7	4	14	245
2. Jatujak	24 Bang Khen 17 Prachaniwate	141	9	7	11	168
3. Klongtaoe	10 Sukumvit 41 Khlong Toei	135	17	1	14	167
4. Bangkhen	-	138	13	5	6	162
5. Bang Khun Thian	42 Tanom Tongsima	118	13	1	7	139
6. Prawet	57 Boonrueng Lumlert	115	9	3	4	131
7. Pathum Wan	5 Chulalongkorn 16 Lumpinee	107	5	-	12	124
8. Pom Prap Sattu Phai	20 Siamcitybang Public Company Limited	58	24	-	40	122
9. Din Daeng	4 Din Daeng 52 Samseannock	100	7	-	13	120
10. Thon Buri	26 Chaokhunpraprayurawong 27 Junt Chimpiboon 36 Bukkhalo	83	20	-	17	120
11. Phra Khanong	32 Maris Tintamusik 34 Porsri	95	13	3	5	116
12. Phasi Charoen	47 Klongkwang 62 Tuangrut Sasanavin-Pakdee Tharnpanya	83	21	3	8	115
13. Bang Rak	23 Siphraya	95	4	-	14	113
14. Huai Khwang	15 Lat Phrao 25 Huai Khwang	86	14	-	12	112
15. Vadhana	21 Wat Tad Thong	102	1	2	6	111
16. Lat Krabang	45 Romklao 46 Kantaratutis	95	5	1	3	104
17. Bangkok Noi	30 Watchaoarm	83	9	2	9	103
18. Wangthonglang	-	94	1	1	5	101
19. Samphantawong	13 Mitrewanit	41	22	-	38	101
20. Ratchathewi	2 Ratchapralop	88	4	2	5	99
21. Chom Thong	29 Chuang Nuchanetre	69	27	-	1	97
22. Bang Su	3 Bang Su 19 Wongsawang	79	9	1	8	97
23. Sathon	63 The Tio Chew Association of Thailand	73	11	3	9	96
24. Pranakorn	1 Saphanmorn 9 Prachatibpatri	71	6	-	18	95
25. Bung Kum	50 Bung Kum 56 Tubjarern	75	11	1	7	94
26. Bang Khae	40 Bang Khae	72	9	2	9	92
27. Min Buri	43 Min Buri	75	8	5	3	91
28. Khlong San	28 Krung Thon Buri	66	13	1	9	89
29. Lat Phrao	66 Shrine of Guanyim at Chokchai 4	80	2	2	5	89
30. Yan Nawa	7 Boonmee Pururatrangsan 55 Thachasumpan	71	8	-	7	86
31. Bang Phlad	31 Erb-Chit Tangsubutr	71	7	-	7	85
32. Don Muang	60 Rossukon Manoshayakorn	67	10	3	2	82
33. Nong Khaem	48 Nakvatcharaoutid	66	9	1	5	81
34. Phaya Thai	11 Pradipat 51 Wat Phaiton	67	4	2	6	79
35. Sai Mai	61 Sangwan Thassanaroum	72	2	2	3	79
36. Rat Burana	39 Rat Burana 58 Lom Pimsen Fukudom	52	15	-	7	74
37. Suan Luang	22 Watpakboi 37 Prasong-Soodsarkorn Tuchinda	66	2	3	3	74

Appendix D: (Cont.)

Districts of Bangkok	Health centers	Types of retail pharmacy				Total
		1	2	3	4	
38. Bang Kho Laem	12 Chantieng Natrvisas 14 Kaew Sriboonrueng 18 Monkol Von Wangtan	44	21	-	8	73
39. Lak Si	53 Tungsonghong	58	3	1	6	68
40. Bang Na	8 Bunrood Rungloung	57	2	2	5	66
41. Bang Bon	65 Raksasuk bang bon	50	8	2	3	63
42. Kannayao	-	51	2	3	4	60
43. Dusit	6 Samosornvanthatnatomyhing 38 Jeed Tongkum Bumpen	43	9	-	5	57
44. Taling Chan	49 Wat Chaiyaprukmala	44	4	2	7	57
45. Nong Chok	44 Lampakchi	41	8	-	3	52
46. Khong Sam Wa	64 Khong Sam Wa	50	-	-	1	51
47. Bangkok Yai	33 Wat Hongrattaram	29	8	-	6	43
48. Taweewattana	67 Taweewattana	22	3	6	2	33
49. Thung-Khru	54 Tudaeim 59 Thung Khru	23	4	2	2	31
50. Saphan Sung	68 Saphan Sung	28	1	-	1	30
Total		3,809	444	79	405	4,737

BIOGRAPHY

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