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ANALYSIS OF COST FUNCTION OF THAILAND FOOD AND DRUG ADMINISTRATION

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วิทยานิพนธ์ฉบับนี้ มีวัตถุประสงค์เพื่อสร้างและวิเคราะห์สมการต้นทุนของสำนักงานคณะกรรมการอาหารและยาประเทศไทย เพื่อใช้เป็นเครื่องมือในการหาแนวทางการจัดสรรทรัพยากรอย่างมีประสิทธิภาพเพื่อการวางแผนงบประมาณขององค์กร

ในการศึกษาครั้งนี้ได้แยกประเภทของสมการต้นทุนเป็น 3 กลุ่มตามบทบาทหน้าที่ของสำนักงานฯ ประกอบด้วย ระบบงานควบคุมผลิตภัณฑ์ก่อนออกสู่ท้องตลาด, ระบบงานควบคุมผลิตภัณฑ์หลังออกสู่ท้องตลาด, และระบบงานอื่นๆ ส่วนตัวแปรอิสระที่ใช้ในการวิเคราะห์สมการต้นทุน ประกอบด้วย ราคาของปัจจัยการผลิต และปริมาณผลงาน นอกจากนี้เหตุการณ์การปฏิรูปองค์กรได้ถูกกำหนดให้เป็นตัวแปรเชิงหุ่นในการวิเคราะห์ โดยใช้ข้อมูลอนุกรมเวลาในระหว่างปีงบประมาณ 2523-2548 ในการศึกษานี้ได้ใช้เครื่องมือทางเศรษฐมิติในการประมาณค่าแบบจำลองสมการต้นทุนแบบทรานสลอก (Translog model) ในรูปแบบสมการส่วนแบ่งต้นทุน (cost share equation) และประมาณค่าโดยวิธี Seemingly Unrelated Regression Estimation (SURE) ซึ่งเป็นวิธีการที่เหมาะสมสำหรับการวิเคราะห์ระบบสมการ

ในการศึกษาครั้งนี้ได้แสดงถึงวิธีการในการวิเคราะห์สมการต้นทุน ซึ่งผลการศึกษาพบว่าสมการต้นทุนของ ระบบงานควบคุมผลิตภัณฑ์ก่อนออกสู่ท้องตลาด, ระบบงานควบคุมผลิตภัณฑ์หลังออกสู่ท้องตลาด, และระบบงานสนับสนุนอื่นๆ ให้ค่าทางสถิติ R^2 (the goodness of fitted) เป็น 77%, 88% และ 78% ตามลำดับ นอกจากนี้ยังพบว่า การขึ้นทะเบียนผลิตภัณฑ์ ของระบบงานควบคุมผลิตภัณฑ์ก่อนออกสู่ท้องตลาด จะมีผลต่อส่วนแบ่งต้นทุนของปัจจัยแรงงานเพิ่มขึ้น ในขณะที่การตรวจสอบสถานที่ผลิต และการตรวจสอบผลิตภัณฑ์ ของระบบงานควบคุมผลิตภัณฑ์หลังออกสู่ท้องตลาด จะมีผลต่อส่วนแบ่งต้นทุนของปัจจัยทุนเพิ่มขึ้น จากผลการวิจัยดังกล่าวสามารถนำไปสู่ประเด็นสำคัญอย่างหนึ่งในด้านการจัดสรรทรัพยากรปัจจัยการผลิตให้มีประสิทธิภาพมากขึ้นได้คือ สำนักงานฯอาจจะจัดสรรทรัพยากร โดยสนับสนุนปัจจัยทุนในระบบงานควบคุมผลิตภัณฑ์หลังออกสู่ท้องตลาดให้มากขึ้น ในขณะเดียวกันควรย้ายปัจจัยแรงงานจากระบบงานดังกล่าวมายังงานขึ้นทะเบียนผลิตภัณฑ์ ในระบบงานควบคุมผลิตภัณฑ์ก่อนออกสู่ท้องตลาดด้วยสัดส่วนที่เหมาะสม จะช่วยให้ให้เกิดการใช้ทรัพยากรที่มีอยู่อย่างจำกัดให้เกิดประโยชน์อย่างสูงสุดและยังเป็นการเพิ่มผลผลิตของสำนักงานฯโดยรวมด้วย

สาขาวิชา เศรษฐศาสตร์สาธารณสุข ลายมือชื่อนิสิต.....

ปีการศึกษา 2548 ลายมือชื่ออาจารย์ที่ปรึกษา.....

4886047629: MAJOR HEALTH ECONOMIC
KEY WORD : FOOD AND DRUG ADMINISTRATION/ COST FUNCTION
ADUN MOHARA: ANALYSIS OF COST FUNCTION OF THAILAND FOOD AND DRUG ADMINISTRATION. THESIS ADVISOR: ASSOC. PROF. PAITOON KRAIPORNSAK, Ph.D., 106 pp. ISBN: 974-14-2912-6.

The objective of this study is to construct and estimate the cost function of Thailand Food and Drug Administration, as a tool for providing the direction with respect to the efficient allocation of resources in budget planning.

This study classified cost function into three functional groups, including pre-marketing system, post-marketing system and the other system. The explanatory variables required to estimate the cost functions, included the input prices, output volumes and dummy variables which represented as reforms. Time series data was collected during 1980-2005 of the fiscal year. This study used the econometrics tool to estimate the translog cost function model in term of cost share equation. In addition, Seemingly Unrelated Regression Estimation (SURE) method was used to estimate the system equation

This study demonstrates the way for analysis of cost function. The empirical results found that the cost function of pre-marketing system, post- marketing system and the other system demonstrated the goodness of fit as 77% 88% and 78%, respectively which were represented by the statistical R^2 values. In addition, this study found that the product registration approval in pre-marketing system affected to increase the cost share of labor factor, moreover, the manufacturing and product inspection in post-marketing system affected to rise in cost share of capital factors. These results bring to an important issue of more efficient resource allocation. Thai FDA should allocate resources by supporting more capital inputs to the post-marketing system. At the same time, Thai FDA ought to shift the labor inputs from such systems to the product registration in pre-marketing system by using appropriate proportion. This can maximize the utilization of limited resources, and increase the whole outputs of Thai FDA.

Field of study Health economics Student's signature: Adun Mohara
Academic Year 2005 Advisor's signature:

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ABBREVIATIONS

FDA = Food and Drug Administration

GMP = Good Manufacturing Practice

IPCS = International Program on Chemical Safety

OA = Office Automation

PBBS = Performance Base Budgeting System

SURE= Seemingly Unrelated Regression Estimation

CHAPTER I

INTRODUCTION

Thailand Food and Drug Administration is the principle organization in Thailand for public health protection by ensuring the efficacy, quality and safety of health products and by promoting proper consumer behavior through reliable scientific evidence and appropriate technology. The functions and responsibilities of each division of the FDA are defined on the basis of a specialist area or control of a specific category of product. Some activities may need cooperation between divisions or departments in order to achieve FDA objectives

The infrastructure of the Thai Food and Drug Administration as officially consists of two main groups.

First, the Health Product Control Division (main division) Group consists of the Bureau of Cosmetic and Hazardous Substances Control, and five other divisions: Drug Control, Food Control, Medical Devices Control, Narcotics Control, Import and Export Inspection, and Public and Consumer Affairs

Second, the Support Division Group consists of three divisions: Rural and Local Consumer Health Products Protection Promotion, Technical and Planning, and the Office of the Secretary. In addition, six internal units have been established to perform particular tasks: Information Technology Center, Health product and Drug Legal Group, Public Sector Development Group, Internal Audit Group, Complementary Health Product Group, and Community Health Product Quality Improvement Coordinating Center.

The main role of the Thai FDA is to protect consumer's health, especially, to ensure safety, quality and efficacy of health products within its remit. These health products include: drugs, psychotropic substances, narcotics, medical devices, volatile substances, cosmetics and hazardous substances available in the country. This has to be implemented in accordance with national legislation and international agreements.

The roles and responsibilities of Health Product Control System; the main function of consumer protection in Thai FDA may be grouped into four main areas:

1. Pre-marketing control

The aim of this activity is control of manufacturing facilities and product quality before product-launch to the market. In each case, compliance is required with the relevant legislation and regulations.

2. Post-marketing control

The aim of this activity is to investigate manufacturing facilities and product quality and to ensure that they maintain compliance with previously-approved national health product standards and with legislation and regulations. For example, samples of products are regularly inspected and taken to check for compliance and quality. Previously-approved products are revisited periodically to ascertain the consistency of manufacturing and product standards over time.

3. Public Education

Consumers are supplied with sufficient, accurate information to enable them to choose products wisely. Access to such information, provided by the FDA, is available from many sources: television, radio, newspaper, leaflets, internet, and so on. FDA’s campaigns on priority topics have been regularly conducted in department stores, schools and villages in many parts of the country. There are many sources for consumers to use so that they can obtain further useful information and be in a better position to protect themselves.

4. Supporting function

4.1 Surveillance program for consumers' safety

The aim of this Program is to detect any adverse effects or unexpected outcomes from consumer use of products. Research and epidemiological data on adverse effects, including technical information, is collected, summarized, interpreted and reported. There are also operational centers, such as the Adverse Product Reaction Monitoring Center (APRMC) and the International Program on Chemical Safety (IPCS). Information is exchanged with other agencies at local and international level.

4.2 Technical Supporting and Cooperation with other agencies

The FDA has conducted many interesting seminars and workshops, with participants from both public and private sectors. On the other hand, officials from the Thai FDA are sent to join seminars and conferences, both local and abroad. As a result, with a widened perspective, they can work more effectively at their homeland. In relation to cooperation in terms of research and development, the FDA is continually supportive of

such endeavors, and some research projects are partly or wholly funded by the agency.

Problem and Its Significance

1) Thai FDA has continuously augmented its size and expanded its types of services offered. With this the size enlargement, the FDA's total budget has increased significantly during the past twenty five years.

- The growth rate of FDA budget increased on the average of 18.11% per annum. This means that the growth of FDA budget grew almost three times faster than GDP, which averaged 4.7% growth per annum during the same 25-year period. These dramatic increases in the FDA's budget can be attributed to several important events during this period. For example, FDA underwent organizational reform, mainly through the establishment of an intranetwork system (IT reformation) and also through the initiation of consumer complaint hot-line services. The reform caused a significant increase in budget expenditure of the office in 1997. In addition, Thailand's economic crisis affected to government budget of Thai FDA during 1999-2003; that is reason of immediately decreasing of total cost of Thai FDA. These events have affected total annual budget of Thai FDA, as shown in Figure 1.

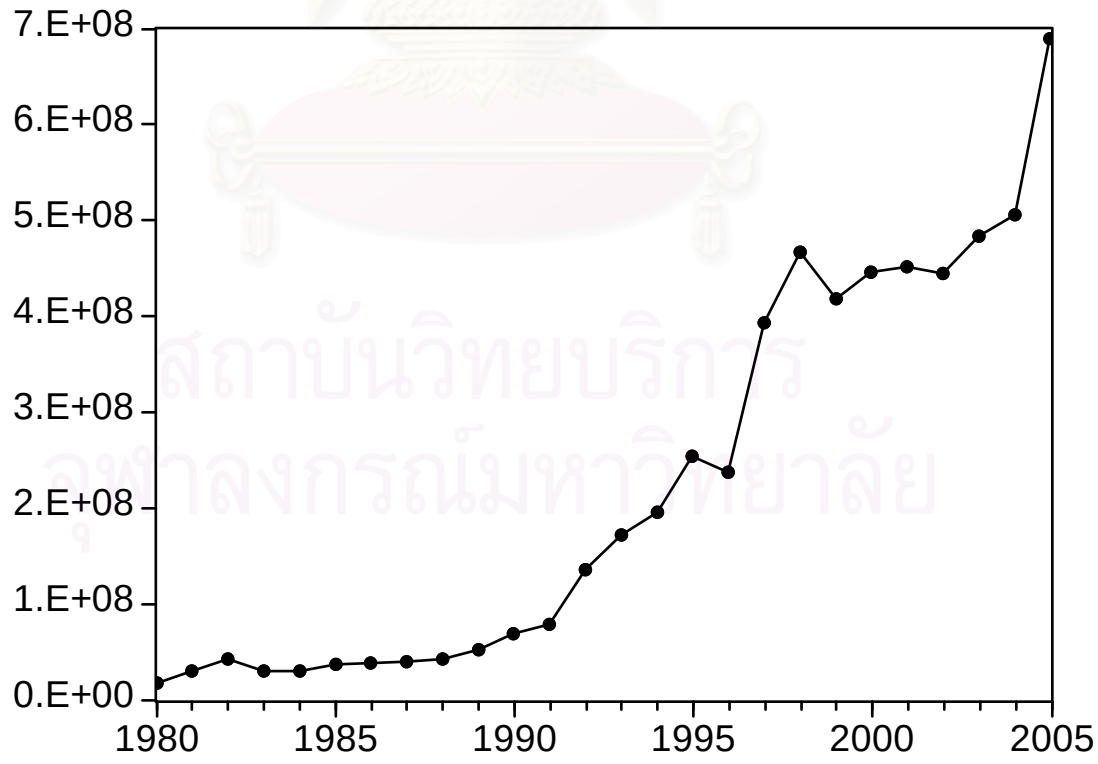


Figure 1: Annual Budget of Thai FDA (1980-2005)

- The growth rate of total cost in three systems of Thai FDA increased by different proportions. The growth rate of total cost in pre-marketing system, post-marketing system and the other system increased on the average of 14.64%, 27.24% and 25.87% per annum, respectively. In the past twenty years, FDA had many organized reform, including policy reform by decentralizing power to provincial health offices in 1992; the information technology reform by the set-up of an intra-network system Office Automation (OA) system in 1997; and the government budgeting policy reformation by promoting Performance Based Budgeting System (PBBS) as well as restructuring organization reform into nine divisions, one bureau and six small entities in 2003. These reforms may have affected each system in a different way, as shown in Figure 2.

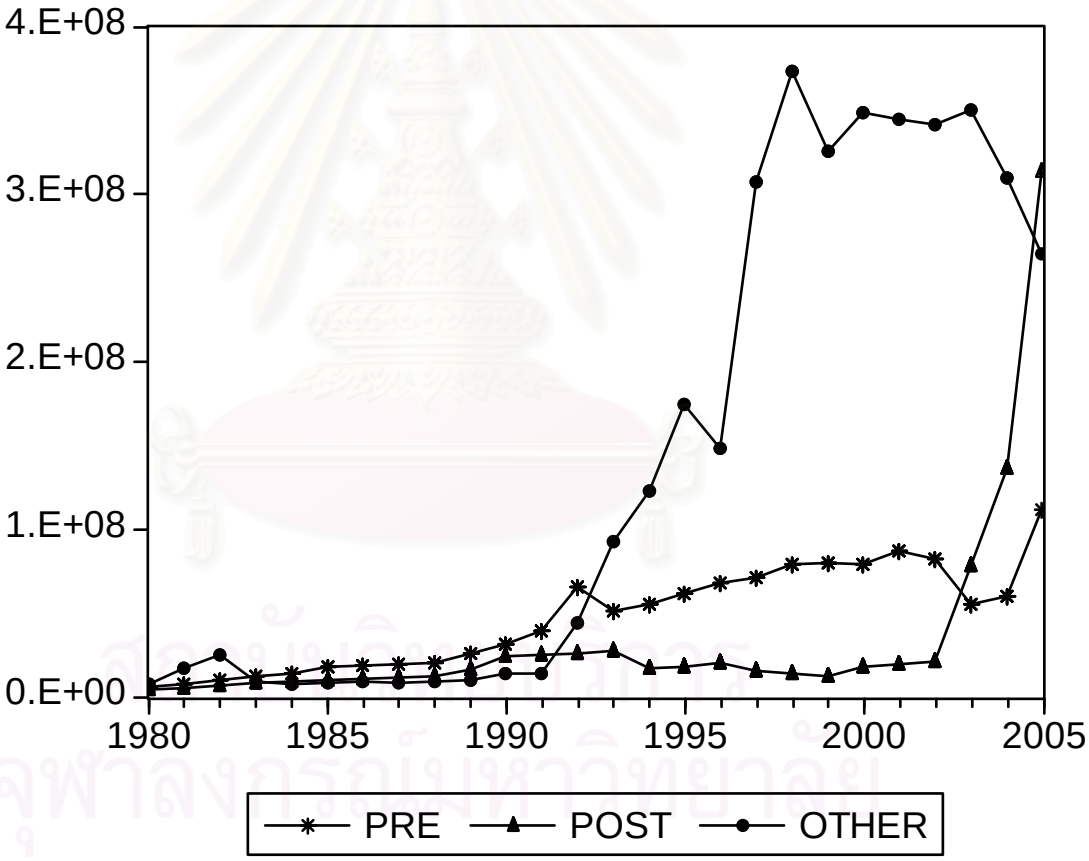


Figure 2: Annual budget of system in Thai FDA (1980-2005);
Classified system into three groups, including pre-marketing system, post-marketing system, and other system

2) According to the public sectors, such as Thai FDA, is augmented its size, expanded its types of services; therefore, this lead to increasing of government budget spending. From the government perspective, something must be done to sure that increases in the government budget, allocated to public sector, are actually used to serve the public. As a result, Thai government imposed budgeting reform in 2003 by introducing the Performance Base Budgeting System (PBBS) in order to implement the output budgeting system instead of the traditional input budgeting allocation system. The PBBS approach includes 3 steps.

Step 1. Government compels all public sectors to review its rules and responsibilities, and promote own outputs to be the concrete object of public service agreements which are the benefits, serving the public.

For Thai FDA presented its output obviously in the strategic plan of FDA organization, including 3 outputs of public service agreement.

1. **Pre-Marketing Function**: manufacturing and product approval is the process of assessing the quality, efficacy and safety of any health product being registered.
2. **Post-Marketing Function** : manufacturing and product inspection is the activities to ensure that health products distributed to consumers are complied with acceptable standard.
3. **Public Education and Consumer Behavior Development Function**: This is the activities of dissemination of knowledge about health product and promotion of pro-active public relations project of engaged activities to public.

Step 2. Government encourages all of public sectors to improve financial plan to be more transparent and accountable.

Step 3. Government encourages all of public sectors to reduce cost and improve efficiency and productivity.

In fact, Thailand FDA formulates financial plan by using the background data in previous periods and policy maker “gut-filling.” The traditional actions may be lack of accountability and lead to an inappropriate budget plan. The interesting question is how to make future proposed budgets to be more transparent and accountable and how to reduce cost and improve efficiency and productivity.

The cost function analysis is one of the solutions for making the reliable future budget plan. It can help policy makers to specify the natural relationship of *cost* and *output* characteristics of organization, to estimate

the appropriate budget for the financial plan, and to elucidate the observed factors that affect to the FDA's cost. That is necessary information for policy makers whether the existing resources of Thai FDA at the present are appropriate. Study of the cost function is important for policy-relevant predictions of budget planning and improvement efficiency, productivity and output performance strategy of Thailand FDA.

Research Objective

To construct and estimate the cost function of the Thai FDA in order to allocate resources efficiently for the future financial plan in multisystem structure of Thai FDA

Research Question

What are the cost function models of Thai FDA in the 3 parts below?

Total cost function of systems in Thai FDA, which includes

- The Pre-marketing function (TC_{Pre})
- The Post-marketing function (TC_{Post})
- The Other function (TC_{O}), including the public education system and supporting system.

Scope of study

The study only focused on cost incurred upon the Thai FDA, in consumer protection operations in Thailand. Time series data of cost and output components were gathered annually over the time period 1980-2005.

Limitation in this study

First of all, this study used the most measurable data in only 26 observations of annual data available on Thai FDA, accounted a few observations for analysis cost functions. Second, this study classified FDA cost function in three parts: pre-marketing system function, post-marketing system function, and the other system function, combined public education system and supporting system together in order to solve the problem of missing cost data, separated between both of them during 1986-1991. Finally, the outputs employed in this study are not homogeneous, combining from several kinds of service activities, for example product

controlling, label controlling and advertisement controlling. They use the different amount of resources spending. Unfortunately, the data available for this study cannot avoid these limitations. It is important to recognize that on may affect to the reliance of the cost functions.

Estimation method

Cost function analysis is used as the total expenditure function in form of using translog cost function model and separating it into the cost share equation as the systematic equation estimation. The estimation method employed is the Seemingly Unrelated Regression Estimation (SURE).

Possible benefits

This study is expected to estimate the cost function, which can be used to explain the behavior of FDA's costs and thus provide benefits for financial planning. First, it could improve financial system to be transparent and accountable for estimating and forecasting appropriate future budgets of Thai FDA to request from the government. Second, this study would investigate the cost behaviors in term of factors, also called elasticity analysis, and their affect on the behavior of Thai FDA's cost function. It could provide some signals for policy maker to improve efficiency and productivity. Third, it could allow managers to anticipate whether current funds are sufficient, or if they need to find an additional source of funding to maintain financial sustainability.

The research benefits listed above can provide a practical budgeting guideline policy for managers who seek strategies to cope with internal and external problems, as well as provide both of offensive and defensive strategies in order to improve organization's performance and sustainability.

CHAPTER II

LITERATURE REVIEW

In case of cost of health protection organization, review of the literature found one relevant work was done by Kaewpanukrungsi W. (1999) in topic of Cost Determinants of the Thai Food and Drug Administration. The data description, total cost of FDA showed a large rising trend at the growth rate 19% on the average during the past 20 years. Labor expense was also a large proportion in the components. Two types of outputs, pre and post-marketing activities increased sharply during the period 1983-1992 and then fluctuated. The costs of post-marketing activities also increased but declined continuously after 1992. The fluctuation and inconsistency of output volumes have been observed, particularly since 1992, due to the administrative structural changes. Wage rates have been also continuously increasing at the average rat 9.6% each year.

The study attempted to investigate cost determinants of the Thai FDA. The multi-product cost functions were constructed, employing the data during 1980-1999 drawn from previous records of actual expenses and various output categories of the Thai FDA. The linear cost functions in which total costs are function of outputs and wage rate were estimated by using ordinary least squares regression analysis. Few points from the conclusion found rather puzzle. The estimated results revealed that the total cost levels of the Thai FDA could not be explained by the quantitative volume of its outputs. The only factor that significantly and negative by related to the cost level is the amount of product registration. It might be concluded that increase in the volume of product registration would lower the level of costs. Cost elasticities with respect to wage rate ranged from 1.5 to 1.9, implies a labor intensive characteristic of the Thai FDA. The results also indicated that a rise in administrative structural changes after the year 1992 might lower the cost level of post-marketing activities. The R^2 values of the total cost function, pre-marketing cost function and post-marketing cost function systems are 0.978, 0.808 and 0.649 respectively. Generally they were high; by infer that the explanatory variables employed in are good determinants of the FDA costs.

Just as the results of this study may no longer be relevant for future, ongoing change may limit the generalizability of the findings presented in this paper. It is interesting to alleviate the shortcoming of this study and to examine in other factors, especially introduction of some new policies that could affect the level of costs, for example in 2003 the

government imposed Thai budgeting reformation by introducing the Performance Base Budgeting System (PBBS) to implement the output budgeting system. The FDA had to adjust its own output obviously in the strategic planning of organization in three functions of outputs as mention in chapter I. In addition, Thai FDA had many organized reform and other event that was a significant change in the cost structure of the FDA in Thailand, i.e. the IT reform in 1997 and Thailand economic crisis during 1999-2003. In this study, however, using ordinary least squares estimation in the equation system can lead to inefficient estimates. The consideration of the cost function estimation is therefore interesting.

Some work related to analysis of cost function in the other views; for example, a multiproduct cost study of savings and loans**;** by Loretta J. Mester (1987); this paper investigates the cost structure of savings and loans. Most studies of financial institutions have failed to take into account the multiproduct nature of these institutions. Using the multiproduct approach, the existence of subadditivity, multiproduct global and product-specific economies of scale and scope, and substitutability between inputs is investigated. A translogarithmic cost function is estimated using 1982 data on California savings and loans. Restrictive functional forms also estimated are rejected. Standard errors for the statistics calculated are estimated, and various statistical tests are conducted. Previous authors have not calculated standard errors for these statistics. No evidence of subadditivity in the industry is found.

Some study estimating time series models using the relevant forecast cost function; by Weiss, Andrew A; (1996). This stud found that in many forecasting problems, the forecast cost function is used only in evaluating the forecasts; a second cost function is used in estimating the parameters in the model. In this paper examine the ways where the forecast cost function can be used in estimating the parameters and, more generally, in producing the forecasts. This study defines the optimal forecast and note that it may depend on the entire conditional distribution of the data, which is typically unknown. then consider three of the steps involved in forming the forecast: approximating the optimal forecast, selecting the model, and estimating any unknown parameters. The forecast cost function forms the basis of the approximation, selection, and estimation. The methods are illustrated using time series models applied to 15 US macroeconomic series and in a small Monte Carlo experiment.

The composite cost function for multiproduct firms with an application to economies of scope in banking; by Pulley, Lawrence B and Braunstein, Yale M (1992). This study found that the composite cost function the authors propose combines a quadratic output structure with a log-quadratic input price structure and is well suited for examining

economies of scope, subadditivity, and other important properties of multiproduct firms. To compare the composite model with an appropriate set of alternative functional forms, they develop a parsimonious--but general specification that nests the standard translog cost function, the generalized translog cost function, a separable quadratic cost function, and the composite cost function. An application to economies of scope in banking confirms the advantages of the composite model.

A translog cost function analysis of U.S. agriculture, 1939-77**;** by Subhash C. Ray (1982). The translog cost function provides a convenient framework for analyzing U.S. agricultural production in a multioutput context. Treating crops and livestock as two distinct outputs, this study utilizes standard results of neoclassical duality theory to obtain measures of pairwise elasticities of substitution between inputs, price elasticities of factor demands, and the rate of Hicks-neutral technical change. Results obtained from joint GLS estimation of parameters of cost and share equations indicate a declining trend in the degree of substitutability between capital and labor. Price elasticity of demand for all inputs increased over time. The measured rate of technical change was 1.8% per year.

Import Demand for the United States: a translog cost function analysis; by Halit Yanikkaya (2004). This paper examines the role of imports as an alternative input to domestically supplied capital and labor in the U. S. economy for the period 1970-1993. the study use the aggregate translog cost function, which permits us to obtain econometric measures of the pair-wise elasticities of substitution between inputs for each year, the annual own- and cross-price elasticities of demand for inputs. The results imply conventionally downward sloping demand curves for inputs but they are inelastic. The demand for labor is most inelastic, followed by imports and capital, respectively. Regression results also show that inputs are gross substitutes; the partial elasticity of substitution between capital and imports is higher than the partial elasticity of substitution between labor and imports.

A comparison of hospital scale effects in short-run and long-run translog cost functions; by Vassilis H (1999). Aletras. Numerous estimates of economies of scale in the hospital setting have been obtained since the early 1980s from both flexible long-run and short-run cost functions. Although the theoretical superiority of the latter approach is widely recognized, it has been previously suggested that the two cost specifications yield quite similar econometric findings regarding scale effects. This paper utilizes a new data set consisting of 91 Greek NHS hospitals in order to empirically examine this proposition by comparing economies of scale estimates derived from both translog total and variable

cost functions. The results indicate that the use of long-run equations might seriously mislead policy makers and that constant returns to scale prevail in Greek public hospitals.

Some study mentioned about the interesting method of a simple characterization of Seemingly Unrelated Regressions Models**;** by Robert Bartels, Denzil G. Fiebig; (1991). Recent contributions to the discussion about the conditions under which ordinary least squares in the seemingly unrelated regressions (SUR) model is the best linear unbiased estimator suggest a characterization of SUR models that is convenient for checking whether these conditions are satisfied. Standard pedagogic examples for SUR's, as well as more complex cases, are easily derived from our characterization.

CHAPTER III

THEORETICAL FRAMEWORK

The Cost Function

A Key element governing the operations of a firm is its cost function. A cost function describes the minimum cost of producing a certain level of output Q, given the prevailing prices the firm must pay for its factor inputs. In the simple case of two factors of production x_1 and x_2 having prices p_1 and p_2, the cost function is denoted

$$C = c(P_1,P_2, Q) \qquad (3.1)$$

In contrast to a production, which is a purely technical relation, the cost function embodies a certain behavioral hypothesis that firms act so as to minimize costs. As an accounting matter, the cost of employing x_1 and x_2 is

$$C = P_1x_1 + P_2x_2 \qquad (3.2)$$

The behavioral hypothesis embodied in (3.1) says that the firm chooses x_1 and x_2 so as to minimize this total cost. These **conditional factor demand functions**

$$x_1(P_1,P_2,Q) \qquad (3.3a)$$

$$x_2(P_1,P_2,Q) \qquad (3.3b)$$

The demand functions are called conditional factor demands because they describe the cost-minimizing choice of factor inputs conditional on a given level of output. From them may be derived demand elasticities such as the own-price elasticity of demand for factor i, defined by

$$\varepsilon_{ij} = \frac{P_i \partial x_i}{x_i \partial P_i}$$

The belief that factor demands are downward sloping is the hypothesis that this elasticity is negative.

The total expenditure Function

The total expenditure of production is defined by

$$TC = \sum_{i=1}^{n} P_i x_i (Q,P) = C(Q,P)$$

Where Tc = total cost

P_i = unit price of i^{th} factor input

x_i = quantity of i^{th} factor input

Q = quantity of output

If there are constant returns to scale, then it can be shown that

$$C = QC(P)$$

Or

$$\frac{C}{Q} = C(P)$$

Where C(P) is the unit or average cost function. The cost-minimizing factor demand are obtained by applying Shephard's (1970)-lemma, which states that if C(Y,p) gives the minimum total cost of production, then the cost-minimizing set of factor demands is given by

$$x_i = \frac{\partial C(Q,P)}{\partial P_i}$$

$$= \frac{Q \partial C(P)}{\partial P_i}$$

Alternatively, by differentiating logarithmically, we obtain the cost-minimizing factor cost shares

$$s_i = \frac{\partial \log C(Q,P)}{\partial \log P_i} = \frac{P_i x_i}{C}$$

Then another accounting quantity related to the identity (3.2) that tends to show up in many aspects of cost analysis is the ***share of factor i in total costs***, denoted by.

$$S_i = \frac{P_i x_i}{C}$$

Given the definition of total costs (3.2), it follows, again purely as an accounting matter that the shares of all factors must sum to 1:

$$\sum_i S_i = \sum_i \frac{P_i x_i}{C} = \frac{1}{C} \sum_i P_i x_i = \frac{1}{C} C = 1$$

The Translog Cost Function

A quite different approach to formulating an estimable cost model; the model specification employed in this study is a translog cost function, which is a second-order Taylor series approximation to the arbitrary cost function that is twice-continuously differentiable. Because mathematics offers many ways of approximating function, however, one has emerged as the empirical model of choice among applied econometricians. It is the transcendental logarithmic, or translog, cost function introduced by Christensen, Jorgenson, and Lau (1973). This parameterizes the translog cost function in the form as below.

$$\log C = \alpha + \beta \log Q + \tfrac{1}{2} \delta (\log Q)^2 + \sum_i \gamma_i \log P_i + \tfrac{1}{2} \sum_i \sum_j \gamma_{ij} \log P_i \log P_j + \sum_h \gamma_{Qi} \log Q \log P_i \quad (3.4)$$

An econometric model such as this that offers at least a second-order approximation to the function of interest is called a flexible functional form. The translog cost function may be derived as a second-order approximation to the logarithm of equation (3.4). Its popularity arises from the fact that it is linear in its coefficients and, although it has considerably more parameters than the Cobb-Douglas model, these are still fairly modest in number.

Parameter Restrictions

Note first that the translog is a generalization of the Cobb-Douglas cost function, in that the Cobb-Douglas is the special case in which

$$\delta = 0$$

$$\gamma_{ij} = 0$$

$$\gamma_{Qi} = 0$$

Because these are just restrictions on the coefficients of the translog model, it is possible to test whether the specialization to the Cobb-Douglas model is supported by the data.

Just as is true of the Cobb-Douglas cost function, linear homogeneity must be imposed on the translog model and, because it involves overidentifying parameter restrictions, is a hypothesis that may be tested. It turns out that the restrictions will ensure a translog cost function that is homogeneous of degree 1 in factor prices, as restriction below.

$$\sum_i \gamma_i = 1$$

$$\sum_i \gamma_{Qi} = 0$$

$$\sum_i \gamma_{ij} = 0 ; \quad \text{for all j}$$

$$\sum_j \gamma_{ij} = 0 ; \quad \text{for all i}$$

However, in contrast to the simpler Cobb-Douglas model, it turns out that linear homogeneity is not the only set of restrictions implied by the microeconomic theory of the firm. Symmetry of cross-price effects requires the symmetry restrictions.

$$\gamma_{ij} = \gamma_{ji} \quad (i \neq j)$$

In the context of the estimation of the cost function (3.4) in isolation, the y_{ij} coefficients are underidentified. The imposition of these symmetry restrictions serves to exactly identify them.

Utilizing the translog which is a flexible functional form, therefore, allows the estimated functions to thoroughly capture the various potential effects of inputs on an output. The translog function, therefore imposes fewer constraints than other functional specifications. The translog does not imposes the structure restrictions regarding returns to scale and elasticity of substitution as other functional forms such as Cobb-Douglas and CES.

Since the translog function requires the estimation of a large number of parameters, the estimation of factor share equations together with the parent cost function as a system equation then reinforces the efficiency of estimation due to an increase in the degree of freedom. Of the i relevant factor share equations, any i-1 are independent because the sum of the factors shares all inputs is equal 1 and disturbances sum identically to zero. One of the share equations is then deleted during estimation to avoid the singularity in the error-covariance matrix. As a result, the system of the translog cost function and i-1 share equations will be estimated so that the parameters can be effectively computed due to an increase in degree of freedom.

The Estimation Method

In this case, ordinary least square (OLS) estimation is not the most appropriate estimation procedure in three system of Thai FDA. This estimation technique yields inefficient estimates because it applies only to a single equation. As result, the problem of loss of efficiency can be resolved by using any of several methods of estimating systems of equations, in which parameters for all equations are determined in a single procedure. This study concentrated on three system equation models of system in Thai FDA that are simultaneous in nature, in which the behavior of the variables is jointly determined for the systems cost functions. Then the appropriate estimation method for simultaneous-equation is *Seemingly Unrelated Regression Estimation (SURE)*. This estimators yield consistent parameter estimates when equation systems are simultaneous. It consists of a series of endogenous variables that are considered as a group because they bear a close conceptual relationship to each other. Thus, we treat the SURE, which consists of a series of equations that are liked because the error terms across equation are correlated. The SURE method achieves an improvement in efficiency by taking into explicit account the fact that cross-equation error correlations may not be zero. This method is employed to estimate the cost function of system in Thai FDA including, pre-marketing system, post-marketing system, and other system.

The Demand Elasticity

In the study interest focuses on aspects of factor use, specifically the price responsiveness of the demand for factors and the degree of substitutability between them. If a construction trades union is able to negotiate artificially high wages, how will this affect the employment of its members? The answer depends on the own-price elasticity of demand. How about the employment of non-union trades? This depends on the cross-price elasticity.

The elasticity of substitution was introduced in the context of two factors of production, there described as capital and labor. Although a natural measure of substitutability when there are just two factors of production, it is problematic in the case of more than two factors. The problem is that it measures the ability to substitute x_1 for x_2, implicitly holding all other factors fixed. But the ability to substitute capital for labor in the face of an increase in relative wages may well depend on the extent to which other factors can also be substituted for labor.

A solution to this problem lies closer at hand than might be apparent; for this broader concept of substitutability has already been captured in the cross-price elasticity εij, which describes the effect on x_i of an increase in p_j by a firm that is simultaneously adjusting its employment of all other factors, consistent with cost minimization. Hence, an elasticity of substitution may be defined as a transformation of εij. The Hicks-Allen partial elasticity of substitution, often simply called the **Allen elasticity,** does just this, transforming εij by the reciprocal of j's cost share:

$$\sigma_{ij} = \frac{1}{S_j} \varepsilon ij \quad (i \neq j)$$

Notice that, rearranging (11.36), these are symmetric:

$$\sigma_{ij} = \sigma_{ji}$$

For the translog cost function, the elasticities of substitution are particularly simple to compute the parameters have been estimated.

$$\sigma_{ii} = \frac{\gamma_{ii} + s_i (s_i - 1)}{s_i^2}$$

$$\sigma_{ij} = \frac{\gamma_{ij} + s_i s_j}{s_i s_j} \; ; \; i \neq j$$

CHAPTER IV

RESEARCH METHODOLOGY AND MODEL SPECIFICATION

A key element, governing the operations of a firm, is its cost function. The study assumes the total expenditure function to be in translog form as being the most flexible functional form of the cost function.

Here, the cost function shows that for any set of input costs and for any output level, the minimum total cost incurred by the firm is

$$C = C(Q, P_L, P_f, P_r)$$

Where Q = amount of outputs that firms want to produce.
P_L = unit price of general labor input
P_f = unit price of professional labor input
P_r = unit price of capital input

In order to find the cost function of the Thai FDA, the multi- product cost functions are estimated using data drawn from the previous record of expenses and output of organization. Since FDA in Thailand has 4 principle systems; i.e., pre-marketing control, post-marketing monitoring, public education and supporting function. Unfortunately this study had to combine the public education system and supporting system to be other system, solving the missing cost data. Then the total cost function of all parts of FDA can be written as

$$\log TC_k = \alpha + \sum_{h}^{2} \beta_i \log Q_{ih} + \tfrac{1}{2}\delta \sum_{h=1}^{2} (\log Q_{ih})^2 + \sum_{i=1}^{3} \gamma_i \log P_i + \tfrac{1}{2} \sum_{i=1}^{3} \sum_{j=1}^{3} \gamma_{ij} \log P_i \log P_j + \sum_{h=1}^{2} \sum_{i=1}^{3} \gamma_{Qh} \log Q_h \log P_i$$

The share equation of those 3 systems are written as follow

$$S_i = \gamma_i + \sum_{j=1}^{3} \gamma_{ij} \log P_j + \sum_{h=1}^{2} \gamma_{Qh} \log Q_h + \varepsilon_i$$

where k = 1,2,3 = pre, post, other function
i, j = 1,2,3 = L, f, r
h = 1,2

The cost shares must sum to 1, which requires, in addition to the symmetry restrictions being imposed,

1. $\sum_{i=1}^{3} \gamma_i = 1$

2. $\sum_{i=1}^{3} \gamma_{ij} = 0$ (column sums equal zero)

3. $\sum_{j=1}^{3} \gamma_{ij} = 0$ (row sums equal zero)

For the translog cost function, the elasticities of substitution will be computed once the parameters have been estimated by

$$\varepsilon_{ii} = \frac{\gamma_{ii} + s_i (s_i - 1)}{s_i}$$

$$\varepsilon_{ij} = \frac{\gamma_{ij} + s_i s_j}{s_i} \quad ; \ i \neq j$$

The system of share equations provides a seemingly unrelated regressions model that can be used to estimate the parameters of the model. To make the model operational, we must impose the restrictions above and solve the problem of singularity of the disturbance covariance matrix of the share equations. The sum of the factors shares all inputs is equal one and disturbances sum identically to zero. One of the share equations is then deleted during estimation to avoid the singularity in the error-covariance matrix.

The total cost function of pre-marketing system in Thailand FDA can be written as

$$\begin{aligned}\log TC_A = {} & C_{0A}+C_{1A}\log P_{L1}+C_{2A}\log P_{f1}+C_{3A}\log P_{r1}+C_{4A}\log Q_{11}+C_{5A}\log Q_{12} \\ & +C_{11A}\,\tfrac{1}{2}(\log P_{L1})^2 + C_{22A}\,\tfrac{1}{2}(\log P_{f1})^2 + C_{33A}\,\tfrac{1}{2}(\log P_{r1})^2 \\ & +C_{44A}\,\tfrac{1}{2}(\log Q_{11})^2 +C_{55A}\,\tfrac{1}{2}(\log Q_{12})^2 +C_{12A}\log P_{L1}\log P_{f1} \\ & +C_{13A}\log P_{L1}\log P_{r1}+C_{14A}\log P_{L1}\log Q_{11}+ C_{15A}\log P_{L1}\log Q_{12} \\ & +C_{23A}\log P_{f1}\log P_{r1}+C_{24A}\log P_{f1}\log Q_{11} +C_{25A}\log P_{f1}\log Q_{12} \\ & +C_{34A}\log P_{r1}\log Q_{11}+C_{35A}\log P_{r1}\log Q_{12}+C_{45A}\log Q_{11}\log Q_{12} \\ & + C_{6A}D_1 + C_{7A}D_2 + C_{8A}D_3 + C_{9A}D_4 + \varepsilon_A\end{aligned}$$

The cost shares equation

$$\begin{aligned}S_{LA} = \frac{\partial \log TC_A}{\partial \log L_A} = {} & C_{1A} + C_{11A}\log P_{L1} + C_{12A}\log P_{f1} \\ & + (-C_{11A}-C_{12A})\log P_{r1} \\ & + C_{14A}\log Q_{11} + C_{15A}\log Q_{12} \\ & + C_{16A}D_1 + C_{17A}D_2 + C_{18A}D_3 + C_{19A}D_4 + \varepsilon_{1A}\end{aligned}$$

$$\begin{aligned}S_{fA} = \frac{\partial \log TC_A}{\partial \log F_A} = {} & C_{2A} + \delta_{12A}\log P_{L1} + \delta_{22A}\log P_{f1} \\ & + (-C_{22A}-C_{12A})\log P_{r1} \\ & + C_{24A}\log Q_{11} + C_{25A}\log Q_{12} \\ & + C_{26A}D_1 + C_{27A}D_2 + C_{28A}D_3 + C_{29A}D_4 + \varepsilon_{2A}\end{aligned}$$

$$\begin{aligned}S_{rA} = \frac{\partial \log TC_A}{\partial \log R_A} = {} & (1-C_{1A}-C_{2A}) \\ & + (-(-C_{11A}-C_{12A})-(-C_{22A}-C_{12A}))\log P_{r1} \\ & + (-C_{11A}-C_{12A})\log P_{L1} \\ & + (-C_{22A}-C_{12A})\log P_{f1} \\ & + (-C_{14A}-C_{24A})\log Q_{11} \\ & + (-C_{15A}-C_{25A})\log Q_{12} + \varepsilon_{3A}\end{aligned}$$

The total cost function of post-marketing system in FDA can be written as

$$\begin{aligned}\log TC_B = {} & C_{0B}+C_{1B}\log P_{L2}+C_{2B}\log P_{f2}+C_{3B}\log P_{r2}+C_{4B}\log Q_{21}+C_{5B}\log Q_{22} \\ & +C_{11B}\,½\,(\log P_{L2})^2 + C_{22B}\,½\,(\log P_{f2})^2 + C_{33B}\,½\,(\log P_{r2})^2 \\ & +C_{44B}\,½\,(\log Q_{21})^2 +C_{55B}\,½\,(\log Q_{22})^2 +C_{12B}\log P_{L2}\log P_{f2} \\ & +C_{13B}\log P_{L2}\log P_{r2}+C_{14B}\log P_{L2}\log Q_{21}+ C_{15B}\log P_{L2}\log Q_{22} \\ & +C_{23B}\log P_{f2}\log P_{r2}+C_{24B}\log P_{f2}\log Q_{21} +C_{25B}\log P_{f2}\log Q_{22} \\ & +C_{34B}\log P_{r2}\log Q_{21}+C_{35B}\log P_{r2}\log Q_{22}+C_{45B}\log Q_{21}\log Q_{22} \\ & + C_{6B}D_1 + C_{7B}D_2 + C_{8B}D_3 + C_{9B}D_4 + \varepsilon_B\end{aligned}$$

The cost shares equation

$$\begin{aligned}S_{LB} = \frac{\partial \log TC_B}{\partial \log L_B} = {} & C_{1B} + C_{11B}\log P_{L2} + C_{12B}\log P_{f2} \\ & + (-C_{11B}-C_{12B})\log P_{r2} \\ & + C_{14B}\log Q_{21} + C_{15B}\log Q_{22} \\ & + C_{16B}D_1 + C_{17B}D_2 + C_{18B}D_3 + C_{19B}D_4 + \varepsilon_{1B}\end{aligned}$$

$$\begin{aligned}S_{fB} = \frac{\partial \log TC_B}{\partial \log F_B} = {} & C_{2B} + C_{12B}\log P_{L2} + C_{22B}\log P_{f2} \\ & + (-C_{22B}-C_{12B})\log P_{r2} \\ & + C_{24B}\log Q_{21} + C_{25B}\log Q_{22} + \varepsilon_{2B} \\ & + C_{26B}D_1 + C_{27B}D_2 + C_{28B}D_3 + C_{29B}D_4 + \varepsilon_{2B}\end{aligned}$$

$$\begin{aligned}S_{rB} = \frac{\partial \log TC_B}{\partial \log R_B} = {} & (1-C_{1B}-C_{2B}) \\ & + (-(-C_{11B}-C_{12B})-(-C_{22B}-C_{12B}))\log P_{r2} \\ & + (-C_{11B}-C_{12B})\log P_{L2} \\ & + (-C_{22B}-C_{12B})\log P_{f2} \\ & + (-C_{14B}-C_{24B})\log Q_{21} \\ & + (-C_{15B}-C_{25B})\log Q_{22} + \varepsilon_{3B}\end{aligned}$$

The total cost function of the other system in FDA can be written as

$$\begin{aligned}\log TC_C = {} & C_{0C}+C_{1C}\log P_{L3}+C_{2C}\log P_{f3}+C_{3C}\log P_{r3} \\ & +C_{4C}\log Q_{31}+C_{5C}\log Q_{32} \\ & +C_{11C}\,\tfrac{1}{2}(\log P_{L3})^2 + C_{22C}\,\tfrac{1}{2}(\log P_{f3})^2 + C_{33C}\,\tfrac{1}{2}(\log P_{r3})^2 \\ & +C_{44C}\,\tfrac{1}{2}(\log Q_{31})^2 + C_{55C}\,\tfrac{1}{2}(\log Q_{32})^2 \\ & +C_{12C}\log P_{L3}\log P_{f3}+C_{13C}\log P_{L3}\log P_{r3}+C_{23C}\log P_{f3}\log P_{r3} \\ & +C_{14C}\log P_{L3}\log Q_{31}+C_{15C}\log P_{L3}\log Q_{32} \\ & +C_{24C}\log P_{f3}\log Q_{31}+C_{25C}\log P_{f3}\log Q_{32} \\ & +C_{34C}\log P_{r3}\log Q_{31}+C_{35C}\log P_{r3}\log Q_{32} \\ & +C_{45C}\log Q_{31}\log Q_{32} \\ & +C_{6C}D_1 + C_{7C}D_2 + C_{8C}D_3 + C_{9C}D_4 + \varepsilon_C\end{aligned}$$

The cost shares equation

$$\begin{aligned}S_{LC} = \frac{\partial \log TC_C}{\partial \log L_C} = {} & C_{1C} + C_{11C}\log P_{L3} + C_{12C}\log P_{f3} \\ & + (-C_{11C}-C_{12C})\log P_{r3} \\ & + C_{14C}\log Q_{31} + C_{15C}\log Q_{32} + C_{16C}\log Q_{33} \\ & + C_{17C}D_1 + C_{18C}D_2 + C_{19C}D_3 + C_{19C}D_4 + \varepsilon_{1C}\end{aligned}$$

$$\begin{aligned}S_{fC} = \frac{\partial \log TC_C}{\partial \log F_C} = {} & C_{2C} + C_{12C}\log P_{L3} + C_{22C}\log P_{f3} \\ & + (-C_{22C}-C_{12C})\log P_{r3} \\ & + C_{24C}\log Q_{31} + C_{25C}\log Q_{32} + C_{26C}\log Q_{33} \\ & + C_{27C}D_1 + C_{28C}D_2 + C_{29C}D_3 + C_{29C}D_4 + \varepsilon_{2C}\end{aligned}$$

$$\begin{aligned}S_{rC} = \frac{\partial \log TC_C}{\partial \log R_C} = {} & (1-C_{1C}-C_{2C}) \\ & + (-(-C_{11C}-C_{12C})-(-C_{22C}-C_{12C}))\log P_{r3} \\ & + (-C_{11C}-C_{12C})\log P_{L3} \\ & + (-C_{22C}-C_{12C})\log P_{f3} \\ & + (-C_{14C}-C_{24C})\log Q_{31} \\ & + (-C_{15C}-C_{25C})\log Q_{32} + \varepsilon_{3C}\end{aligned}$$

Variables

TC_A = total cost of pre-marketing system function per year

TC_B = total cost of post-marketing system function per year

TC_C = total cost of the other system function per year

P_L = unit price of general labor input per year

P_f = unit price of professional labor input per year

P_r = unit price of capital input per year

Q_{ih} = the number of output (i,h) being as follows

Q_{11} = the number of manufacturing license approval per year

Q_{12} = the number of product registration approval per year

Q_{21} = the number of manufacturing inspection per year

Q_{22} = the number of product inspection per year

Q_{31} = the number of disseminated topic knowledge to consumer per year

Q_{32} = the number of research and development of consumer health protection

Definition and measurement of variables

Dependent variable

Costs

Total cost was defined as total cost which incurred by the Thai FDA to operate its tasks. That is summation of labor, capital and operational expenditures.

- Labor expenditure was obtained by the summation of total salaries of civil servants.
- Operational expenditure was computed from real payment.
- Capital expenditure was computed from real payment.

Note; the main capital expenditure of FDA comprised the real payment on vehical and computers intra-network system of Information technology reformation.

Independent variable

Outputs

The data was collected from annual performance report of the Thai FDA. It can be summarized in to 4 groups as follows:

1. The outputs of pre-marketing activities can be grouped in two principal parts;

- number of manufacturing license approval per year
- number of product registration approval per year

Note; Type of product registrations classified into 2 groups as the following: first, therapeutic product such as drug, narcotic, and medical device; second, non-therapeutic product such as food, cosmetic, hazardous substance. Before these items were summarized in to the whole outputs (Q12); they had been weighted by the value presented as cost spending from each type of product registration. From recommendation of the experts working at the Thai FDA, they indicated that the therapeutic product type should be 70% weighted, and non therapeutic product type should be 30% weighted.

2. The output of post-marketing activities can be grouped in two principal parts;

- number of manufacturing inspection per year
- number of product inspection per year

3. The output of other system, including output of public education system and output of supporting system can be grouped in principal part;

- the number of topic of disseminated knowledge to consumer per year
- the number of research and development of consumer health protection

Wage rate

Labor input factor classified into two groups of labor: general labor and professional labor input are defined as being civil servant, working for Thai FDA at position of C1-C7 and C8-C11, respectively. The unit price of labor inputs are all income including actual salary and fringe benefit can be grouped in principal part;

- Unit price of general labor input is salary
- Unit price of professional labor input is salary plus fringe benefit

The average weight of the labor unit price are calculated as follow

$$P_j = \frac{\Sigma\ PiNi}{\Sigma\ Ni}$$

where j = L, f = general labor , professional labor

The professional labor (f); as i is labor at position of C8 - C11
The general labor (L); as i is labor at position of C1 – C7

Interest rate

The unit price of capital input is usually defined as the rate of interest. The saving deposit rate will be used here in order to present perspective of opportunity loss for investment.

Dummy Variable;

Organization reformation event

D_1 = Public health policy reformation by decentralization to provincial health offices in 1992

D_2 = Information technology reformation by set up intra-network system Office Automation (OA) system as well as establishing consumer complaint hot-line services; in 1997

D_3 = Government budgeting policy reformation by promoting Performance Base Budgeting System (PBBS) as well as organization structure reform of post marketing system; in 2003

D_4 = Economic crisis impact on budgeting of Thai FDA, during 1999-2003

All dummy variables (D_1, D_2, D_3 and D_4) are given as being equal to 1, if the reform has been taken place. They are given to be zero; if otherwise (the reform has not been taken place).

CHAPTER V

RESULT AND DISCUSSION

5.1 Empirical Results

5.1.1 Estimation Result

In the previous chapter, this study employed translog cost function model and Seemingly Unrelated Regression Estimation (SURE) method in order to estimate simultaneous-equation of the systems in Thai FDA. The model inspection of cost function in three systems consists of pre-marketing system, post-marketing system and the other system. Each of them is separated into three types of input factors cost share equations, including general labor, professional labor, and capital input. In process of estimation, one of the share equations is then deleted during estimation to avoid the singularity in the error-covariance matrix. In this study, the capital cost share equations are omitted in the estimating process of three systems cost functions.

The estimation results manifested in this chapter, classified in three sections. First, the statistical estimation results are presented by Eview program's table form which shows the estimated result in term of coefficient of explanatory variable and other important statistical values of share equations. This provides the relationship between cost share of input factors and its explanatory variable such as price of input factors and its output performance. Second, the price elasticity of demand for input factors measures the percentage change in the quantity demanded resulting from a 1- percent increase in price of input factors. This study presented price elasticity in term of Allen's elasticity and then separated into two groups, including own-price elasticity and cross-price elasticity. Third, the simulation of total expenditure of three systems employed the own cost share equation with highest R^2 value to be the best representative of fitted cost share of input factors. They should be then used to estimate fitted total expenditure of pre-marketing, post-marketing and the other systems. As purpose of this study, we expected that the empirical result could provide some practical budgeting guideline for policy maker to improve financial system in term of efficiency and productivity. The possible policy implication for future financial plan would be discussed in the last section of this chapter.

The statistical estimation result of pre-marketing system as table below,

Table 5.1 The statistical estimation result of pre-marketing system

System: Pre-Marketing System
Estimation Method: Seemingly Unrelated Regression
Date: 04/26/06 Time: 13:02
Sample: 1980 2005
Included observations: 26
Total system (balanced) observations 52
Convergence achieved after: 1 weight matrix, 4 total coef iterations

	Coefficient	Std. Error	t-Statistic	Prob.
C(1)	0.923455	0.264674	3.489028	0.0013
C(11)	0.068974	0.011432	6.033661	0.0000
C(12)	-0.108520	0.010391	-10.44361	0.0000
C(14)	-0.068241	0.033542	-2.034464	0.0495
C(15)	0.059632	0.024396	2.444291	0.0197
C(16)	-0.087906	0.036574	-2.403507	0.0217
C(17)	0.017031	0.023332	0.729930	0.4703
C(18)	0.079387	0.034923	2.273194	0.0293
C(19)	-0.004864	0.022137	-0.219707	0.8274
C(2)	0.596784	0.221109	2.699043	0.0106
C(22)	0.083968	0.011324	7.415001	0.0000
C(24)	-0.053033	0.027564	-1.923997	0.0625
C(25)	0.040703	0.020126	2.022413	0.0508
C(26)	-0.066719	0.030008	-2.223361	0.0327
C(27)	0.010514	0.019239	0.546476	0.5882
C(28)	0.059284	0.028716	2.064520	0.0464
C(29)	-0.006215	0.018165	-0.342163	0.7343
Determinant residual covariance		1.56E-08		

Equation: SL1 = C(1) + C(11)*LNPL1+ C(12)*LNPF1 + (-C(11)-C(12))
*LNPR + C(14)*LNQ11 + C(15)*LNQ12 + C(16)*D1 + C(17)*D2 +
C(18)*D3 + C(19)*D4
Observations: 26

R-squared	0.553508	Mean dependent var	0.174430
Adjusted R-squared	0.343394	S.D. dependent var	0.040609
S.E. of regression	0.032906	Sum squared resid	0.018407
Durbin-Watson stat	1.437292		

Equation: SF1 = C(2) + C(12)*LNPL1+ C(22)*LNPF1 + (-C(22)-C(12))
*LNPR + C(24)*LNQ11 + C(25)*LNQ12 + C(26)*D1 + C(27)*D2 +
C(28)*D3 + C(29)*D4
Observations: 26

R-squared	0.769871	Mean dependent var	0.132001
Adjusted R-squared	0.661575	S.D. dependent var	0.046436
S.E. of regression	0.027014	Sum squared resid	0.012406
Durbin-Watson stat	1.417725		

According to statistical result of pre-marketing system in table 5.1 appear that D2 and D4 are denoted insignificant. As a result this model has to omit them, including D2 and D4 as the information technology reform in 1997 and Thailand economic crisis in 1999-2003, respectively. The adjusted result of improvement as shown in table below.

Table 5.2 The statistical result of pre-marketing system after adjustment

System: Pre-Marketing System
Estimation Method: Seemingly Unrelated Regression
Date: 04/26/06 Time: 13:02
Sample: 1980 2005
Included observations: 26
Total system (balanced) observations 52
Convergence achieved after: 1 weight matrix, 4 total coef iterations

	Coefficient	Std. Error	t-Statistic	Prob.
C(1)	0.846750	0.244760	3.459512	0.0013
C(11)	0.071203	0.009196	7.742609	0.0000
C(12)	-0.102849	0.008287	-12.41078	0.0000
C(14)	-0.068410	0.030103	-2.272509	0.0286
C(15)	0.055579	0.021834	2.545591	0.0150
C(16)	-0.086504	0.032230	-2.683929	0.0106
C(18)	0.079111	0.030291	2.611709	0.0127
C(2)	0.590315	0.202060	2.921487	0.0058
C(22)	0.080066	0.008453	9.471741	0.0000
C(24)	-0.052685	0.024703	-2.132734	0.0393
C(25)	0.038493	0.017948	2.144731	0.0383
C(26)	-0.063667	0.026405	-2.411167	0.0207
C(28)	0.063084	0.024849	2.538730	0.0152
Determinant residual covariance		1.67E-08		

Equation: SL1 = C(1) + C(11)*LNPL1+ C(12)*LNPF1 + (-C(11)-C(12)) *LNPR + C(14)*LNQ11 + C(15)*LNQ12 + C(16)*D1 + C(18)*D3
Observations: 26

R-squared	0.544897	Mean dependent var	0.174430
Adjusted R-squared	0.401180	S.D. dependent var	0.040609
S.E. of regression	0.031424	Sum squared resid	0.018762
Durbin-Watson stat	1.437502		

Equation: SF1 = C(2) + C(12)*LNPL1+ C(22)*LNPF1 + (-C(22)-C(12)) *LNPR + C(24)*LNQ11 + C(25)*LNQ12 + C(26)*D1 + C(28)*D3
Observations: 26

R-squared	0.765990	Mean dependent var	0.132001
Adjusted R-squared	0.692092	S.D. dependent var	0.046436
S.E. of regression	0.025767	Sum squared resid	0.012615
Durbin-Watson stat	1.398100		

Translog cost function model of pre-marketing system are illustrated in cost share equation. Share values of pre-marketing system cost functions classified into 3 equation of type of input factor as functions below

Function 5.2 Share equation of pre-marketing system, which includes

1) Function of general labor input factor share equation

$$
\begin{aligned}
Sl = \; & 0.8467498429 + 0.071203412 * LNPL1 \\
& - 0.1028486418 * LNPF1 + 0.031646 * LNPR \\
& - 0.06840970183 * LNQ11 + 0.05557935968 * LNQ12 \\
& - 0.0865036113 * D1 + 0.07911135542 * D3
\end{aligned}
$$

2) Function of professional labor input factor share equation

$$
\begin{aligned}
Sf = \; & 0.5903147402 - 0.1028486418 * LNPL1 \\
& + 0.0800663612 * LNPF1 + 0.022783 * LNPR \\
& - 0.05268499821 * LNQ11 + 0.03849277784 * LNQ12 \\
& - 0.06366748306 * D1 + 0.06308443342 * D3
\end{aligned}
$$

3) Function of capital input factor share equation

$$
\begin{aligned}
Sr = \; & -0.437065 + 0.031646 * LNPL1 \\
& + 0.022783 * LNPF1 - 0.054429 * LNPR \\
& + 0.121095 * LNQ11 - 0.094072 * LNQ12
\end{aligned}
$$

Figure 5.21 Share values of general labor in pre-marketing system

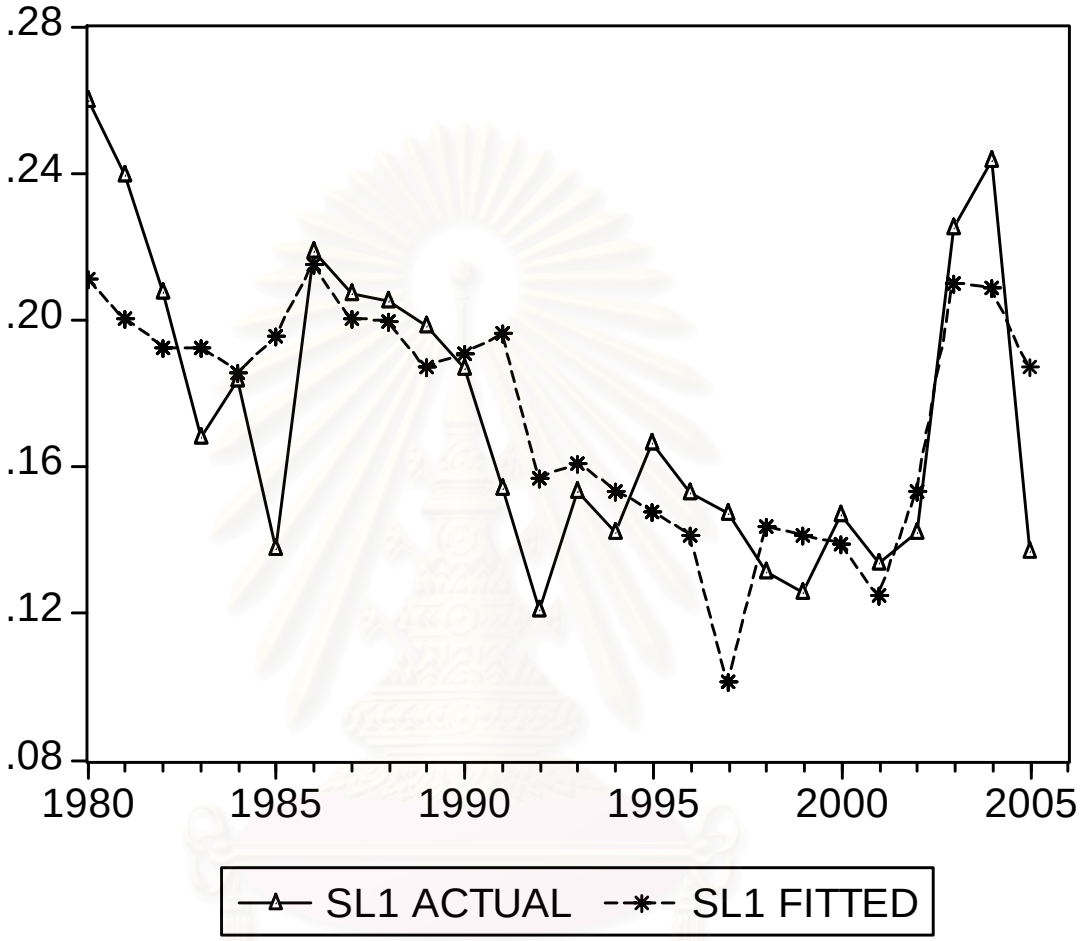
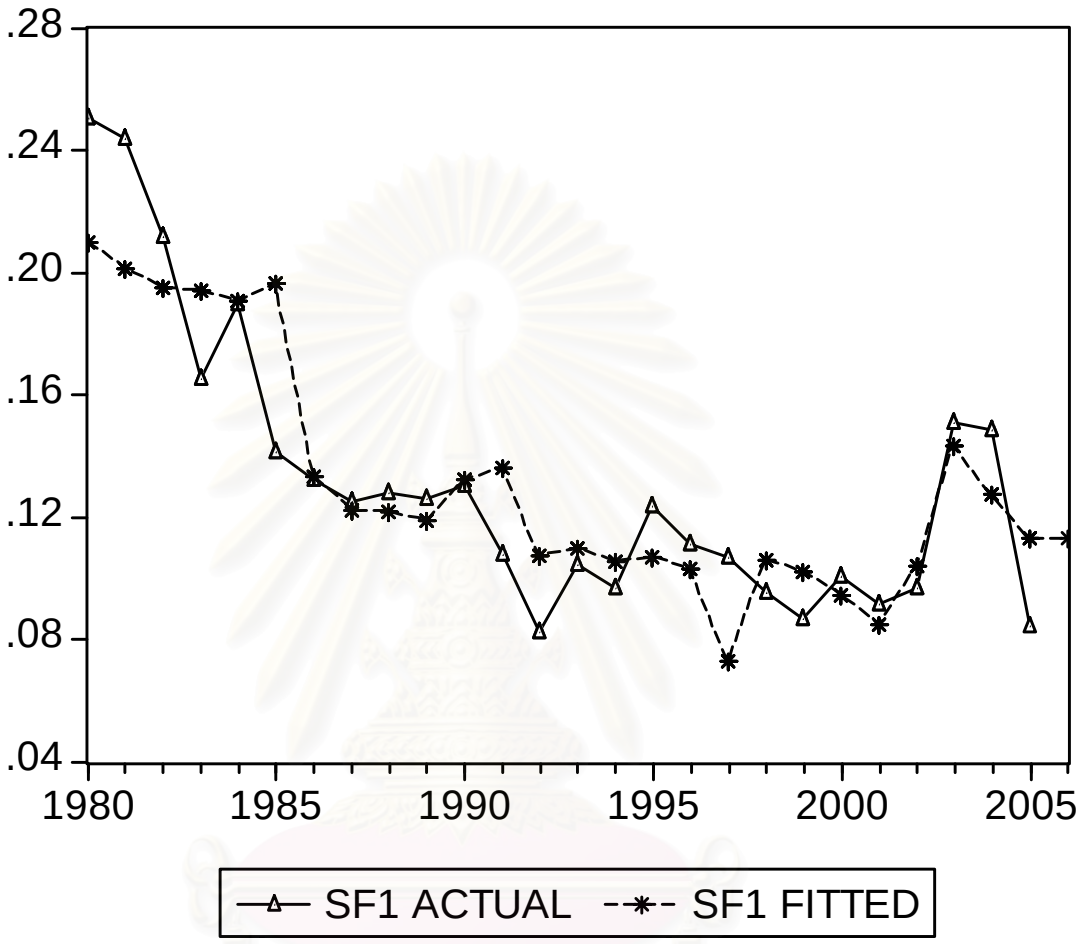


Figure 5.22 Share values of professional labor in pre-marketing system



The statistical estimation result of post-marketing system as table below,

Table 5.3 The statistical result of post-marketing system

System: Post-Marketing System
Estimation Method: Seemingly Unrelated Regression
Date: 04/26/06 Time: 14:16
Sample: 1980 2005
Included observations: 26
Total system (balanced) observations 52
Convergence achieved after: 1 weight matrix, 4 total coef iterations

	Coefficient	Std. Error	t-Statistic	Prob.
C(1)	2.071404	0.783267	2.644569	0.0122
C(11)	0.117154	0.027243	4.300302	0.0001
C(12)	-0.129151	0.017629	-7.325904	0.0000
C(14)	-0.038253	0.049495	-0.772871	0.4448
C(15)	-0.107922	0.035978	-2.999707	0.0050
C(16)	-0.021931	0.113760	-0.192786	0.8482
C(17)	0.263988	0.060102	4.392358	0.0001
C(18)	-0.200299	0.133504	-1.500324	0.1425
C(19)	0.020148	0.047893	0.420695	0.6766
C(2)	1.214812	0.475781	2.553303	0.0152
C(22)	0.115380	0.014915	7.735891	0.0000
C(24)	-0.023317	0.029905	-0.779680	0.4408
C(25)	-0.061804	0.021736	-2.843329	0.0074
C(26)	-0.009653	0.068886	-0.140131	0.8894
C(27)	0.167291	0.036342	4.603237	0.0001
C(28)	-0.090793	0.080695	-1.125142	0.2682
C(29)	-0.006043	0.028950	-0.208748	0.8359

Determinant residual covariance 2.11E-07

Equation: SL2 = C(1) + C(11)*LNPL2+ C(12)*LNPF2 + (-C(11)-C(12)) *LNPR + C(14)*LNQ21 + C(15)*LNQ22 + C(16)*D1 + C(17)*D2 + C(18)*D3 + C(19)*D4
Observations: 26

R-squared	0.898754	Mean dependent var	0.405092
Adjusted R-squared	0.851109	S.D. dependent var	0.206430
S.E. of regression	0.079654	Sum squared resid	0.107861
Durbin-Watson stat	1.568955		

Equation: SF2 = C(2) + C(12)*LNPL2+ C(22)*LNPF2 + (-C(22)-C(12)) *LNPR + C(24)*LNQ21 + C(25)*LNQ22 + C(26)*D1 + C(27)*D2 + C(28)*D3 + C(29)*D4
Observations: 26

R-squared	0.886165	Mean dependent var	0.239947
Adjusted R-squared	0.832595	S.D. dependent var	0.117560
S.E. of regression	0.048100	Sum squared resid	0.039331
Durbin-Watson stat	1.491103		

According to statistical result of post-marketing system in table 5.3 appear that D1, D2 and D4 are denoted insignificant. As a result, this model has to omit them, including D1, D2 and D4 as decentralization to provincial health offices in 1992, the information technology reform in 1997 and Thailand economic crisis in 1999-2003. The adjusted result of improvement as shown in table below.

Table 5.4 The statistical result of Post-Marketing System after adjustment

System: Post-Marketing System
Estimation Method: Seemingly Unrelated Regression
Date: 04/26/06 Time: 14:17
Sample: 1980 2005
Included observations: 26
Total system (balanced) observations 52
Convergence achieved after: 1 weight matrix, 4 total coef iterations

	Coefficient	Std. Error	t-Statistic	Prob.
C(1)	2.811725	0.644894	4.359983	0.0001
C(11)	0.100514	0.023290	4.315773	0.0001
C(12)	-0.142006	0.015557	-9.128267	0.0000
C(14)	-0.029416	0.034167	-0.860943	0.3943
C(15)	-0.146213	0.018028	-8.110272	0.0000
C(17)	0.273712	0.055175	4.960790	0.0000
C(2)	1.504959	0.378216	3.979096	0.0003
C(22)	0.116934	0.013939	8.388994	0.0000
C(24)	-0.018313	0.019891	-0.920686	0.3626
C(25)	-0.078889	0.010498	-7.514849	0.0000
C(27)	0.160840	0.032223	4.991507	0.0000
Determinant residual covariance		4.54E-07		

Equation: SL2 = C(1) + C(11)*LNPL2+ C(12)*LNPF2 + (-C(11)-C(12)) *LNPR + C(14)*LNQ21 + C(15)*LNQ22 + C(17)*D2
Observations: 26

R-squared	0.882950	Mean dependent var	0.405092
Adjusted R-squared	0.853687	S.D. dependent var	0.206430
S.E. of regression	0.078961	Sum squared resid	0.124698
Durbin-Watson stat	1.857371		

Equation: SF2 = C(2) + C(12)*LNPL2+ C(22)*LNPF2 + (-C(22)-C(12)) *LNPR + C(24)*LNQ21 + C(25)*LNQ22 + C(27)*D2
Observations: 26

R-squared	0.878662	Mean dependent var	0.239947
Adjusted R-squared	0.848328	S.D. dependent var	0.117560
S.E. of regression	0.045784	Sum squared resid	0.041923
Durbin-Watson stat	1.693058		

Translog cost function model of post-marketing system are illustrated in cost share equation. Share values of post-marketing system cost functions classified into 3 equation of type of input factor as functions below

Function 5.4 Share equation of post-marketing system, which includes

1) Function of general labor input factor share equation

$$Sl = 2.811724857 + 0.1005140742 * LNPL2 - 0.142005528 * LNPF2 + 0.041492 * LNPR - 0.02941589617 * LNQ21 - 0.146213388 * LNQ22 + 0.2737117174 * D2$$

2) Function of professional labor input factor share equation

$$Sf = 1.504958925 - 0.142005528 * LNPL2 + 0.1169341893 * LNPF2 + 0.025072 * LNPR - 0.01831315693 * LNQ21 - 0.07888920689 * LNQ22 + 0.160840132 * D2$$

3) Function of capital input factor share equation

$$Sr = -3.316684 + 0.041492 *LNPL2 + 0.025072 *LNPF2 - 0.066564 *LNPR + 0.047729 *LNQ21 + 0.225102 *LNQ22$$

Figure 5.41 Share values of general labor in post-marketing system

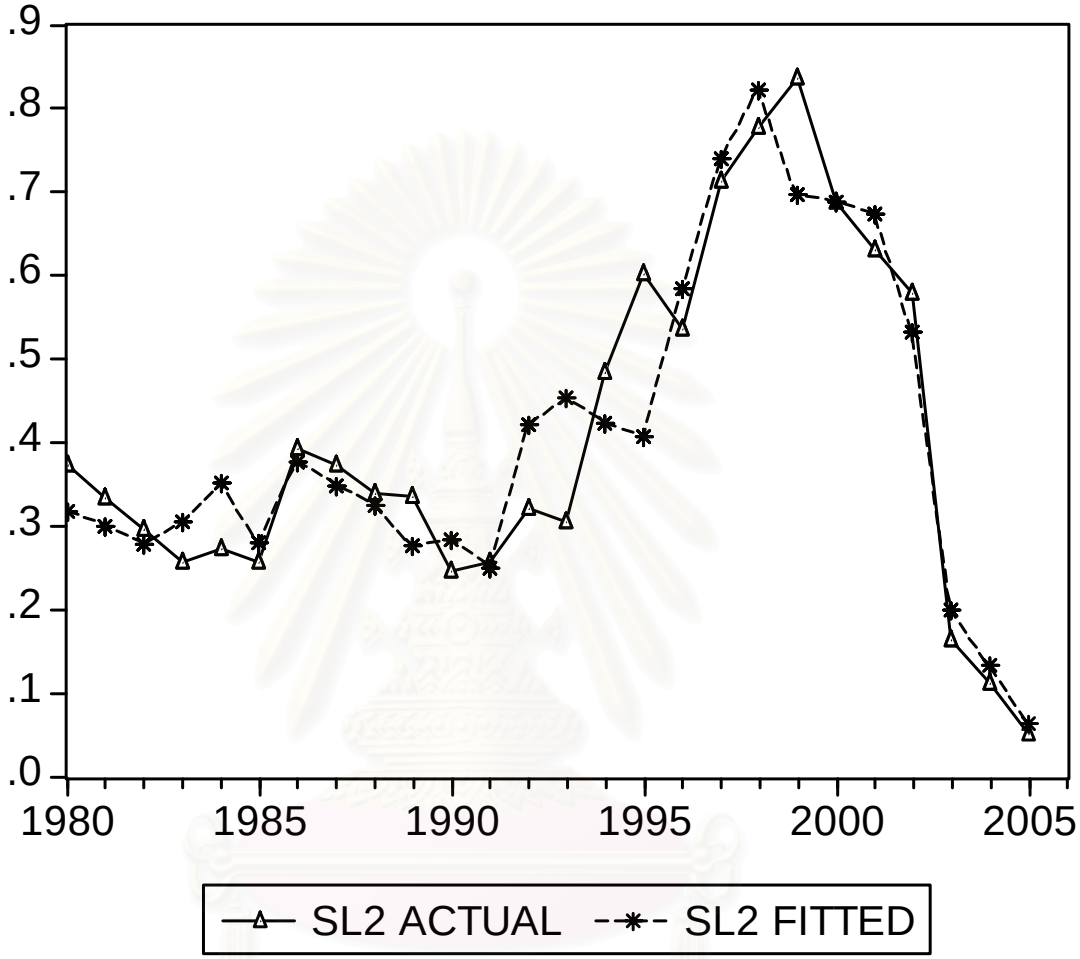
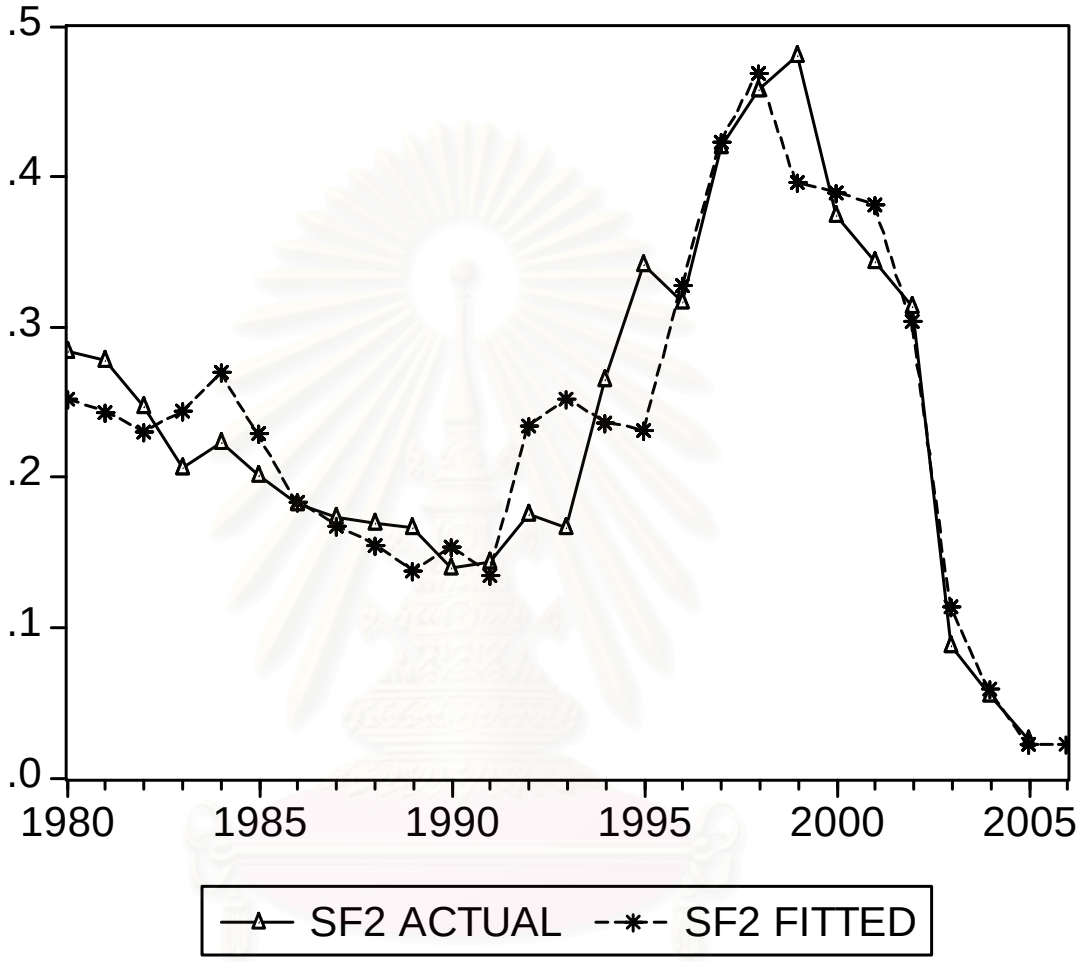


Figure 5.42 Share values of professional labor in post-marketing system



The statistical estimation result of other system as table below,

Table 5.5 The statistical result of Other System

System: The Other System
Estimation Method: Seemingly Unrelated Regression
Date: 04/26/06 Time: 14:31
Sample: 1980 2005
Included observations: 26
Total system (balanced) observations 52
Convergence achieved after: 1 weight matrix, 4 total coef iterations

	Coefficient	Std. Error	t-Statistic	Prob.
C(1)	-10.44622	1.422338	-7.344398	0.0000
C(11)	0.737725	0.091349	8.075903	0.0000
C(12)	0.111401	0.059391	1.875739	0.0691
C(14)	0.105644	0.063162	1.672582	0.1033
C(15)	-0.774868	0.107347	-7.218373	0.0000
C(16)	-1.077617	0.186260	-5.785554	0.0000
C(17)	0.246580	0.168250	1.465563	0.1517
C(18)	-0.758466	0.182033	-4.166642	0.0002
C(19)	-0.594661	0.132469	-4.489061	0.0001
C(2)	-0.993301	0.687273	-1.445278	0.1573
C(22)	-0.034002	0.091585	-0.371258	0.7127
C(24)	0.013715	0.017753	0.772515	0.4450
C(25)	-0.053167	0.033375	-1.593044	0.1201
C(26)	-0.062274	0.052827	-1.178834	0.2464
C(27)	-0.013857	0.046726	-0.296560	0.7686
C(28)	-0.079280	0.061801	-1.282827	0.2080
C(29)	-0.054385	0.040753	-1.334496	0.1907

Determinant residual covariance	1.42E-05

Equation: SL3 = C(1) + C(11)*LNPL3+ C(12)*LNPF3 + (-C(11)-C(12)) *LNPR + C(14)*LNQ31 + C(15)*LNQ32 + C(16)*D1 + C(17)*D2 + C(18)*D3 + C(19)*D4
Observations: 26

R-squared	0.947841	Mean dependent var	0.781479
Adjusted R-squared	0.923295	S.D. dependent var	0.748989
S.E. of regression	0.207437	Sum squared resid	0.731514
Durbin-Watson stat	2.088905		

Equation: SF3 = C(2) + C(12)*LNPL3+ C(22)*LNPF3 + (-C(22)-C(12)) *LNPR + C(24)*LNQ31 + C(25)*LNQ32 + C(26)*D1 + C(27)*D2 + C(28)*D3 + C(29)*D4
Observations: 26

R-squared	0.774093	Mean dependent var	0.074146
Adjusted R-squared	0.667784	S.D. dependent var	0.056730
S.E. of regression	0.032698	Sum squared resid	0.018176
Durbin-Watson stat	0.992360		

According to statistical result of other system in table 5.5 appear different result of professional and general labor share equation that D2 is denoted insignificant in professional share equation, while general labor share equation is denoted insignificant in all dummy variable. Therefore, this model has to omit the insignificant dummy variable.

However, the external factor of economic crisis is still remained in both of the labor share equation, because it should affect to both of them, although it is denoted insignificant in professional labor share equation.

Table 5.6 The statistical result of Other System after adjustment

System: The Other System
Estimation Method: Seemingly Unrelated Regression
Date: 04/26/06 Time: 20:20
Sample: 1980 2005
Included observations: 26
Total system (balanced) observations 52
Convergence achieved after: 1 weight matrix, 4 total coef iterations

	Coefficient	Std. Error	t-Statistic	Prob.
C(1)	-10.46209	1.461817	-7.156904	0.0000
C(11)	0.703046	0.091556	7.678873	0.0000
C(12)	0.152826	0.056996	2.681354	0.0107
C(14)	0.077978	0.063552	1.226995	0.2272
C(15)	-0.710929	0.089888	-7.909060	0.0000
C(16)	-1.089890	0.174259	-6.254408	0.0000
C(18)	-0.716809	0.184301	-3.889334	0.0004
C(19)	-0.470481	0.109529	-4.295509	0.0001
C(2)	-0.168184	0.421386	-0.399120	0.6920
C(22)	-0.128081	0.074209	-1.725951	0.0923
C(24)	0.007480	0.015280	0.489548	0.6272
C(25)	-0.054782	0.021707	-2.523698	0.0158
C(29)	-0.033524	0.027365	-1.225091	0.2279
Determinant residual covariance		1.74E-05		

Equation: SL3 = C(1) + C(11)*LNPL3+ C(12)*LNPF3 + (-C(11)-C(12)) *LNPR + C(14)*LNQ31 + C(15)*LNQ32 + C(16)*D1 + C(18)*D3 + C(19)*D4
Observations: 26

R-squared	0.942598	Mean dependent var	0.781479
Adjusted R-squared	0.920275	S.D. dependent var	0.748989
S.E. of regression	0.211481	Sum squared resid	0.805039
Durbin-Watson stat	1.713511		

Equation: SF3 = C(2) + C(12)*LNPL3+ C(22)*LNPF3 + (-C(22)-C(12)) *LNPR + C(24)*LNQ31 + C(25)*LNQ32 + C(29)*D4
Observations: 26

R-squared	0.783525	Mean dependent var	0.074146
Adjusted R-squared	0.729406	S.D. dependent var	0.056730
S.E. of regression	0.029510	Sum squared resid	0.017417
Durbin-Watson stat	1.018344		

Translog cost function model of the other system are illustrated in cost share equation. Share values of the other system cost functions classified into 3 equation of type of input factor as functions below

Function 5.6 Share equation of the other system, which includes

1) Function of general labor input factor share equation

```
Sl =  - 10.46208655  + 0.7030457735 * LNPL3
      + 0.1528263028 * LNPF3  - 0.855872  * LNPR
      + 0.07797833841 * LNQ31  - 0.7109290611 * LNQ32
      - 1.089889923 * D1  - 0.7168091548 * D3  - 0.4704814794 * D4
```

2) Function of professional labor input factor share equation

```
Sf =  - 0.1681836798  + 0.1528263028 * LNPL3
      - 0.1280808483 * LNPF3  - 0.024745 * LNPR
      + 0.007480482398 * LNQ31  - 0.05478216322 * LNQ32
      - 0.03352436287 * D4
```

3) Function of capital input factor share equation

```
Sr =  11.630274  - 0.855872 * LNPL3
      - 0.024745 * LNPF3  + 0.880617 * LNPR
      - 0.085458 * LNQ31 + 0.765711 * LNQ32
```

Figure 5.61 Share values of general labor in the other system

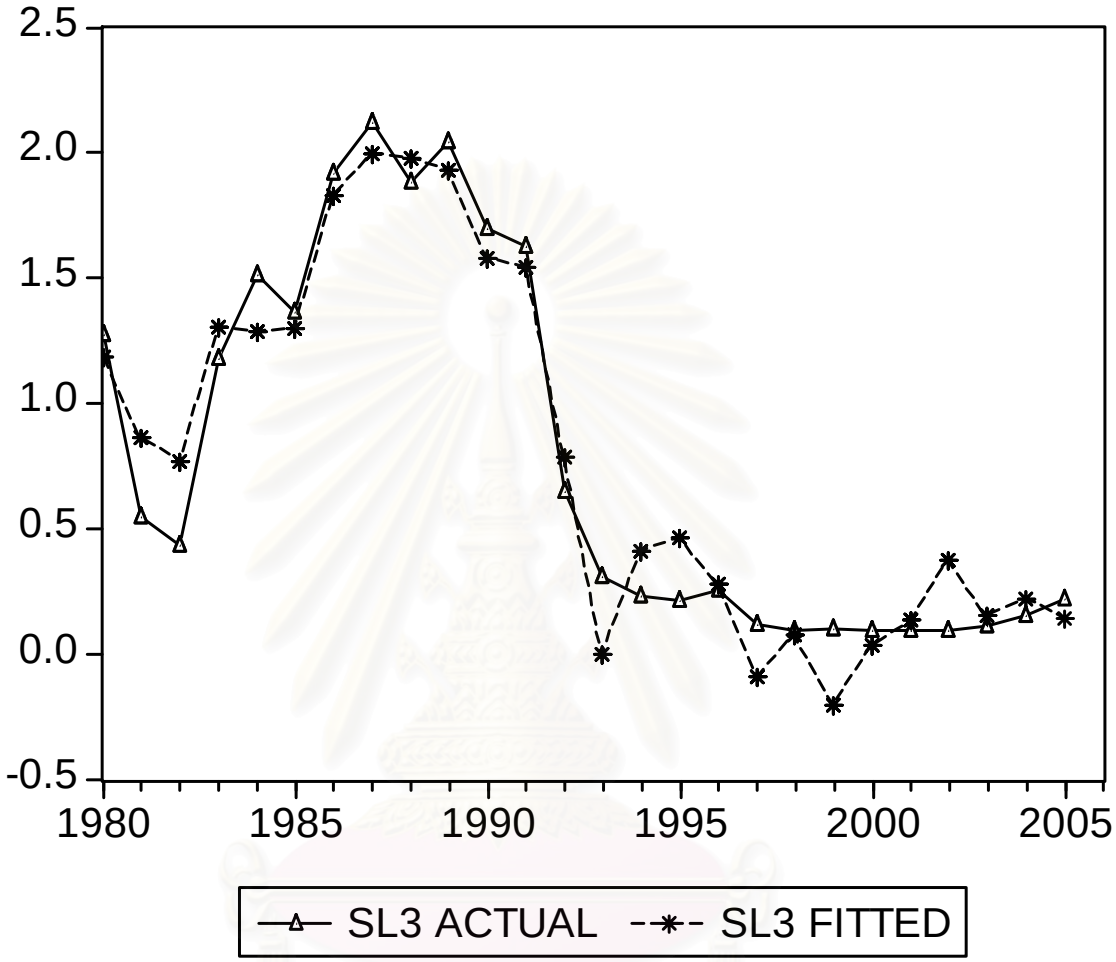


Figure 5.62 Share values of professional labor in the other system

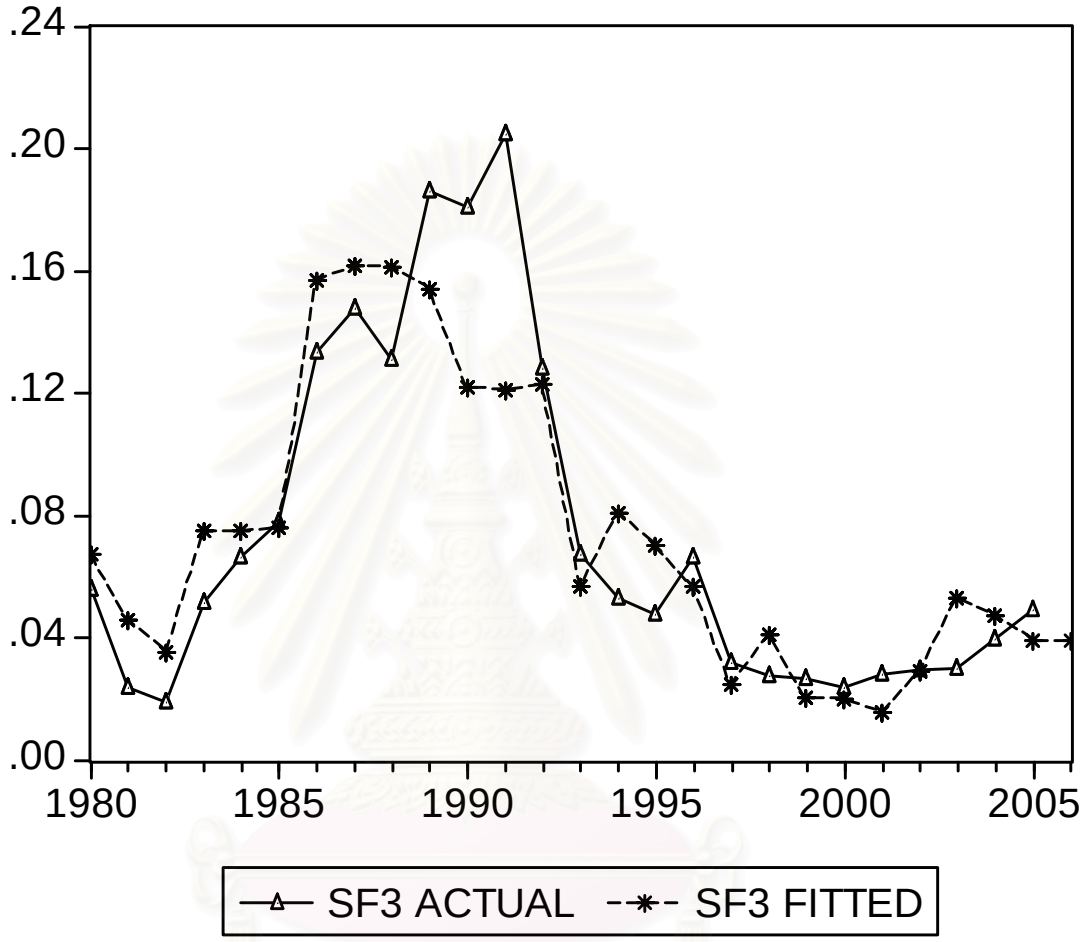


Table 5.7 Summary of coefficient and statistical significant value.

	Pre-Marketing			Post-Marketing			Other System		
Price of Input	sl	sf	sr	sl	sf	sr	sl	sf	sr
PL1	0.0712*	-0.1028*	0.0316						
PF1	-0.1028*	0.0801*	0.0228						
PL2				0.1005*	-0.1420*	0.0415			
PF2				-0.1420*	0.1169*	0.0251			
PL3							0.7031*	0.1528*	-0.8559
PF3							0.1528*	-0.128**	-0.0247
PR	0.0316	0.0228	-0.0544	0.0415	0.0251	-0.0666	-0.8559	-0.0247	0.8806
Output									
Q11	-0.0684*	-0.0527*	0.1211						
Q12	0.0556*	0.0385*	-0.0941						
Q21				-0.0294	-0.0183	0.0477			
Q22				-0.1462*	-0.0789*	0.2251			
Q31							0.07798	0.0075	-0.0855
Q32							-0.7109*	-0.0548*	0.7657
Dummy									
D1	-0.0865*	-0.0637*					-1.0899*		
D2				0.2737*	0.1608*				
D3	0.0791*	0.0631*					-0.7168*		
D4							-0.4705*	-0.0335	
Constant	0.8468	0.5903	-0.4371	2.8117	1.5049	-3.3167	-10.4621	-0.1682	11.6303

* Statistical significance at the 0.05 level
** Statistical significance at the 0.10 level

From summary of the coefficient and statistical significant value in table 5.7, the critical values of t-stat and other statistics value were based on the significant level of 0.05 and 0.10. These indicate the relationship among cost share of input factors and explanatory variable such as its output volume, and reformation event. Notice that the relationship of cost share of input factors and unit price of input factors could not investigate only by its coefficient; it had to further study about price elasticity as shown in section 5.2

Cost function of pre-marketing system

For output aspect, Q11 as the number of manufacturing license approval appear the significantly negative coefficient in labor share equation but positive coefficient in capital share equation. This means that if output of Q11 increase, the cost share of labor will decrease, but cost share of capital will increase. In contrast, Q12 as the number of product registration approval is denoted significantly positive coefficient in labor share equation but negative coefficient in capital share equation. This means that if output of Q12 increase, the cost share of labor will increase, but cost share of capital will decrease. In short, these results imply that Q11 is output that increase capital cost while Q12 is output that increase labor cost.

In additional, the significant dummy variables for pre-marketing cost share function consist of D1 and D3. The coefficient of dummy 1 shows the significantly negative sign in labor share equation. This confirms that decentralization in 1992 significantly decrease cost share of labor. The coefficient of dummy 3 as government budgeting policy reformation in 2003 shows the significantly positive sign. This means that it would tend to increase the cost share of labor. In the other hand, D2 and D4 as establishing OA system in 1997 and economic crisis during 1999-2003, respectively, are not significantly affect to pre-marketing system.

Cost function of post-marketing

For output aspect, Q21 and Q22 as the number of manufacturing inspection and the number of product inspection, respectively, appear the negative coefficient in labor share equation and positive coefficient in capital share equation. This result means that if the output of Q21 or Q22 increase, cost share of labor will decrease, but cost share of capital will increase. In short, these results imply that they are outputs that increase capital cost.

The coefficient of dummy variable for post marketing cost share equation show that D2 is only one dummy variable, which significantly

affect to post marketing system. Dummy 2 as establishing consumer complaint hot-line services in 1997 appears positive coefficient at labor share equation. This implies that this reformation would tend to increase cost share of labor. In contrast, the other dummy variable such as D1, D3 and D4 as decentralization reform in 1992, the organization structure change of post-marketing in 2003, and economic crisis during 1999-2003, respectively, are not significantly affect to post marketing system cost function.

Cost function of other system

For output aspect, Q31 as the number of disseminated topic knowledge to consumer appears insignificantly positive coefficient in labor share equation and negative coefficient in capital share equation. This means that if output of Q31 increase, the cost share of labor will also increase, but cost share of capital will decrease. In contrast, Q32 as the number of research and development appears significantly negative coefficient in labor share equation and positive coefficient in capital share equation. This means that if output of Q32 increase, the cost share of labor will decrease, but cost share of capital will increase. These results imply that Q31 is output increase labor cost while Q32 is output increase capital cost.

The three coefficients of significant dummy variable, including D1, D3 and D4 as the decentralization reform in 1992, government budgeting policy reformation in 2003, and economic crisis during 1997-2003, respectively, in general labor share equation appear negative sign. These results confirm that these reformations significantly tend to decrease cost share of general labor. In contrast, all of dummy variables are not significantly affect to cost share of professional labor.

5.1.2 Elasticity

For the translog cost function, the price elasticities of demand for input factors in term of **Allen elasticity** are particularly simple to compute the parameters have been estimated.

$$\sigma_{ii} = \frac{\gamma_{ii} + s_i (s_i - 1)}{s_i^2}$$

$$\sigma_{ij} = \frac{\gamma_{ij} + s_i s_j}{s_i s_j} \; ; \; i \neq j$$

Notice that, the cross price elasticities themselves are symmetric.

$$\sigma_{ij} = \sigma_{ji}$$

These elasticities will differ at every data point. It is common to compute them at some central point such as the means of the share data.

Table 5.8 Summary of price elasticity value.

Means of Share Data			
	Pre	Post	Other
Sf	0.132001	0.239947	0.074146
SL	0.17443	0.405092	0.781479
Sr	0.693569	0.35496	0.144375

Own Elasticity			
	Pre	Post	Other
εll	-2.39274	-0.85605	0.87157
εff	-1.98061	-1.13659	-35.7843
εrr	-0.55497	-2.34552	36.32148

Cross-Elasticity			
	Pre	Post	Other
εlf	-3.46686	-0.46095	3.637493
εfl	-3.46686	-0.46095	3.637493
εlr	1.261582	1.288556	-6.58578
εrl	1.261582	1.288556	-6.58578
εfr	1.248854	1.29437	-1.31158
εrf	1.248854	1.29437	-1.31158

According to summary of price elasticity value in table 5.8; classified the price elasticity into two groups, including own price elasticity and cross price elasticity of demand for input factors.

The result found that own price elasticity of three input factors appear negative sign in pre-marketing system and post-marketing system, which follow the law of demand. As the result of own price elasticity of demand for three type of input factors in pre-marketing system mean that: the general labor input, increase by 1% of general labor price lead to decreasing in demand for general labor by 2.39%; the professional labor input, increase by 1% professional labor price lead to decreasing in demand for professional labor by 1.98%; the capital input, increase by 1% of capital factor price lead to decreasing in demand for capital factor by 0.05%. As the result of own price elasticity in post-marketing system mean that: the general labor input, increase by 1% of general labor price lead to decreasing in demand for general labor by 0.86%; the professional labor input, increase by 1% professional labor price lead to decreasing in demand for professional labor by 1.14%; the capital input, increase by 1% of capital factor price lead to decreasing in demand for capital factor by 2.35%. As the result of own price elasticity in the other system, it appears negative sign only in professional labor, which follow the law of demand. This means that increase by 1% of professional labor price lead to decreasing in demand for professional labor by 35.78%. Surprisingly, the general labor and capital input factors in the other system appear positive sign, which break the law of demand. These results mean that: the general labor input, increase by 1% general labor price lead to increasing in demand for general labor by 0.87%; the capital input, increase by 1% capital factor price lead to increasing in demand for capital factor by 36.32%. These strange results may be caused from the heterogeneous inputs and outputs of the so called “The Other System.”

For the cross-price elasticity in pre marketing system, the results show that cross price elasticity of the professional and the general labor appear negative sign. This means that if price of either professional or general input factor increase by 1% lead to decreasing in demand for another by 3.47%, which implies that general and professional labors are complementary in pre-marketing system. In contrast, the cross price elasticity of capital input factors and both of the labor factors appear positive sign. The meaning is that if price of either general labor or capital input factor increase by 1% lead to increasing in demand for another by 1.26%, and if price of either professional labor or capital input factor increase by 1% lead to increasing in demand for another by 1.25%. This

result implies that labor and capital input factor are substitution in pre-marketing system.

As the results of the post-marketing system show that cross price elasticity of professional and general labor show negative sign. This mean that if price of either professional or general input factor increase by 1% lead to decreasing in demand for another by 0.46%, which implies that general and professional labors are complementary in post-marketing system. In contrast, the cross price elasticity of capital input factors and both of the labor factors denoted positive sign. The meaning is that if price of either general labor or capital input factor increase by 1% lead to increasing in demand for another by 1.29% and if price of either professional labor or capital input factor increase by 1% lead to increasing in demand for another by 1.29%. This result implies that both of the labor and capital input factors are substitution in post-marketing system.

For the cross-price elasticity in the other system, the results show that cross price elasticity of professional and general labor show positive sign. This mean that if price of either professional or general input factor increase by 1% lead to decreasing in demand for another by 0.46%. This implies that general and professional labors are substitution in the other system. In contrast, the cross price elasticity of capital input factors and both of the labor factors denoted positive sign. The meaning is that if price of either general labor or capital input factor increase by 1% lead to increasing in demand for another by 6.59% and if price of either professional labor or capital input factor increase by 1% lead to increasing demand for another by 1.31%. This result implies that both of the labor and capital input factors are complementary in the other marketing system.

Table 5.9 Statistical Value of share equation in three system of Thai FDA

Parameters	Pre-marketing		Post-marketing		Other system	
	SL	Sf	SL	Sf	SL	Sf
R^2	0.5448967	0.7659898	0.8829499	0.8786621	0.9425982	0.7835252
Adjust R^2	0.4011799	0.6920919	0.8536874	0.8483277	0.9202753	0.7294064
SE. of regression	0.0314245	0.0257673	0.0789613	0.0457838	0.2114814	0.0295103
D.W stat	1.4375023	1.3980999	1.8573714	1.6930578	1.7135112	1.0183438
M dependent V	0.1744301	0.1320006	0.4050925	0.2399472	0.7814792	0.0741461
SD. dependent V	0.0406088	0.0464363	0.2064302	0.1175597	0.7489894	0.0567303
SSR	0.0187625	0.0126151	0.1246976	0.0419231	0.8050387	0.0174172

According to the statistical result value of share equation in table 5.9, we found that R^2 of professional and general labor share equation are different each other. This result implies that the changing of each type of labors is not good proportion to total cost. As a consequence, the highest R^2 value of share equation should be the best representative of fitted cost share of input factors for estimation of the total cost in such system. Because of R^2 indicate the suitability of estimated model in term of the goodness of fit for baseline data.

Through the R^2 of pre-marketing system, professional labor share equation are higher than general labor share equation; therefore, the professional share equation should be the best representative model to calculate total expenditure in pre-marketing system. But post-marketing system, R^2 of professional labor and general labor share equation are not different more. In this study choose the professional share equation to be representative model to calculate total expenditure in post-marketing system because professional labor should have an influence on post marketing activities than general labor. For The other system, the result of fitted cost share of general labor give the negative result of share value, which lead to the variant estimation result. As a result, this study choose the professional labor to be the representative model to calculate total expenditure in other system although R^2 of general labor higher than professional labor.

In summary, the best representative of fitted cost share of input factors, which are employed to calculate fitted total expenditure in all three systems of Thai FDA, are the professional labor share equation.

5.1.3 The simulation of total expenditure in system of FDA in Thailand

The best simulation should be calculated from the fitted value of professional share equation to estimate the fitted total expenditure in each system, regarding the relationship of share equation and total expenditure as below.

$$\Sigma \text{ Exp} = \frac{Pf * Nf}{Sf}$$

Figure 5.10 Total expenditure of pre-marketing system

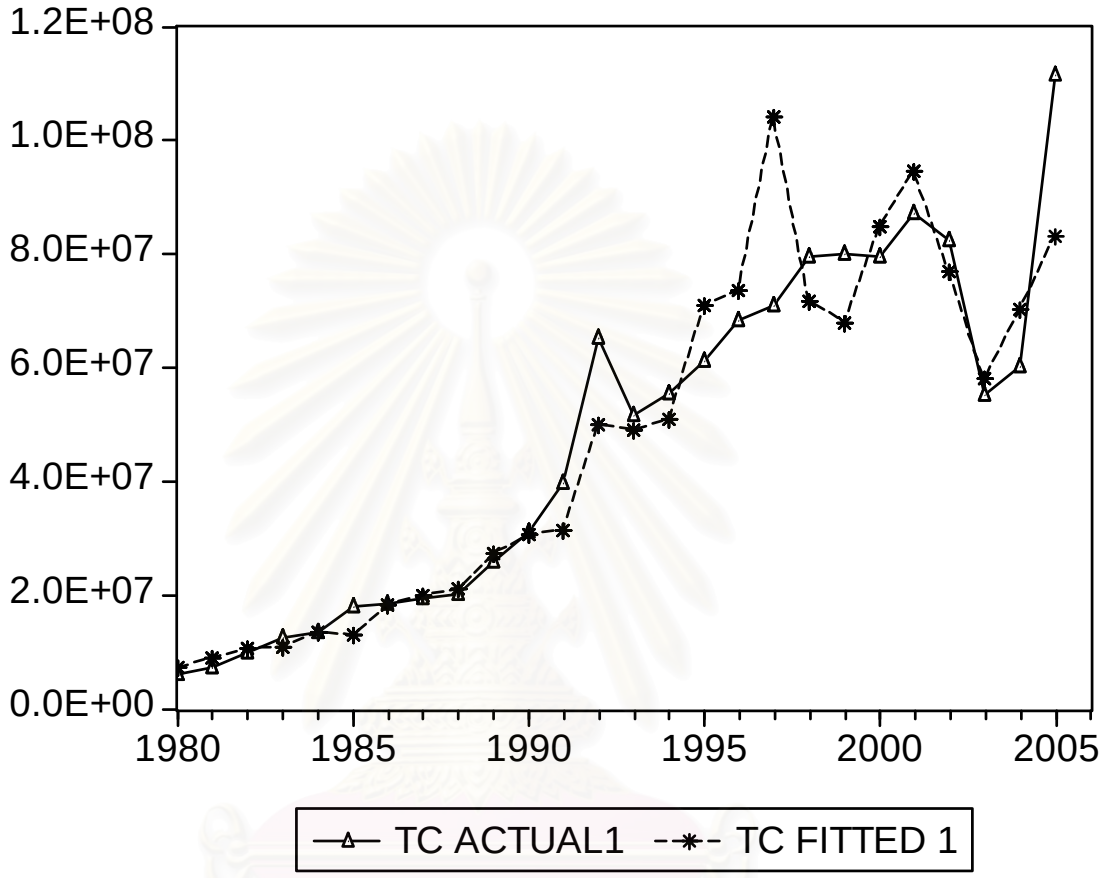


Table 5.10 Numerical comparison of fitted and actual total expenditure in pre-marketing system

OBS	ACTUAL1	FITTED1
1980	6,043,500.00	7,213,478.88
1981	7,337,500.00	8,888,599.79
1982	9,861,500.00	10,714,370.06
1983	12,630,300.00	10,754,963.37
1984	13,533,700.00	13,476,614.35
1985	18,041,800.00	12,967,000.54
1986	18,382,500.00	18,252,692.05
1987	19,397,769.00	19,905,556.32
1988	20,150,887.00	21,170,411.77
1989	25,788,864.00	27,304,085.94
1990	31,062,066.00	30,564,269.00
1991	39,608,570.00	31,338,598.12
1992	65,233,383.00	50,008,078.29
1993	51,542,959.00	48,911,224.30
1994	55,509,288.00	50,935,911.51
1995	61,305,576.00	70,897,399.22
1996	68,245,812.00	73,621,871.42
1997	70,904,816.00	104,121,498.88
1998	79,485,909.00	71,695,323.24
1999	80,153,765.00	67,991,977.04
2000	79,516,836.00	84,743,784.19
2001	87,249,675.00	94,504,049.66
2002	82,497,536.00	76,993,987.18
2003	55,328,206.00	58,186,584.20
2004	60,222,000.00	70,320,243.39
2005	111,490,000.00	83,135,079.39

Figure 5.11 Total expenditure of post-marketing system

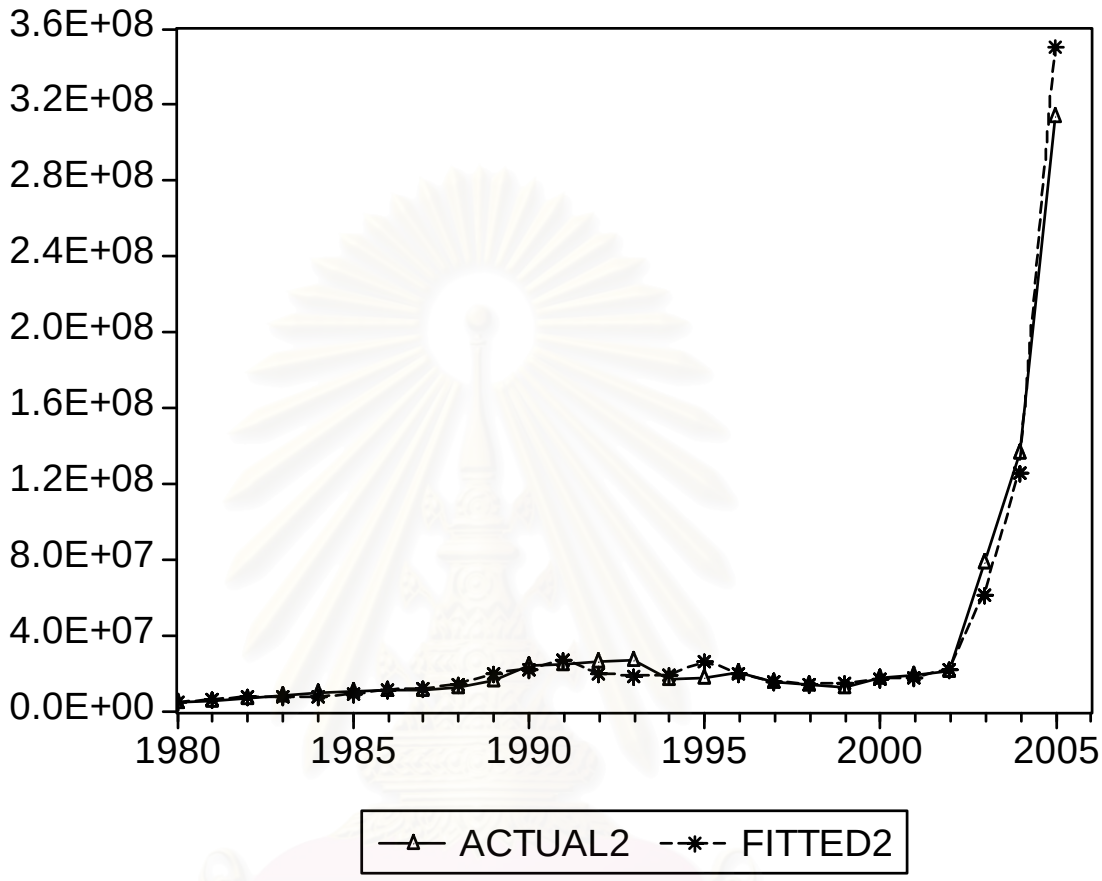


Table 5.11 Numerical comparison of fitted and actual total expenditure in post-marketing system

OBS	ACTUAL2	FITTED2
1980	4,369,300.00	4,916,382.23
1981	5,445,600.00	6,243,770.45
1982	7,146,900.00	7,668,061.53
1983	8,554,100.00	7,225,149.61
1984	9,356,400.00	7,743,196.94
1985	10,282,600.00	9,043,249.73
1986	10,791,800.00	10,758,595.75
1987	11,387,831.00	11,775,783.78
1988	12,533,453.00	13,702,984.17
1989	16,040,164.00	19,476,259.58
1990	24,221,193.00	21,948,377.97
1991	24,998,868.00	26,654,530.47
1992	25,776,542.00	19,367,023.83
1993	27,170,149.00	17,948,172.20
1994	17,057,544.00	19,139,918.71
1995	17,742,768.00	26,247,109.34
1996	20,385,190.00	19,677,508.08
1997	15,339,750.00	15,234,262.37
1998	14,073,451.00	13,748,355.77
1999	12,306,490.00	14,930,079.63
2000	17,648,926.00	16,953,786.58
2001	19,241,532.00	17,339,240.71
2002	21,058,679.00	21,749,057.78
2003	78,639,968.00	61,035,663.93
2004	136,211,000.00	125,412,355.78
2005	313,582,000.00	350,266,913.07

Figure 5.12 Total expenditure of the other system

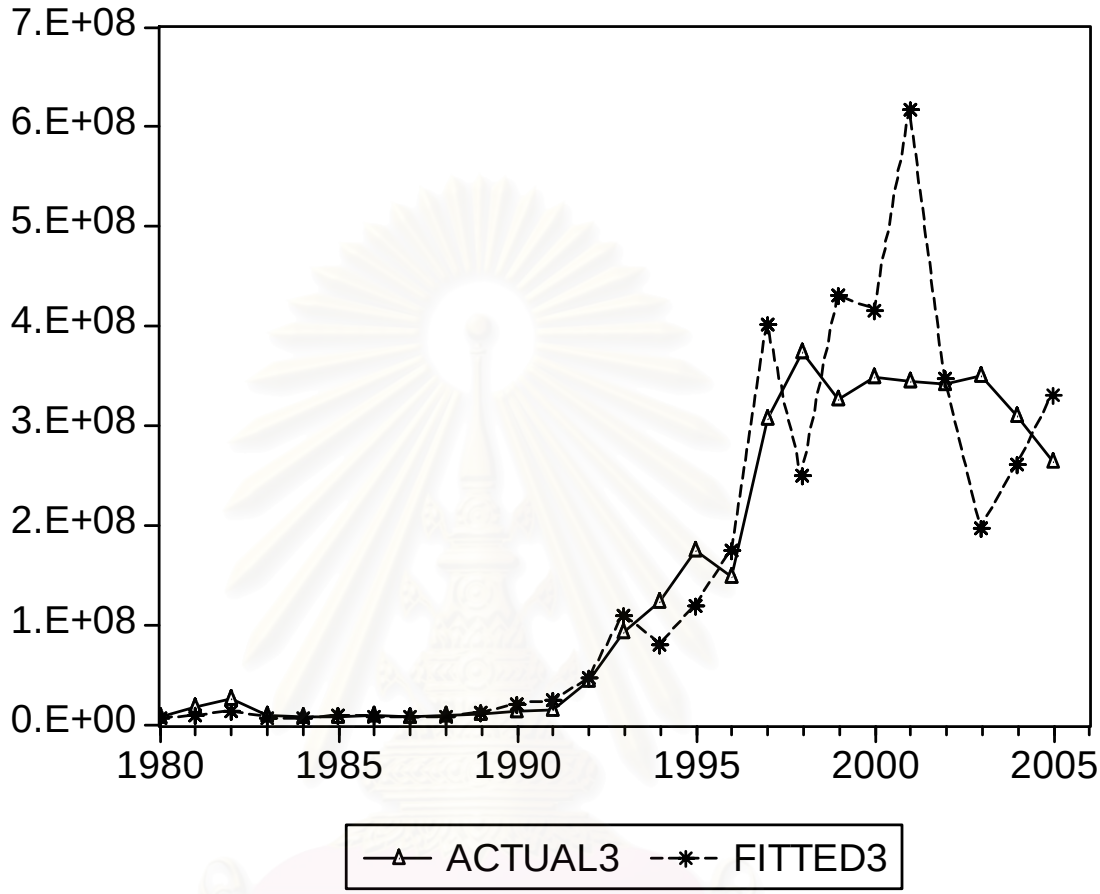


Table 5.12 Numerical comparison of fitted and actual total expenditure in other system

OBS	ACTUAL3	FITTED3
1980	7,391,600.00	6,117,879.14
1981	17,280,360.00	9,038,279.77
1982	25,390,300.00	13,684,174.64
1983	9,323,400.00	6,413,057.81
1984	7,255,500.00	6,418,262.50
1985	8,161,600.00	8,369,945.11
1986	9,095,800.00	7,743,169.99
1987	8,225,500.00	7,514,502.96
1988	9,262,660.00	7,528,982.74
1989	10,275,726.00	12,414,425.04
1990	13,655,441.00	20,293,807.90
1991	14,258,528.00	24,191,941.56
1992	44,184,978.00	46,015,581.80
1993	92,561,463.00	109,587,660.99
1994	122,782,617.00	80,445,646.95
1995	174,495,925.00	119,178,362.07
1996	148,292,415.00	174,324,895.45
1997	307,318,299.00	401,868,671.22
1998	373,487,812.00	250,339,171.22
1999	325,678,495.00	431,221,873.25
2000	348,425,161.00	415,898,310.15
2001	344,699,548.00	617,174,559.50
2002	341,588,406.00	346,693,363.96
2003	350,072,618.00	196,371,821.88
2004	309,996,000.00	261,153,443.51
2005	264,207,000.00	330,734,326.71

5.2 Discussion

In summary, the explanatory variables in this study can be classified in 2 groups: price of inputs and quantity of outputs. The variables with highest statistical significance are the level of unit price of labor input, including professional (P_f) and general (P_L) labor. FDA outputs also showed significant effects on cost in the three systems. Specifically, the empirical results found that the number of manufacturing license approval (Q11), the number of manufacturing inspection (Q21), number of product inspection (Q22) and the number of research and development of consumer health protection (Q32) are outputs that increase cost share of capital factor whereas number of product registration approval (Q12) and the number of disseminated topic knowledge to consumer (Q31) are outputs that increase the cost share of labor factor.

The empirical results show that product registration approval (Q12) and disseminated topic knowledge (Q31) raise the cost share of labor factor. Because these activities ought to use the knowledge and skill of officer personnel to work. In contrast, the manufacturing license approval in pre-marketing system (Q11), manufacturing and product inspection in post-marketing system (Q21,Q22), and research and development activity in other system (Q32) are outputs that increase the cost share of capital factor. One possible explanation is that the manufacturing approval activity, the post-marketing inspection activity and research & development activity are field work, which often requires vehicles, a large component of capital costs.

These models also include 4 dummy variables representing event of organization reformation, used for cost function estimation.

Dummy variable D1 refers to decentralization, when some jobs were delegated to provincial health offices in 1992. This variable demonstrates a significantly negative sign in pre-marketing and the other system cost functions, indicating that it decreases the cost share of labor. Shifting of non serious tasks to the provincial level might decrease expenditure, especially to approve plant layout of local manufacturers and to disseminate knowledge about health products through exhibitions and distribution of printed materials to consumers in local areas.

Dummy variable D2 represents the set-up of an intra-network of office automation system and establishing consumer complaint hot-line services in 1997. The information technology reformation brought about the provision of IT infrastructure such as hardware, software and intra-network servers to take care of the technical staff. This reform appears

insignificant to expenditure of pre-marketing and other system. However, the prior hypothesis was that IT reform would affect pre-marketing and the other system, which work in office. This is expected that IT reformation should lead to decreased cost share of labor and increase a higher cost share of capital. The study demonstrates that only the other system follows this assumption, reducing labor cost share, probably though reduction of administrative tasks. But the pre-marketing system did not follow the earlier hypothesis because approval activities have to use the knowledge and skill of specialists for work. Consequently, IT reform cannot decrease cost share of labor in pre-marketing system. The other reformation in 1997 was the establishment of a consumer complaint hot-line service. This service allowed consumers who suffer harm from using health product can file a complaint to FDA center. The complaint will be forwarded to the post-marketing to inspect the quality and safety of the suspected health product with the specific aim of investigating and gathering evidence necessary for legal action. Accordingly, this reform significantly increases cost share of labor in post marketing system.

The dummy variable D3 represents Government budgeting policy reform by introducing the PBBS system, as well as structural organization of FDA reform in 2003. The effect of government policy such as PBBS policy is expected to motivate public sectors to improve their output performance to meet the challenge target. At present, the pre-marketing system was faced with the crucial problem of work overload, which brings about delayed product approval and lower output performance. As a result, FDA had to increase the number of personal officers, especially newly graduated pharmacists and insists that current employees work harder to improve their output performance in order to achieve the challenge target. As a result, this reform significantly increases cost share of labor in pre-marketing system. Under government budgeting policy reform, FDA tries to amend and revise strict regulations and get rid of the complicated process in order to improve efficiency, productivity and flexibility. This adaptation tends to significantly decrease the cost share of labor in other system. Another reform in 2003 was the post-marketing structure reform, combining health product control function, and sharing resources to improve efficiency and productivity; therefore, this reform affect to insignificantly reduce cost share of labor in post marketing system.

The dummy variable D4, Thailand economic crisis affected government budget by immediately reducing total cost of Thai FDA during 1999-2003. This external factor impacted total cost of Thai FDA, especially in other system, which indicated a significant decrease in the cost share of general labor input factor.

The price elasticity of demand for input factor showed several interesting results. The own price elasticity of pre-marketing system and post-marketing system, or the demand for its input factors, including general labor, professional labor and capital input factors follow the law of demand, which states that if price of input factor increases, demand for such input factors will decrease. In contrast the other system, only professional labor input factor follows the law of demand, but it is broken in general labor and capital input factor. On the other hand, the cross price elasticity perspective has prior hypothesis that the general labor and professional labor should to be complementary, but both of the labor input factor and capital input factor are substitutionary. The empirical study found that pre-marketing system and post-marketing system follow prior assumption. In contrast the empirical result found that the cross price elasticity of the other system does not follow this hypothesis: not only are in general labor and professional labor substitutionary, but also the cross price elasticity of capital input factor and the labor price input factors are complementary. The surprising result of price elasticity of demand for input factors in the other system might be explained that the public sector characteristic; wage rate is set and fixed by the government. Although, the government raises the wage rate, the employment still can grow further due to the increasing demand for them. The exception is for professional labor when the wage rate is quite competitive.

According to statistical values in Table 5.5, R^2 value in each system indicates that professional share equations are 77%, 88%, and 78%, respectively. This mean that the model is fitted quite well. The high value of these R^2 values demonstrates the most accurate representation of actual costs share of input factors and thus should be used to estimate total expenditure of pre-marketing, post-marketing and the other systems. In other words, the high R^2 means that the variables on the right hand side of equation are quite good determinants of labor share of expenditure in each system and can be further utilized to estimate total costs. It is important to recognize several limitations and weaknesses of this study, which may have a significant affect on the reliance of the explored cost functions and variance of empirical result. First of all, this study used the most measurable data in only 26 observations of annual data available on Thai FDA, accounted a few observations for analysis cost functions. Second, the outputs employed in this study are not homogeneous output, combining from several kinds of service activities, for example product controlling, label controlling, and advertisement controlling. Moreover, different types of drugs differ in the drug registration, which incurs significant difference in cost spending, especially, between new drug registration and generic

drug registration as shown in appendix B. Unfortunately, the annual report of Thai FDA is only one source of information for this study and the available data in these sources can not avoid these limitations.

In addition, it should be noted that the general labor cost share equation in the other system swang too extreme: presented negative cost share value in 1993, 1997 and 1999; and cost share value greater than one during 1983-1991 (Figure 5.61). Moreover, the price elasticity of demand for input factors in this system showed an inconsistent result, contradicting predictions based on economic theory. This strange result likely originated from the weakness of raw data in the other system. First, the other function combined the public education and supporting systems together to solve the problem of cost data missing during 1986-1991. Next, the outputs in other system, including number of disseminated topic knowledge to consumer per year (Q31) and number of research and development per year (Q32), employed in this study are not representative of all outputs in the other activities, noticed from the low statistical significance. Finally, the available data for the two output used in other system were not available in every period of the time series, 1980-2005. As result, the researcher had to use the relationship between total expenditure of other system and its output performance to estimate the values of missing outputs data, during 1980-1991.

The final aim of this study is to focus on the possible policy implications. The empirical results found that the product registration approval output in pre-marketing will increase labor cost share. This implies that if FDA would like to increase such output to achieve a challenge target, FDA has to increase budget allocated to labor in product registration approval activity. On the other hand, the approval of manufacturing license in pre-marketing, the inspection of manufacturing and product in post-marketing are outputs that increase capital cost share. This implies that if FDA would like to increase these outputs to reach the target challenge, FDA has increase capital investment budget in such activities. In summary, FDA should concentrate on how to allocate the budget to achieve efficient allocation by increasing budgets for input factors in the different proportions. In practice, however, FDA allocates personnel to work for pre-marketing and post marketing system at the same proportion; therefore, this might not be the most efficient allocation. The inefficient allocation might be cause of existing problem, which is lack of personnel and work overloads in product registration approval of pre-marketing system. The suggestion from this empirical study is that if FDA wants to increase the whole output, FDA should allocate its budget of capital factor to activities, which produce the outputs of manufacturing approval, manufacturing inspection and also product inspection. It can then

shift labor input factors to product registration approval activities. The allocation recommendation obtained from this cost function can help to improve efficient allocation and also achieve the advance output performance, based on optimal utilization of limited resources.

CHAPTER VI

CONCLUSION

6.1 Conclusion

The aim of this study is to construct and estimate the cost function of Thailand FDA to allocate resources efficiently for the future financial plan. As a result of the government's budget reforms through the introduction of PBBS, the public sector is motivated to make their financial plans to be transparent and accountable, and to further improve efficiency and productivity. Accordingly, FDA can utilize the cost function presented in this study to estimate total expenditure at approximately optimal budget forecasts; moreover, it paves the way for adopting policy of financial improvement to allocate resources efficiently in order to reduce cost and also advance efficiency and productivity.

The cost function analysis in this study employs time series data during 1980-2005, to define cost functions for the three systems, including pre-marketing system, post-marketing system and the other system, combining public education system and supporting system. Two basic groups of explanatory variables required to estimate the total cost functions include output volume and input prices. The main systems in Thai FDA produce several types of outputs: the pre-marketing system, output available consist of the number of manufacturing license approval and number of product registration approval; in parallel, the post marketing system consist of the number of manufacturing inspection and number of product inspection; the output variables public education system being the number of disseminated topic knowledge to consumer. All forms of output have been formally designated in organization strategic plan of Thai FDA as performance measures, used to defend annual budget under the PBBS policy. However, the aim of this study is to estimate annual total expenditure; therefore, the study could not disregard other supporting system which assist and support main systems to achieve the organization's targets. The other supporting systems have diverse output categories; therefore, this study selects the best significant relationship with cost spending, which is the number of research and development of consumer health protection. On the other hand, this study divided labor input factors into general labor and professional labor, complying with officials holding position of C1-C7 and C8-C11; therefore, unit price would be salary and salary plus fringe benefit, respectively. Another input factor is capital input; employed the average saving deposits rate being

price of capital input to represent opportunity cost of the investment. In addition this study also includes dummy variable representing reforms impacting expenditure and spending patterns of the organization: decentralization reform in 1992; IT reforms and the establishing consumer complaint hot-line services in 1997; government budgeting policy reforms as well as organization structure reform in 2003; and the impact of the economic crisis on budgets of Thai FDA during 1999-2003. This study includes all three types of variables: output volume, input price and also dummy variable to be the explanatory variable of cost function of Thailand FDA.

The cost function analysis of Thai FDA in this paper, employed translog cost function model as the most flexible model and Seemingly Unrelated Regression Estimation (SURE) method to obtain efficiency. This approach must have been the best estimation method, used to estimate simultaneous-equation of three system cost function in Thai FDA. The statistical result of R^2 value of simulation cost function in pre-marketing system, post-marketing system, and the other system, indicated through a goodness of fit of 77%, 88%, and 78%, respectively. This means that the variables on the right hand side of equation are quite good determinants of and can be used to estimate total expenditure in each system. However, it is worth to recognize the existent limitations in this study. Too few observations of the data in 26 annual data available in FDA annual report. Output category especially, in pre and post marketing system are not homogeneous, combining different kind of service activities, i.e. product controlling, label controlling and advertisement controlling. Moreover, pre-marketing activity of drug registration has different process of application which yields to different cost spending, especially, new drug registration and generic drug registration. Unfortunately, the available data for study cannot avoid this limitation.

In summary, this investigation of the relationship between cost share input and output performance found that the product registration approval output will increase labor cost share. In contrast, the manufacturing license approval, the manufacturing and product inspection will increase capital cost share. As a consequence, FDA should to concentrate about how to allocate the input factor to achieve efficient allocation by increasing budget for input factor at the different proportion. In practice, though, FDA allocates personnel to work for pre-marketing and post marketing system in similar proportions. Therefore, this unsuited allocation may lead to a lack of personal and task overload in product approval of pre-marketing system.

6.2 Implications for Policy Implementation

The empirical results in this study discovered that Thai FDA has problem of inefficiently resources allocation. The suggestion from this study is that FDA should allocate the budget for capital factor to activities that produce manufacturing approval, manufacturing inspection and product inspection, and then shifting labor inputs to the product registration approval activities. The allocation recommendation obtained from this cost function can help to improve efficient allocation and also achieve the advance output performance, based on optimal utilization of limited resources.

6.3 Recommendation for Further Studies

In order to gain more knowledge to adopt a policy to improve efficiency, effectiveness and productivity, future research should focus on the following suggestions.

1) The limitation of this study is that it is important to recognize that reliance on even the best data may be somewhat problematic for the purpose of consistent forecasting of total expenditure. Future research should alleviate this shortcoming of this study and improve the quality of data when better information is available.

2) The results of this study may no longer be relevant in the future; ongoing change in the current situation may limit the generalizability of the findings presented in this paper. The related trends in demand and supply sides of health product regulation have become challenge for the government sector to cope with unexpected circumstance of increasingly competitive market, which leads to a higher variety and more complex health products available in the market, oriented nature of demand side and the paradigm shifted to reformation of public sectors as supply agency to provide services, regarding efficiency, effectiveness and productivity. Future studies should examine in other component, especially the internal and external factors affecting the cost function of Thai FDA

3) The study area in the managerial capacity of Thai FDA is able to utilize the limited available resources to maximize its outputs within the minimum levels of expenditure. Some interesting issues such as analysis of economies of scale, economies of scope, efficiency and productivity could evolved from the cost function of the FDA in Thailand.

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APPENDICES

OVERVIEW OF THAILAND

FOOD AND DRUG ADMINISTRATION

Thailand Food and Drug Administration is the principle organization in Thailand for public health protection by ensuring the efficacy, quality and safety of health products and by promoting proper consumer behavior through reliable scientific evidence and appropriate technology. The functions and responsibilities of each division of the FDA are defined on the basis of a specialist area or control of a specific category of product. Some activities may need cooperation between divisions or departments in order to achieve FDA objectives

Vision

"By the year 2007, the FDA will be the principal and most trusted organization in Thailand in public health protection by ensuring the quality and safety of health products and promoting proper consumer behavior through reliable scientific evidence and appropriate technology"

Mission

- To regulate and monitor health products to meet quality and efficacy standards.

- To promote Good Manufacturing Practice in the production and quality control of health products to ensure consumer safety and to encourage exports.

- To research and develop the effectiveness of the consumer protection system for health products.

- To promote and support the capability of health product consumers and society to be able to protect themselves and be self-reliant.

- To encourage and enable all stakeholders and non-government parties to share in the consumer protection role.

Historical Background

The protection of consumer's health in Thailand can be traced back as far as 1909 when there was concerned about counterfeit and contaminated products. The agencies which were subsequently established have been

transformed many times along the way, and the scope of their responsibilities has been broadened to keep pace with contemporary needs

Below is a summary of some key events which occurred prior the birth of the Thai Food and Drug Administration (Thai FDA):

- In 1922, the Narcotics Act was promulgated. This was the occasion of the establishment of the Narcotic Division, which was then under the Public Health Department, Ministry of the Interior.

- In 1937, the Narcotics Division was restructured and renamed the Food and Drug Division.

- In 1942, the Consumer Support Division, a division of the Department of Public Welfare, was integrated with the Food and Drug Division. There were three sub-divisions in this new structure: Food, Drugs, and Statistics and Registration.

- In 1953, the Food and Drug Division was transferred to the Office of the Permanent Secretary, Ministry of Public Health. The name of the division was changed to the Food and Drug Control Division.

- In 1972, the Food and Drug Control Division was transferred as a division under the Department of Health Promotion and the Regional Inspection Subdivision was established

- In 1974, a major change took place: the Food and Drug Control Division was promoted to become a department and named the Food and Drug Administration. The new organization was originally divided into eight divisions: Food Control, Drug Control, Cosmetics Control, Narcotics Control, Inspection, Technical, Public Relations and Advertising Control, and the Office of the Secretary.

- In 1985, the Legal Affairs Task Group, which was formerly under the Office of the Secretary, was established directly under the FDA Secretary-General.

- In 1990, two new divisions were set up. They were the Medical Devices Control Division and the Toxic Substances Control Division.

- In 1992, there were 10 divisions: Food Control, Drug Control, Cosmetics Control, Toxic Substances Control, Narcotics Control, Inspection, Technical, Medical Devices Control, Public Relations and Advertising Control, and the Office of the Secretary. There were also

three small internal entities: the Legal Affairs Task Group, the Rural Consumer Health Protection Promotion Group and the Office of Experts.

From 2003 to the present, in order to streamline working processes in line with government policy, the FDA has been restructured into nine divisions, one bureau and six small entities as described in the following section.

Organization Structure

Currently, the Thai FDA is under the cluster of Public Health Service Support under the Ministry of Public Health. This is a group of departments working on an integrated program in order to achieve greater efficiency and effectiveness. The Cluster of Public Health Service Support comprises three departments: the FDA, Health Service Support and Medical Sciences as described in Chart 1.

The infrastructure of the Thai FDA as shown in Chart 2, officially consists of two main groups. First, the Health Product Control Division group consists of the Bureau of Cosmetic and Hazardous Substances Control, and five other divisions: Drug Control, Food Control, Medical Devices Control, Narcotics Control and Import and Export Inspection.

Secondly, the Support Division group consists of three divisions: Public and Consumer Affairs, Rural and Local Consumer Health Products Protection Promotion, Technical and Planning, and the Office of the Secretary. In addition, six internal units have been established to perform particular tasks: Information Technology Center; Food and Drug Legal Group; Public Sector Development Group; Internal Audit Group; Complementary Health Product Group, and Community Health Product Quality Improvement Coordinating Center.

Roles and responsibilities

The main role of the Thai FDA is to protect consumers health, especially, to ensure safety, quality and efficacy of health products within its remit. These include: foods, drugs, psychotropic substances, narcotics, medical devices, volatile substances, cosmetics and hazardous substances available in the country. This has to be implemented in accordance with national legislation and international agreements as follows:

1. Drug Act, B.E. 2510 (1967)

2. Psychotropic Substances Act B.E. 2518 (1975)

3. Food Act, B.E. 2522 (1979)
4. Narcotics Act, B.E. 2522 (1979)
5. Medical Devices Act, B.E. 2531 (1988)
6. The Emergency Decree on Prevention of Abuse of Volatile Substances, B.E. 2533 (1990)
7. Cosmetics Act, B.E. 2535 (1992)
8. Hazardous Substances Act, B.E. 2535 (1992)
9. The Single Convention on Narcotic Drugs 1961, commentary on the protocol amended in Geneva on March 25, 1972.
10. The International Convention on Psychotropic Substances, 1971.
11. The International Code on Marketing of Breast Milk Substitute, 1981
12. The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

By law, certain important issues are decided by committees, whose members, all experts in their fields, are appointed by the Minister of Public Health. Currently, there are six committees: Drugs, Food, Cosmetics, Narcotics, Psychotropic Substances and Medical Devices.

There are two committees whose members are appointed by the other ministries. They are the Committee on the Prevention of Abuse of Volatile Substances appointed by two ministers (Industry and Public Health), and the Hazardous Substance Committee appointed by three ministers (Public Health, Industry and Agriculture).

At the national level, the Cabinet appoints three committees: the National Drug Committee, the National Food Committee and the National Chemical Safety Committee. The national committees are mainly assigned policy and development issues and collaborative action with other agencies to facilitate the implementation of the food, drug and chemical safety program as well as the control system.

The overview of function of system of the Thai FDA

The function and responsibilities of Thai FDA may be grouped into two main areas:

1. The Health Product Control Function ; is the main function of consumer protection of Thai FDA, consists of three main functions.

1.1 Pre Marketing System

The aim of activity in pre-marketing system includes control of manufacturing facilities, product quality and advertising before product-launch to the market. In each case, compliance is required with the relevant legislation and regulations. The procedures for such operations are the following:

Product Registration

If a health product, either manufactured or imported, is categorized as the specially-controlled health product, it must be registered. Analyses of the product as well as details of the process and ingredients are required for the registration process. Furthermore, the standard of these health products has to meet the standards specified in the Ministerial Notifications.

Labeling

Health product labeling can be a useful mean to inform consumers about the health products and to provide an opportunity of choice for consumers, mislabeling of health products may deceive and even endanger consumers. The principles of health product labeling control are to make sure that the content on the label is correct and concise, causes no confusion to the consumer, or does not mislead the consumer.

Advertisements

An advertisement has provisions concerning advertisements in two aspects. First is false or deceptive advertising of the quality, usefulness, or indication of the product is prohibited. Second is Advertisement of qualities, usefulness, or indication of the product by any means for business purposes must submit the sound, pictures or films or text of the advertisement to the authority for consideration and getting an approval. Therefore, health product advertisements must be correct and reliance.

Importation Licence

A licence is required for the import of health product into Thailand A licensed importer may import various kinds of health product providing

that they are approved by the Thai FDA. The designated storage or warehouse has to be inspected and approved by the Thai FDA before a licence is issued. The importation licence is to be renewed every three years as well.

Manufacturing Licence

The plant layout is to be submitted for approval. The plant inspection by a health product inspector is required before the manufacturing licence is issued. The licence is to be renewed every three years.

Good Manufacturing Practices (GMP)

Health product hygiene and good practices in the manufacturing process would provide a safe health product and ensure the quality of health product as a protective measure. Several technical training courses have been conducted and technical information services are in progress.

Technical Supporting in Pre-Marketing System

The FDA has conducted many interesting seminars and workshops, with participants from both public and private sectors. On the other hand, officials from the Thai FDA are sent to join seminars and conferences, both local and abroad. As a result, with a widened perspective, they can work more effectively at home. The Good Manufacturing Practice (GMP) program is another example demonstrating successful cooperation with other organizations, in this case, with universities and drug manufacturers. In relation to cooperation in terms of research and development, the FDA is continually supportive of such endeavor, and some research projects are partly or wholly funded by the agency.

1.2 Post Marketing System

The aim of activity in post-marketing system is to investigate manufacturing facilities and product quality and to ensure that they maintain compliance with previously-approved national health product standards and with legislation and regulations. For example, samples of products are regularly inspected and taken to check for compliance and quality. Previously-approved products are revisited periodically to ascertain the consistency of manufacturing and product standards over time. As a result, this measure deals primarily with the activities of enforcement. Inspections of all health product factories and premises throughout the country have been conducted regularly, together with the sampling of health products for analysis and assaying to ensure compliance with legal requirements. In case of violations, actions like seizure, recall, and prosecution are taken. In general, there are two types of inspections:

Regular Inspection

This is a planned inspection to ensure that the FDA annual plan on health product is implemented successfully.

- Routine Inspection. This is a periodic inspection particularly to the premises that received licences.

- Follow-up Inspection. This is to confirm that the certain corrective actions by the licence-holders or firms have been taken as indicated after the previous inspection.

- Check Point Inspection. This is done by the health product inspectors stationed at the Check Points to ensure the safety of health products entering the country and the compliance with the relevant regulations.

Suspected or Petitioned Inspection

- This is a particular type of inspection with a specific aim of investigating and gathering necessary evidence for legal action.

- This includes an inspection to find out the cause of complaint or rejection from the importing country, so as to solve the problems of health product manufacturers and health product products.

The Department of Medical Sciences, Ministry of Public Health, provides health product analytical services for all health product control activities of Food and Drug Administration.

Other Activities

For the purpose of administration and facilitating the implementation of health product control activities, the system development subdivision plays an important role as an administrator and facilitator for the establishment and development of law and regulations, human resource development, international cooperation and information services. Furthermore, the development of policies and plans for health product safety has become a major concern of the health product control measures.

The law and regulations have been promulgated and revised regularly. Therefore, a clarification process has to be undertaken, such as informing the public and government personnel of the details and

requirements of the regulations, the implementation period, etc. In addition, training courses have been conducted in order to increase the capability of personnel to perform precisely according to the regulations.

The international activities include international meetings on health product standards; and bilateral as well as multilateral agreements become more important for the health product industries and trade. The Health product Control Division, as the regulatory body, has to facilitate and participate in the international forums for negotiation with other countries on health product standards or other related aspects.

Apart from this, the Health product Control Division also collaborates with other countries for consumer protection, for example, in the Strengthening of Health product Sanitation Program, which is supported by the Japanese International Cooperation Agency. The Health product Sanitation Training Program (2000–2005) is being implemented in order to develop the health product safety in the neighboring countries, i.e. Lao PDR, Cambodia , Myanmar , and Vietnam .

Technical Supporting in Post-Marketing System

Surveillance program for consumers' safety; the aim of this Program is to detect any adverse effects or unexpected outcomes from consumer use of products. Research and epidemiological data on adverse effects, including technical information, is collected, summarized, interpreted and reported. There are also operational centers, such as the Adverse Product Reaction Monitoring Center (APRMC) and the International Program on Chemical Safety (IPCS). Information is exchanged with other agencies at local and international level.

1.3 Public Education System

Consumer Education

Consumers are supplied with sufficient, accurate information to enable them to choose products wisely. Access to such information, provided by the FDA, is available from many sources: television, radio, newspaper, leaflets, internet, and so on. FDA’s campaigns on priority topics have been regularly conducted in department stores, schools and villages in many parts of the country. There are many sources for consumers to use so that they can obtain further useful information and be in a better position to protect themselves.

Each year, FDA has regularly provided knowledge about health product through mass media. The TV programs or spots, radio programs or

spots are duplicated and distributed to institutes or agencies as their requests. Printing materials i.e. poster, pamphlet and handout have been continually produced to support the Provincial Health Office activities and also distribute to serve people needs. Furthermore, exhibition sets are also prepared for lending or distributing as requested.

There are 5 projects that were successfully conducted:

- Reading Label Before Purchasing Project
- Raising Awareness to Protect Consumer's Rights Project
- Reading Nutrition Label Project
- Health product Safety Project
- FDA Consumer Hotline 1556 Project.

The objectives of these projects are to enhance people knowledge, to boost their safely consumption behavior, and to strengthen their capability to protect themselves from unsafe health product and fraudulent claims. The target group is varied each year such as students, housewives, or workers. The appropriate activities and media are utilized for each target group.

Public Relations

FDA has kept good mutual understanding with the staffs and consumers through various communication media. The intercom, monthly journal, and public relations boards are used for communicating with internal people, while press releases and press conferences are continually performed to inform the public of FDA activities, or to raise public awareness of unsafe health products. All the press releases will also be posted to FDA website that people can get an access of the information conveniently. The Pro-active Public Relations Project is to hold each year to publicize the needed information for consumers and entrepreneurs concerned.

The objective of public relations is to enhance the knowledge and understanding of health product to the concerned groups i.e. consumers, stakeholder’s entrepreneurs, mass media, and others to make them feel confident in consumer protection activities of FDA and voluntarily support the activities.

Consumer Complaint Services

FDA has established Complaint Service Center which is located at Public and Consumer Affairs Division. Consumers who get an unfair treat by using health products can file a complaint by many ways through:

- Telephone number 0-2590-7354-5 and 0-2590-7000 ext. 6
- (recorded after working hour)
- Facsimile number 0-2591-8472
- Leaving message at FDA Hotline number 1556 ext. 1005
- Mailing at P.O. Box 52 Nonthaburi 11000
- Sending e-mail to prac@fda.moph.go.th

The complaint will be forwarded to responsible agencies both inside and outside FDA such as Provincial Health Office, Consumer Protection Board, and Bangkok Metropolitan Administration etc.

The overview of divisions in Thailand FDA

The divisions of Thai FDA may be classified into two main groups: Health product control division group and supporting division group

1. The Health Product Control Division group; consists of the Bureau of Cosmetic and Hazardous Substances Control, and five other divisions: Drug Control, Food Control, Medical Devices Control, Narcotics Control and Import and Export Inspection.

1.1 Drug Control Division

The Drug Control Division has set a vision as an institute with reliability and good reputation in consumer protection. The public is thus assured of accessibility to safe and efficacious marketed pharmaceutical products of standard quality, to reliable and adequate information, and to advance technology. The Division promotes the production capacity of local pharmaceutical industries to the extent that they are able to export medicines of standard quality.

The Division carries out its mission in consultation or cooperation with experts in science, medicine, pharmacy and public health, consumers,

manufacturers, importers, distributors and retailers of drugs. It works closely with several other organizations (e.g. universities, industries, hospitals, health-care professional groups, consumer groups, other relevant agencies and foreign governments) in the drug development and review processes.

Historical Background of Drug Control Division

The regulation of pharmaceutical products in Thailand began in 1909 when the adulteration of drug products and narcotic substances was prohibited. There had been practically no control of drugs before 1909. The first legislation promulgated in 1922 was the Harmful and Habit-forming Drugs Act. However, the duties for manufacturing and dispensing medicines were not assigned to pharmacists until 1929.

The manufacture and sale of alcoholic preparations containing indigenous medicinal herbs became more and more extensive until the widespread use caught the attention of the Medical Association of Thailand. The problems eventually led to the promulgation of the Sales of Drugs Act in B.E. 2479 (1936). The first legislative measure implemented in the field of pharmaceutical regulation dealt only with sale practices regardless of formulas or ingredients. At that time, neither manufacturers nor importers/retailers paid much attention or assumed their responsibilities to quality and safety of their drug products.

The improvement in pharmaceutical regulation in Thailand was observed after the Sales of Drugs Act of B.E. 2493 (1950) came into force in 1951. The Act encompassed many aspects of drug control other than the control of sale practices. For instance, the control of production and registration of pharmaceutical products as well as the standard requirements of drug quality were included in the Act.

The Act eliminated substandard, deteriorated and adulterated drug products on the local market. Consequently, manufacturing standards of local pharmaceutical firms and dispensaries were upgraded to some extent. The Act was applicable not only to production, importation and sale practices, but also to product registration, labeling requirements and pharmaceutical advertisement control. A few amendments to the Sales of Drugs Act were undertaken from time to time in order to make the law up to date and to cope with changing circumstances in the pharmaceutical business.

After several years of endeavor, the Drug Act of B.E. 2510 (1967) was promulgated to supersede the 1950 Sales of Drugs Act. The 1967 Drug Act covering substantial aspects in drug regulation was enforced for almost two decades. There were four amendments to the Act to cope with

the growing numbers of pharmaceutical manufacturers and changing situations until the enactment of the Drug Act of B.E. 2530 (1987), which has major features as follows:

1. Medicines are classified into two major groups: modern and traditional drugs .

Modern Drugs are further divided into four categories, namely 1) household remedies whose sales require no licence; 2) ready-packed drugs that can be sold in drugstores by nurses or other medical professionals; 3) dangerous drugs; and 4) specially controlled drugs. Dangerous drugs can be bought without a prescription but must be dispensed by pharmacists. Drugs which may possess a potentially harmful effect on health, if misused, will be listed in the last category whose sales require a prescription.

Traditional drugs are those intended to be used in indigenous or traditional medical care as monographed in the official pharmacopoeia of traditional medicines or those declared by the Minister of Public Health as traditional medicines or those permitted to be registered as traditional medicines. The control and registration of drugs in this group are less stringent than those for modern drugs.

2. The Ministry of Public Health is authorized to publish in the Government Gazette a list of specially-controlled products, a list of dangerous drugs as well as the lists of particular drugs requiring additional labeling (e.g. expiration date, warning, etc.)

3. Licensing for manufacture, importation and sale of pharmaceutical products is required by law. Applications for licences are to be conducted in accordance with the rules, measures and conditions prescribed in the Ministerial Regulations.

4. Duties of licensees and pharmacists at the place of production, importation or sale are also described. For instance, a licensee who manufactures modern drugs must have finished products of each batch analyzed for quantities of their active constituents before the products are released to the market.

5. Licensees must register their products before manufacture or importation. Details of the products and their formulas, as being registered, cannot be altered without prior approval or permission from the authorities.

6. The Minister of Public Health is empowered to either suspend or revoke the licence from violating or non-compliance licensees.

1.2 Food Control Division

Recently, the severe food borne diseases could effect to health and economic impacts to many parts of the world such as BSE and Avian Flu. Many diseases are also investigated that might be occurred by the influence of introducing new chemicals or ingredients in foods. Therefore, food safety becomes a major concern in this century.

For the purpose of ensuring food safety and quality, the Food Control Division has responsibilities for protecting consumer's health from hazardous and deteriorated foods.

Its functions include pre-marketing approval and post-marketing activities, e.g. licensing for manufacturing and importation of food commodities and registration of specially controlled food. The purpose is to screen for good quality and safe food only to enter into markets. These have been undertaken and regulated by Thai FDA under the provision of the Food Act B.E. 2522.

The main responsibilities for food control are to ensure the quality and safety of food according to the Food Act B.E. 2522, which summarize as follows:

1. setting up food standards and specifications as well as hygienic and labeling requirements;
2. controlling the production and importation of food products;
3. reviewing/granting approvals for the registrations of specially controlled foods;
4. reviewing/granting approvals for advertisements;
5. reviewing/granting approvals for packaging materials;
6. inspecting food manufacturing premises and sellers;
7. conducting sampling and quality assessments of food products;
8. taking legal actions, e.g. seizure, product recalls, prosecution;
9. conducting epidemiological studies;
10. promoting consumer awareness and voluntary compliance of food manufacturers;
11. controlling food-producing plants so that they meet national standards by using GMP;

12. collaborating with other government agencies, the private sector as well as international organizations in the matters related to technical corporation;
13. assembling, disseminating and exchanging information related to food; and issuing certifications, e.g., certificates of free sale.

1.3 Narcotic Control Division

The control of narcotics in Thailand has been undertaken for centuries since opium was the only known narcotic drug. The first regulation concerning opium was proclaimed in 1360 according to the Penal Code, which allowed authorized officers to imprison traffickers as well as opium addicts until they were able to overcome addiction.

The Morphine and Cocaine Act of B.E. 2456 (1913) prohibited importation into the Kingdom and international trade of morphine and cocaine. Thailand also joined the International Opium Convention held in the Hague, Netherlands, in 1914. The objective of the Convention was to suppress the use of the harmful narcotics. As a result, the Narcotics Act of B.E. 2465 (1922) was promulgated to assure proper control of importation, sale, possession, production and consumption of narcotics.

In 1934, the Cannabis Act was enacted to protect the public from being addicted to cannabis. And in 1939, the Kratom Act was promulgated to limit the use and propagation of Kratom trees (Mitragyna speciosa).

In June 1959, the Royal Thai Government decided to abolish smoking and selling of opium after the practice had been legally allowed since the reign of King Rama IV (in around 1857). Then, came the emerging time for a new opium substitute, “heroin”, which rapidly spread among certain groups of population. The Narcotics Act of B.E.2465 (1922) was then amended and raised the maximum penalty to death sentence. In addition, the Ministry of Public Health worked in close cooperation with the Ministry of Interior on the establishment of a sanatorium for treatment of the increasing numbers of drug addicts in Bangkok .

The problem of narcotics does not decline and has been considered as a global problem. Modern communication and transportation facilitates smuggling and illegal distribution of harmful narcotics all over the world. Since Thailand became a member of the Single Convention on Narcotic Drugs of 1961, the government has put every effort in cooperation with international organizations in combating illicit trafficking of narcotics. The Narcotics Act of B.E. 2522 (1979) was consequently promulgated in order to govern the enforcement, licensing, registration, importation, exportation, manufacture, purchase and exemption of narcotic drugs.

During the last decade, abuse of psychotropic substances has become a serious problem. The Thai government decided to join the International Convention on Psychotropic Substances Act of 1971. As a result, the Psychotropic Substances Act of B.E. 2518 (1975) was promulgated to control the problem.

In order to face the problem of abuse of volatile substances such as thinners and lacquers which widely spread among young people, the Ministry of Public Health, therefore, promulgated the Emergency Decree on Prevention against Abuse of Volatile Substances of B.E. 2533 (1990).

The tasks of this Division are to control and monitor the production, distribution, import, export and possession of narcotics and psychotropic substances which are legally used for medical and scientific purposes according to the Narcotics Act and the Psychotropic Substances Act. The Division fulfills these tasks by issuing licences and monitoring the licensees. It also provides and distributes narcotics and psychotropic substances to meet the local demand for medical use. Another duty of the Division is to safeguard the confiscated narcotics and destroy them when the case is finally decided by the court.

1.4 Medical Device Control Division

In the past, when there was no law relating to medical device control, the Ministry of Public Health normally solved the problems pertaining to medical devices by referring to the provisions of the Drug Act. The terminology and control measures in the Act were often found not pertinent to the fact and nature of medical devices, which are instruments or apparatus, not medicines. Moreover, upon application of the Drug Act to medical devices whose technology has been increasingly advanced, we often came across the limitation of the Act. This limitation caused the control and quality assurance of medical devices to be insufficient and inefficient. To ensure effective control of quality, efficacy and safety of medical devices emerging with the technological advancement, the Medical Device Act of B.E. 2531 (1988) was enacted and has become effective since May 23, 1988.

On August 3, 1988, an ad hoc task force was appointed within the FDA to implement the Act and to take responsibilities for the control of medical devices. On June 22, 1990, the Medical Device Control Division was officially established and has since been recognized as an authoritative agency under the FDA. Now about 25 pharmacists work for this Division.

The activities under the above Act are conducted under the supervision of the Medical Device Committee, which gives consent and

advice, and makes recommendations to the Secretary-General of the Food and Drug Administration

1.5 Cosmetic Control Group

Currently, the cosmetic control in Thailand has been implemented by the Cosmetic Act B.E. 2535 (1992). The cosmetic regulation consists of various activities in two major areas: pre-marketing and post-marketing activities. Any products having pharmaceutical characteristics such as those affecting or altering the functions or structure of human body or presenting as pharmaceutical products will be outside the scope of cosmetic regulation.

According to the Cosmetic Act of B.E. 2535 (1992), the focus of regulation has been recently shifted from pre-marketing activities to post-marketing activities. This effort originated on the notion that the utilization of technical requirements and the practice of good manufacturing guidelines can ensure the quality of cosmetic products manufactured.

1.6 Hazardous Substances Control Group

Prior to 1967, there was virtually no control over the production, importation, exportation, sale or handling of toxic substances. The term “toxic substance” means any substance that may cause hazard to human health either directly or indirectly. Examples of toxic chemicals are those used as pesticides, rodenticides, insecticides, household cleaning products, etc. As the consumption of diverse toxic substances is increasing, the intoxication occurrences caused by certain toxic chemicals have become more and more common. Parts of the problems may be due to a lack of adequate information or appropriate instructions on the use of such toxic substances as well as the absence of proper regulatory measures. Other parts are due to individual ignorance or unawareness of the chemical's toxicity. The ever-increasing occurrences alert authorities to take action on these toxic chemicals. Upon suggestions from the groups concerned, the government started working on a law to control the utilization of toxic substances for various purposes. Hence, the “Toxic Substance Act of B.E.2510 (1967)” was promulgated in 1967. Later in 1973, some more measures on registration procedures of toxic substances were added to the amendment of the Act, which was promulgated as the “Toxic Substance Act, 2 nd Amendment, B.E.2516 (1973)”.

Later on, a great number of hazardous substances were used in various industries and businesses. Some of these hazardous substances had evidently caused serious injuries to humans, animals, plants, properties and the environment. Several Ministries, Bureaus and Departments administered the then existing laws. As a consequence, different

proclamations were made during different periods of time, resulting in discrepancies and incomprehensiveness of their provisions. So agencies concerned collaborated in the revisions and integration of the then existing laws on toxic substances into one law, i.e. Hazardous-substance Act of B.E.2535 (1992). The new Act has expanded the scope of its application to cover all kinds of hazardous substances. The definition of "Hazardous-substance" in the new law covers more substances than that in the former one. In addition, it has adopted better criteria with more practical procedures and promoted collaboration among agencies concerned on the control and supervision of hazardous substances use.

The Hazardous Substances Control Group is responsible for supervising the use of hazardous substances in households and public health programs. According to the Hazardous-substance Act of B.E.2535 (1992), responsible agencies must firstly study and consider which chemicals or substances should be classified as hazardous substances by type of such substances. Then the agencies must propose the decisions to the Committee on Hazardous Substances. If the Committee agrees, the Ministry of Industry will issue a notification.

The Hazardous Substances Committee has appointed three subcommittees to handle the tasks, two of which are under the responsibility of the Ministry of Public Health:

1. Subcommittee on Standards of Hazardous Substances Used in Households and Public Health.
2. Subcommittee on Registration of Hazardous Substances Used in Households and Public Health.
3. Subcommittee on Standards of Pesticides Control Operations.

The regulatory procedures range from monitoring to control and total prohibition according to the degrees of toxicity and hazard of the substances. In addition, other factors, e.g. environmental impact, abuse, etc., are taken into consideration in classifying them as hazardous substance type 1, 2, 3, or 4 (see detailed in item 7 under the topic Law and Regulations).

1.7 Import and Export inspection Division

In the past, the Food and Drug Checkpoints Subdivision is under the Inspection Division and responsible for the whole range of inspections: inspection at the facilities of manufacturers, importers, and sellers – both in Bangkok and upcountry. Currently, with the notion of "one-stop service", each product control division has its own inspectors. Consequently, a great number of officers of the Inspection Division were transferred elsewhere, for example, to the Food Control Division and the Drug Control Division.

And the tasks of the Inspection Division have been reduced to only those involving the import control at the checkpoints. As a result, the name of the division was recently changed to Import and Export Inspection Division

1.8 Public and Consumer Affairs Division

Public and Consumer Affairs Division is not newly established but renamed from Public Relations and Advertisement Control Division, in accordance with its mission which exclude advertisement control. The tasks and responsibilities are in 5 areas:

- to disseminate knowledge of health products through mass media and activities for the purpose of consumer behavior development in safely consuming health products,
- to create good understanding between FDA and the public and the groups concerned through public relations activities,
- to render complaint service,
- to conduct research for the good of strengthening consumer's ability , and
- to support and strengthen Non-government Organization (NGO) in consumer protection activities.

Each year, FDA has regularly provided knowledge about health product through mass media. The TV programs or spots, radio programs or spots are duplicated and distributed to institutes or agencies as their requests. Printing materials i.e. poster, pamphlet and handout have been continually produced to support the Provincial Health Office activities and also distribute to serve people needs. Furthermore, exhibition sets are also prepared for lending or distributing as requested.

There are 5 projects that were successfully conducted:

- Reading Label Before Purchasing Project
- Raising Awareness to Protect Consumer's Rights Project
- Reading Nutrition Label Project
- Food Safety Project
- FDA Consumer Hotline 1556 Project.

The objectives of these projects are to enhance people knowledge, to boost their safely consumption behavior, and to strengthen their capability to protect themselves from unsafe health product and fraudulent claims. The target group is varied each year such as students, housewives, or workers. The appropriate activities and media are utilized for each target group.

2. Supporting System Division group ; consists of three divisions: Public and Consumer Affairs, Rural and Local Consumer Health Products Protection Promotion, Technical and Planning, and the Office of the Secretary. In addition, six internal units have been established to perform particular tasks: Information Technology Center; Food and Drug Legal Group; Public Sector Development Group; Internal Audit Group; Complementary Health Product Group, and Community Health Product Quality Improvement Coordinating Center.

2.1 Technical and Planning Division

The functions and responsibilities of each division of the FDA are defined on the basis of a specialist area or control of a specific category of product. Some activities may need cooperation between divisions or departments in order to achieve FDA objectives. For example, an administrative strategy and policy development, an annual plan and its budgeting, the formulation of a strategic plan, and its transformation into an action plan, must be merged to form a united single FDA plan. It is the job of the Technical and Planning Division (TPD) to serve as facilitator and coordinator for such activities so that they can be initiated and achieved efficiently and effectively. In addition, the FDA's performance against its strategy, and the coherence of activity across divisions is monitored.

The roles of the Technical and Planning Division are to

1. To establish and coordinate plans according to ministerial guidelines, oversee and evaluate the operations performed by other divisions under the Thai Food and Drug Administration
2. To acquire, store, and effectively utilize the information available in the agency, and be the information focal point of the FDA
3. To coordinate with foreign agencies in relation to health and medical issues, arrange meetings and international conferences as assigned
4. To monitor and improve the monitoring system about untoward effects from the consumption of health-products
5. To improve national chemical safety measures, and be the central agency for international cooperation in this area
6. To be the academic center for consumer protection in the field of health products, as well as an information provider according to the Information Law

7. To support and work together with officials from other relevant agencies as required.

Policy and Planning

Development of policy, and the strategic and action plans for the FDA are major tasks of this division. In accordance with the new restructuring of the Ministry of Public Health into clusters, the TPD plays an important role in initiating the corporate plan with other departments. This needs significant collaboration to consolidate the integrated plan for ensuring its effective implementation.

In addition, TPD makes situation analyses and policy recommendations in order to improve FDA performance.

Monitoring and Evaluation

Monitoring of the FDA's performance has been continuously conducted so that the implementation of plans and projects has conformed to policy, strategy and objectives.

TPD is also responsible for improvement of the monitoring and control system for obtaining and evaluating strategies of the consumer health protection plan, including analyzing and evaluating its progress and outcomes.

Each year many activities at the FDA are carried out to assure consumer safety, and a great deal of effort and finance are expended. It's TPD's responsibility to oversee and assess the operational performance of the FDA in order to help develop and improve strategy formulation and planning. Surveys and studies, such as the survey on Thailand's Consumer Health Protection Situation, have been periodically conducted. Other documents such as the annual report, and information and statistics on consumer health protection, are regularly disseminated to all divisions and appropriate officers both at the center and in the provinces.

The FDA's management system is intermittently evaluated, and attitude surveys of FDA personnel and of private sector contacts are conducted in order to determine levels of satisfaction.

Technical Development and Foreign Affairs

Human resources development is regarded as a key element of TPD's responsibility and organizational development program. The Personnel Capacity Building Master Plan has been initiated and integrated into the FDA master plan. This includes the knowledge management program, and the study program in indispensable areas.

Training programs are also regularly run for the purpose of increasing the knowledge and skills of officers in working effectively and

efficiently: training on research methodology and sampling techniques, English proficiency; team building management; and leadership are amongst the many topics. Participation in international training programs is also necessary for FDA personnel to keep up with the advances of science, technology and product development. Staff also attend national and international symposia.

Concern with foreign affairs is currently increasing and has become more important to the FDA's activities. International cooperation and collaboration are major global concerns, either bilateral or multilateral relationships, especially in the area of free trade. Such relationships introduce a large number of cooperative programs. TPD serves as a focal point in foreign affairs, including negotiating in bilateral and multilateral meetings. TPD also occasionally makes arrangements and training programs for overseas visitors on request.

Additionally, collaborative projects have been conducted with other sources of funding or cooperation, such as the Department of Technical and Economic Cooperation; other international organizations, FAO, WHO, JICA; and some countries such as Australia, Canada, China, and USA. The purpose of all these relationships is the enhancement of the FDA's performance and the development of its personnel.

Health Products Safety Development

The FDA's principal responsibility is to protect consumers from hazardous chemicals or products. TPD pays more attention to prevention and closely monitors products that may cause adverse effects.

In relation to this priority, the Adverse Product Reaction Monitoring Center (APRMC) has been set up. The center is mainly responsible for the collection and interpretation of reports of adverse events from health products. Such reports are made voluntarily by professionals, officials or healthcare personnel when they become aware of harm caused to a consumer. Formerly concerned solely with adverse drug reactions (a major worldwide concern), the Center's responsibilities have been considerably widened to include many of the products under the FDA's remit.

At the international level, the Center collaborates with the WHO Programme for International Drug Monitoring (pharmacovigilence) and the activities of its more than seventy member countries. At the national level, the network of hospitals across the country transfers reports to the APRMC. The center also regularly disseminates reports and provides feedback to health personnel on adverse effects data.

Studies on the evidence of well-known and new adverse effects have been conducted including investigations of rare and severe adverse effects,

incidence of adverse effects and related causes such as genetics, gender, age, drug interaction, and misuse of drugs.

Chemical Safety

The responsibilities of the Chemical Safety Section are principally to serve as a national focal point for IFCS (Intergovernmental Forum on Chemical Safety) and IPCS (International Programme on Chemical Safety), to improve national chemical safety measures and to serve as the principal agency for international and national cooperation on these issues. The Chemical Safety Section works under the National Coordinating Committee on Chemical Safety (NCCS) which was appointed by the Cabinet as the national coordinating body. The committee is composed of high-level representatives of all concerned governmental agencies and NGOs, chaired by Public Health Minister with the FDA serving as the secretariat. The body then sets up cooperation among participating agencies and develops the National Master Plan on Chemical Safety (NMP).

The major task is to develop the NMP, including the Action and Budget Plans under the Master Plan. At the time of publishing this document, the first NMP (1997-2001) and 2nd NMP (2002-2006) have been endorsed by the cabinet (1997 and 2001, respectively), and translated into action by all relevant organizations. The third NMP (2006-2015) is being formulated, targeted for submission to the cabinet for endorsement by October 2005.

In addition, many other areas of activity have been launched: the national poison center network; the National Chemicals Management Profile; a chemical safety newsletter and guidebook; the dissemination of chemical safety information to concerned organizations in Thailand, the public, and other countries. (The electronic files for these can be found on the FDA website: www.fda.moph.go.th/ipcs) Research/analyses and criteria development for the risk management of chemicals are regularly conducted.

Apart from this, the Section also takes action and participates in international collaborations and forums: WHO/SEARO, IPCS and the Canadian Center of Occupational Health and Safety (CCOHS) in running an IPCS/INTOX workshop. Last but not least, Chulabhorn Research Institute and the Ministry of Public Health, Chemical Safety Section, on behalf of the Thai Government, organized the IFCS Forum IV, at the United Nations Conference Center, Bangkok in November 2003. The Forum was an event significant enough to move global chemical safety forward.

Library and Information Services

TPD's library and Information Services include technical information about consumer protection in the field of health products and legislation, as well as journals, texts, research papers, magazines, and newspapers. FDA employees and the public are welcome to used the library and information services.

In addition, the library has developed an online technical database of health products as an evidence-base for research. There is also a Data Warehouse that is a repository of integrated information from heterogeneous sources, as it is generated, available for queries and analysis. This makes it much easier and more efficient to run queries over data that originally came from different sources. Visitors can access the library's Webpages directly at www.fda.moph.go.th/lib.

The library also serves as an e-knowledge center and the FDA's information center under the Official Information Act, B.E., 2540 (1997) so as to provide information in line with the provisions of the Act.

2.2 The Rural and Local Consumer Health Products Protection Promotion

In 2002, the Rural and Local Consumer Health Products Protection Promotion [RLCP] Division was established in the Food and Drug Administration (FDA) of the Ministry of Public Health.

Major roles and responsibilities of the RLCP are as the following:

1. To promote, support, supervise, monitor and evaluate the consumer health products protection in the rural and local areas.
2. To promote and support both government and non-governmental organizations for the consumer health products protection.
3. To promote, support and develop the health product quality and safety in the communities.
4. To serve as the cooperating center for the community health products development.
5. To cooperate with or support the other related organizations as assigned.

2.3 Office of the Secretary

The responsibilities of the office are the administration of finance, personnel, procurement, and maintenance. In addition general facilitation

services are also the responsibility of this office such as welfare of the officers, cafeteria, parking-lot, house-keeping, security and other facilities.

2.4 Legal Affairs Task Group

The main responsibility of the Legal Affairs Task Group is act as an advisory body for all FDA' laws under the jurisdiction of the FDA, for example, Food Act, Drug Act. Not only giving consultation to FDA's front line officials, but also acts on behalf of the FDA in suing law violators.

2.5 Information Technology Center

Information Technology Center 's responsibilities are mainly to develop and maintain the information system such as hardware, software, and peopleware including the network both intra- and inter- network. The purpose is to facilitate working system to become efficiency and effectiveness.

In addition, The IT center also serve as the facilitator to establish electronic services e.g. Call Center and E-submission according to the Government's policy on transparency and E-Government.

2.6 Administration System Development Group

As a result of introducing the Good Governance and the Government's policy to restructure and streamline the organization infrastructure and performance of the governmental officers, the Administration System Development Committee (ASDC) has been initiated. The committee shall suggest the cabinet of the improvement of government infrastructure, the system development including financial, personnel, moral and ethics, welfares, recompense, and others.

Administration System Development Group (ASD) of FDA also set up in order to corporate with the ASDC and FDA' new administration system. The purpose of the ASD's task is to accelerate activities and monitor operating performance for good governance of FDA.

2.7 Internal Audit Unit

Internal Audit Unit is accountable for the internal audit to ensure management's efficiency in providing Good Corporate Governance, transparency, audibility, accountability and responsibility, enhancing of efficiency and effectiveness of performance. Furthermore, it could be perform as the balance measure of authority and serve as the warning signals for the FDA system. The purpose of the internal unit is to corporate and monitor operating performance for good governance of FDA.

Chart 1 Organization of the *Ministry of Public Health*

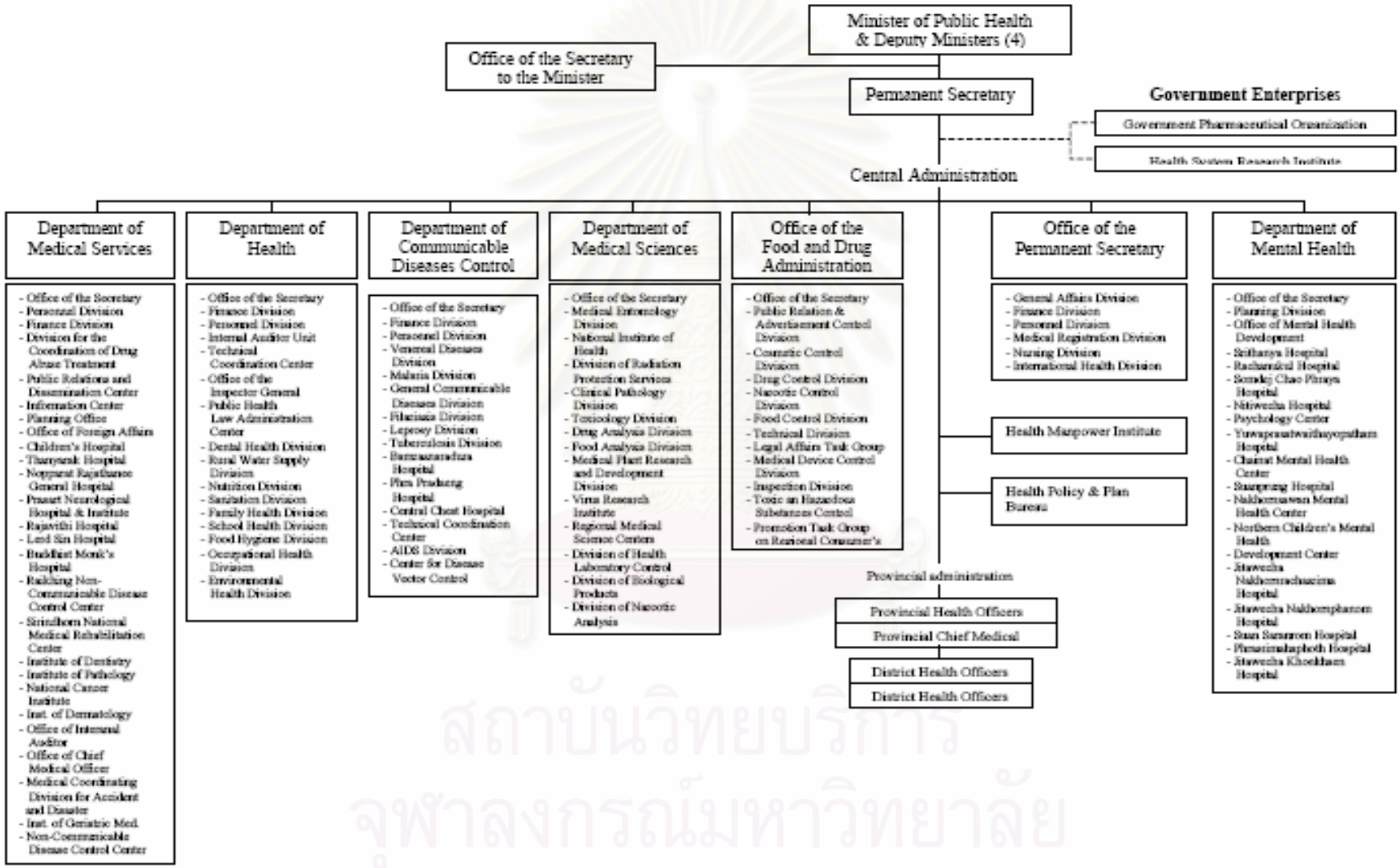
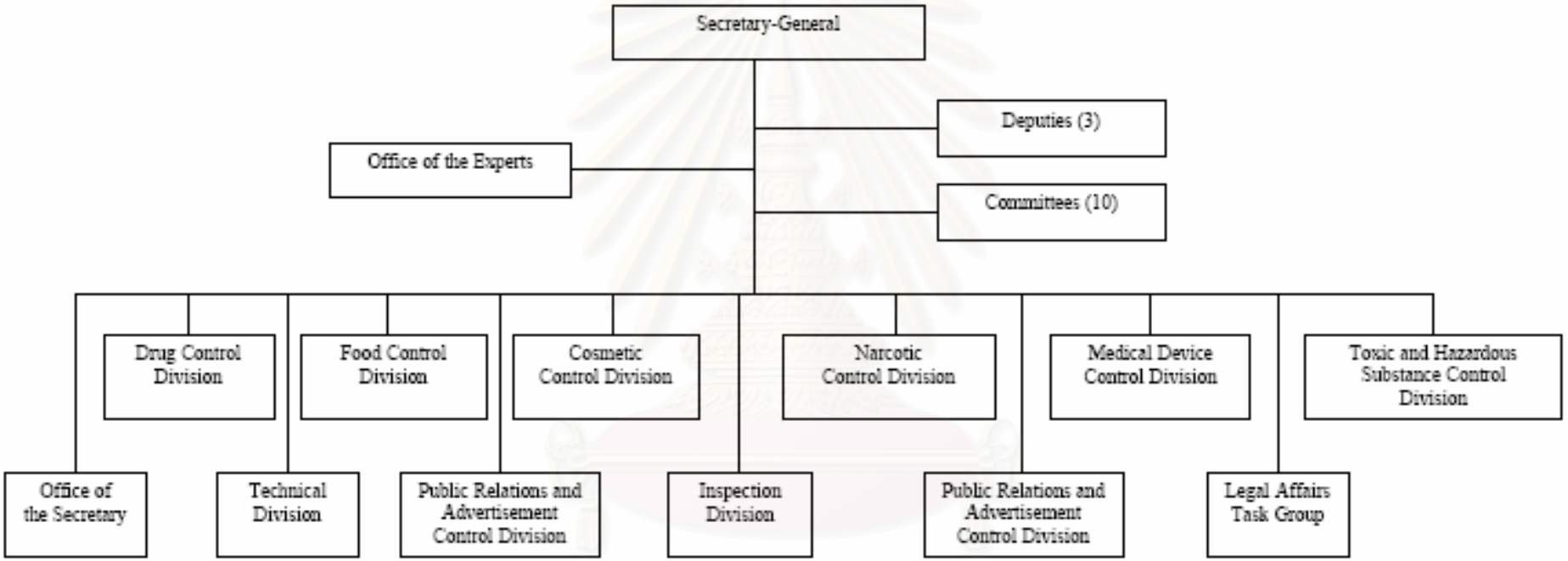


Chart 2 Organization of the *Food and Drug Administration*



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Current Status and Practice in Pharmaceutical Regulations and Technical Requirements in Thailand

Before 1909, there was practically no control of drugs in any aspects. In 1909, regulations were begun only on prohibition of adulteration in drug products and control of narcotic substances. The first legislation promulgated was the *Harmful Habit-forming Drug Act 1922 (B.E. 2465)*. Control of production, of pharmacists and of their rights to dispense drugs had been enforced since 1929. The outbreak of the problems on extensive manufacture and sale of alcoholic preparations containing indigenous, medicinal herbs had attracted an attention of the Medical Association of Thailand. The problems eventually led to promulgation of an *Act on Sale of Drugs 1936 (B.E. 2479)*. The first legislative measure implemented in the field of drug control dealt only with sale practices regardless of formulas or ingredients. At that time, neither producers, importers nor retailers paid much attention or assumed their responsibilities to either quality or safety of the drugs.

The control of drugs was much improved following an enactment of the *Sale of Drug Act 1950 (B.E. 2493)*, which became effective in 1951. This law encompassed many more aspects of drug control other than the control of sale practices. For instance, control of production and registration of pharmaceutical products, and standard requirements of drug quality were included in the Act 1950.

The Act made possible the elimination of substandard, deteriorated and adulterated drugs. Consequently, manufacturing standard of local drug firms and dispensaries was upgraded to a certain extent. The Act did not only apply to production, importation and sale practices but also to product registration, labelling requirements, and advertisement control as well. Few revisions were emerged from time to time to update the law and to cope up with the changing circumstances of pharmaceutical businesses.

Pharmaceutical Affairs Administration

Started in 1922, drug control in Thailand were merely on adulteration of toxic substances in drugs. The first legislation promulgated was the **Harmful Habit-forming Drug Act, 1922 (B.E. 2465)** . The authorized agency was the Division of Habit-Forming Drugs, Ministry of Interior. Later in 1942, the Division was transferred to the Ministry of Public Health and was renamed as **Food and Drug Division**. The division was divided into three sections : food, drug and statistic sections. The name of the division was once again changed in 1965 to **Food and Drug Control Division** functioning as a separate unit under the Office of the

Permanent Secretary for Public Health. The division was also expanded to five sections namely, technical, registration, narcotic, advertisement control and inspection division. The Division was then transferred to be under Health Promotion Department and reorganized into six subdivisions: technical, provincial inspection, central inspection, narcotic and toxic substances, registration, advertisement and information subdivisions.

On **December 11, 1974** , the Food and Drug Control Division was promoted to be the **Office of Food and Drug Administration** , having status equivalent to a department of the Ministry of Public Health. The Office of Food and Drug Administration (FDA) is one of the departments under the Ministry of Public Health

Laws / Regulations covering Pharmaceutical Affairs

After several years of endeavouring, the *Drug Act 1967 (B.E. 2510)* was promulgated to supersede the 1950 Drug Act. The Drug Act 1967 has been employed for almost two decades, it brought in quite substantial improvement in all aspects of drug control. However, four more revisions were subsequently emerged in order to cope up with the growing numbers of pharmaceutical manufacturers and the world situation. The latest *Drug Act 1987(B.E. 2530)* comprises the following important features.

I. Drugs are classified into two major groups – *modern* and *traditional drugs.*Modern Drugs are further divided into four categories, namely (1) household remedies of which sale requires no licence; (2) ready-packed drugs sold in stores by nurses or other medical professions; (3) dangerous drugs; and (4) specially controlled drugs. Drugs which may possess a potentially harmful effect to health, if misused, will be enlisted in the last category of which sale requires a prescription. Dangerous drugs can be bought without prescription but must be dispensed by pharmacists. Traditional drugs are the group of those intended to be used in indigenous treatment as monographed in the official pharmacopoeia of traditional medicines or those declared by the Minister of Public Health as traditional drugs or those permitted to be registered as traditional drugs. The control and registration of drugs in this group are less stringent than those of the modern drugs.

II. The Ministry of Public Health is authorized to publish in the Government Gazettes, the list of specially-controlled drugs, the list of dangerous drugs as well as the lists of particular drugs requiring additional labelling (e.g. expiration date, warning, etc.)

III. Licensing for manufacturing, importation and sale of drugs is required by law. Applications for permission and licences are in

accordance with the rules, measures and conditions as prescribed in the Ministerial Regulations.

IV. Duties of licensees and pharmacists on duty at the place of production, importation or sale of drugs are also described. For instance, a licensee who produces modern drugs must have each batch of finished products analyzed for quantities of their active constituents before the products can be released to the market.

V. Licensees must register the drugs before they can manufacture or import them. Details of the drugs and their formulas, as being registered, cannot be altered without approval or permission from the authorities.

VI. The Minister is empowered to either suspend or revoke the licence if the licensee vidate the Act.

Product Registration and Licensing System for Pharmaceuticals

1. Subcommittees

According to the *Drug Act 1987 (B.E. 2530)*, a Drug Committee has been appointed every two years to advise the Minister of Public Health on both regulatory and technical aspects concerning administration of the drug control. The committee is also authorized to approve pharmaceutical registration and to withdraw or suspend the licences. There are 14 regular members in the committee; five of them are positionally appointed from related organizations; the others are drug experts. The committee can then appoints subcommittees to assist them. Up to now ten subcommittees are appointed; these are:

1. Subcommittee on Approval of Human Drug Registration.

2. Subcommittee on Approval of Veterinary Drug Registration and Standard Usage of Veterinary Drug in Animal Feeds.

3. Subcommittee on Approval of Traditional Drug Registration.

4. Subcommittee on Approval of Investigation of Manufacturing Premises and Warehouses.

5. Subcommittee on Adverse Drug Reaction.

6. Subcommittee on Approval of Drug Advertisement.

7. Subcommittee on Setting up Requirements of Biological Products.

8. Subcommittee on Approval of New Drug Registration

9. Subcommittee on Re-evaluation of Human Drugs.

10. Subcommittee on Evaluation and Approval of Drug Quality and Analytical Control Method.

2. Licensing

The Drug Act requires that any persons who wish to sell, produce or import drugs into the Kingdom must obtain licences from the licensing authorities. The Drug Control Division is the licensing authority for manufacture, import and selling of drugs in Bangkok metropolitan and its territories. Provincial Health Offices are the licensing authorities for manufacture and import of traditional drugs and sale of drugs in other provinces.

Application for a licence must be submitted to the licensing authority. Buildings and facilities will then be inspected. A licence will be given after the inspection has confirmed that the applicant has adequate capabilities of doing such business, and he/she can secure appropriate facilities and personnel for that purpose.

There are nine different categories of licences:

- Licence to produce modern drugs
- Licence to sell modern drugs
- Licence as a wholesaler of modern drugs
- Licence to sell ready-packed modern drugs which are neither in the categories of dangerous nor specially-controlled drugs
- Licence to sell ready-packed modern veterinary drugs
- Licence to import modern drugs
- Licence to manufacture traditional drugs
- Licence to sell traditional drugs
- Licence to import traditional drugs

3. Drug Registration

Registration process is necessary to ensure efficacy, safety and effectiveness of the drugs freely sold in Thailand. Only the authorized licensees are qualified to apply for drug registration certificates. The manufacturing plant, in which a drug is manufactured, is subject to inspection for compliance with WHO GMP (Good Manufacturing Practices of the World Health Organization) and quality assurance. According to the Drug Act 1987 (B.E. 2530), the granted certificate is valid to the validity of its authorized licensee.

The process of drug registration is divided into 5 procedures:

1. Generic drug registration

2. Traditional-drug registration

3. New drug registration

3.1 Original New Drug

3.2 New Generic Drug

4. Biological product registration

5. Herbal medicine registration

Generic Drug Registration (see Chart 3) involves *three* steps:

1. Application for permission to manufacture or import of drug samples. (at Food and Drug Administration)

2. Application for an approval of drug quality control and analytical methods. (at Department of Medical Science)

3. Application for granting of a drug registration certificate. (at Food and Drug Administration)

Traditional Drug Registration (see Chart 4) is much simpler than that of the generic drugs. Applicants simply apply for drug registration certificates without application for an approval of analytical methods.

New Dru g Registration is the most stringent of all. New drugs cover products of new chemical entities, of new indications, of new combinations or of new delivery systems. The new amended procedure for new drugs, adopted in **August 1989**, involves a period of safety monitoring program and of limited distribution is required prior to an approval for unconditional registration and distribution. Meanwhile, generic products have to pass
bioequivalence studies in order to assure their efficacious quality. The bioequivalence data must be submitted as a proof of their standard quality to the FDA along with an application for drug registration. It is the responsibility of the Expert Subcommittee on Approval of New Drug Registration, appointed in August 1989, to evaluate efficacy and safety of new drugs, both original and generic, before a registration certificate can be issued.

Original New Drug Registration Procedures (see Chart 5)

1. Apply for a permission to import or manufacture product samples at the Drug Control Division.

2. Submit an application for registration along with a suitable quantities of samples and complete evidence or technical data on efficacies, safety and quality of the drugs. The required evidence and data are as follows:
- Application forms,
- Labels and leaflets,
- Animal – pharmacological and toxicological data,
- Human – pharmacological and clinical data,
- Chemical and pharmaceutical data,
- Certificate of free sales for importing drugs,
- Certificate of raw materials for local manufacturing drugs,
- Current status of drug approval in foreign countries.

3. After receiving a conditional approval, the company has to perform the followings:
a) Sell the drugs only in medical institutes (government or private section) with close supervision of doctors, in which safety monitoring can be proceeded.
b) Concisely record, evaluate all adverse drug reactions and report to the FDA at the end of the monitoring program along with other drug information experienced in foreign countries.

4. The FDA will approve the registration unconditionally provided that the submitted data and reports are scientifically correct and complete. The drug can then be distributed through normal market channels.

New Generic Drug Registration Procedure (see Chart 6)

1. A protocol on Bioequivalence Study must be submitted for an approval at the Drug Control Division.
2. Application for a permission to import or manufacture the drug samples.
3. Performing the Bioequivalence Study according to the approved protocol in a specified government institute.
4. Submitting an application for registration along with the bioequivalency report and other useful documents.

Biological Products registration is similar to Generic Drugs and Original New Drugs (Chart 3 and Chart 4) excluding stage II in Chart 3, is not applicable to vaccine for veterinary use.

Herbal medicines registration is similar to Generic Drugs and Original New Drugs.

Chart 3 Diagram showing the registration process of *Generic Drugs*

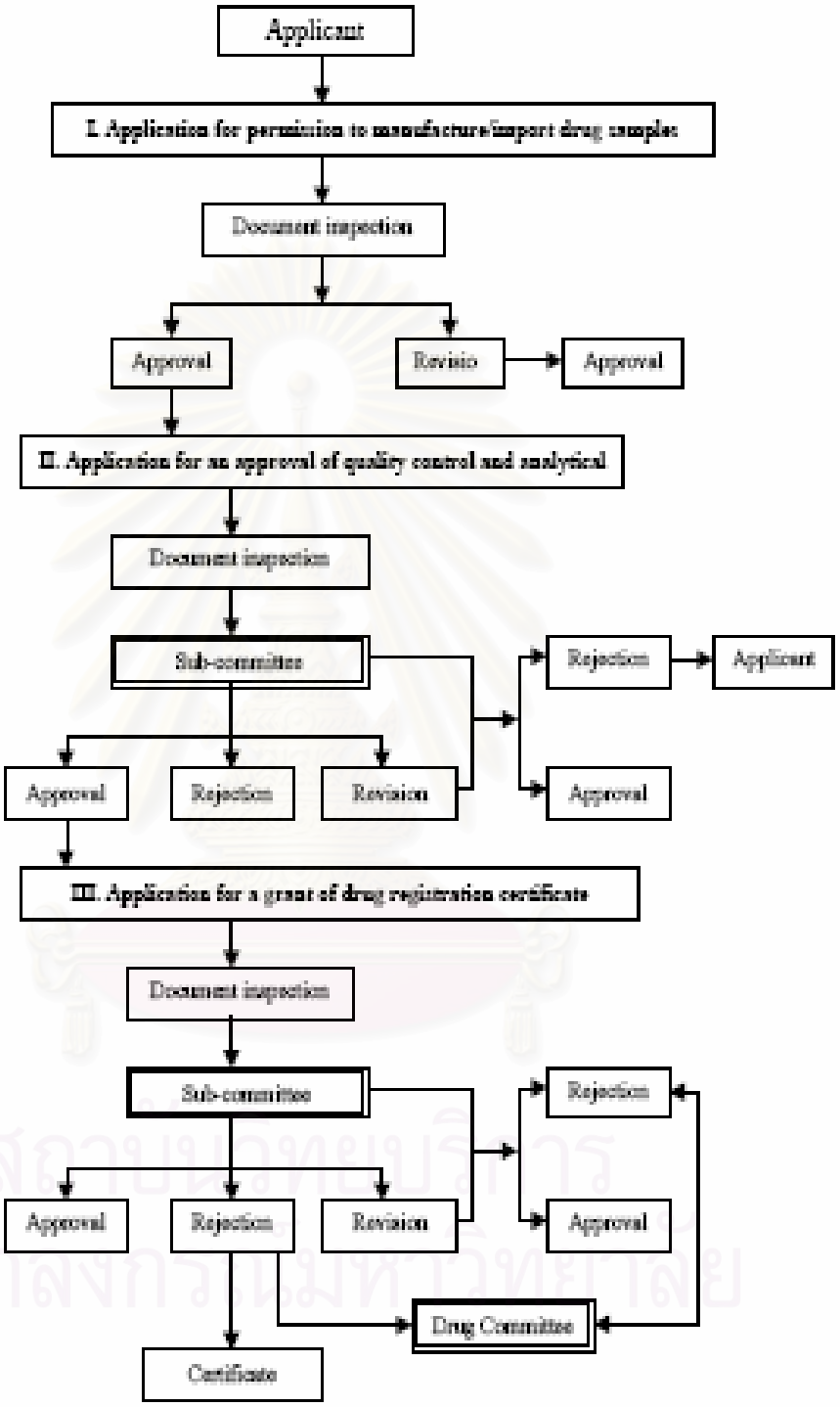

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Chart 4 The registration process of *Traditional Drugs*

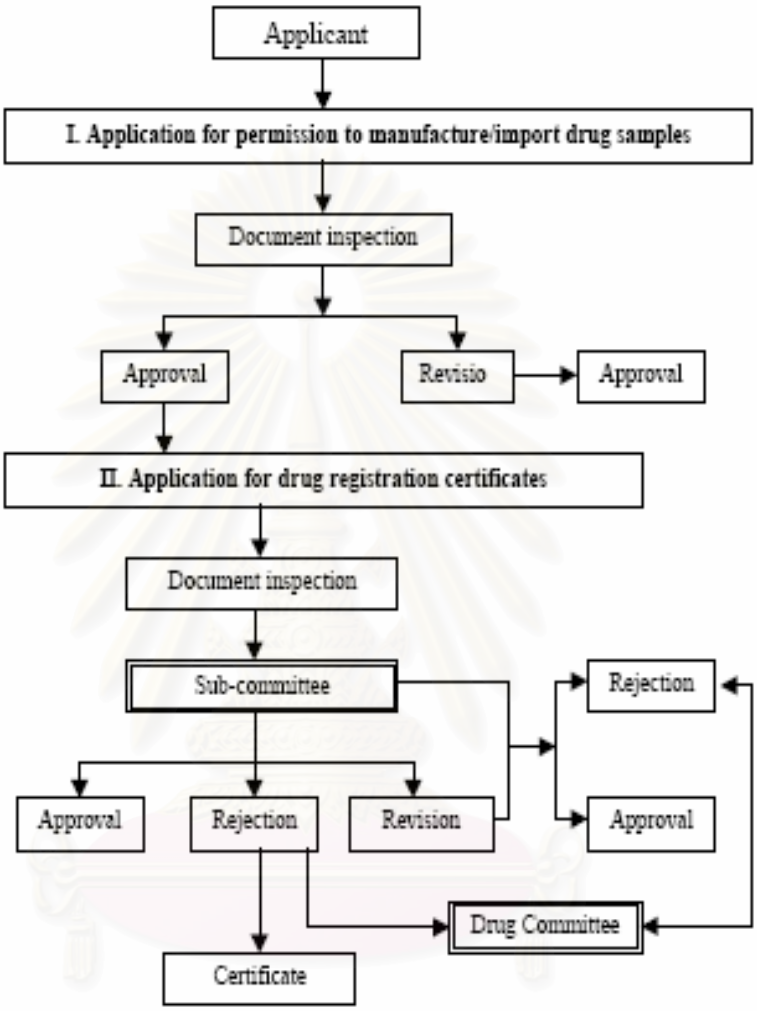

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Chart 5 *Original New Drug* Registration Process

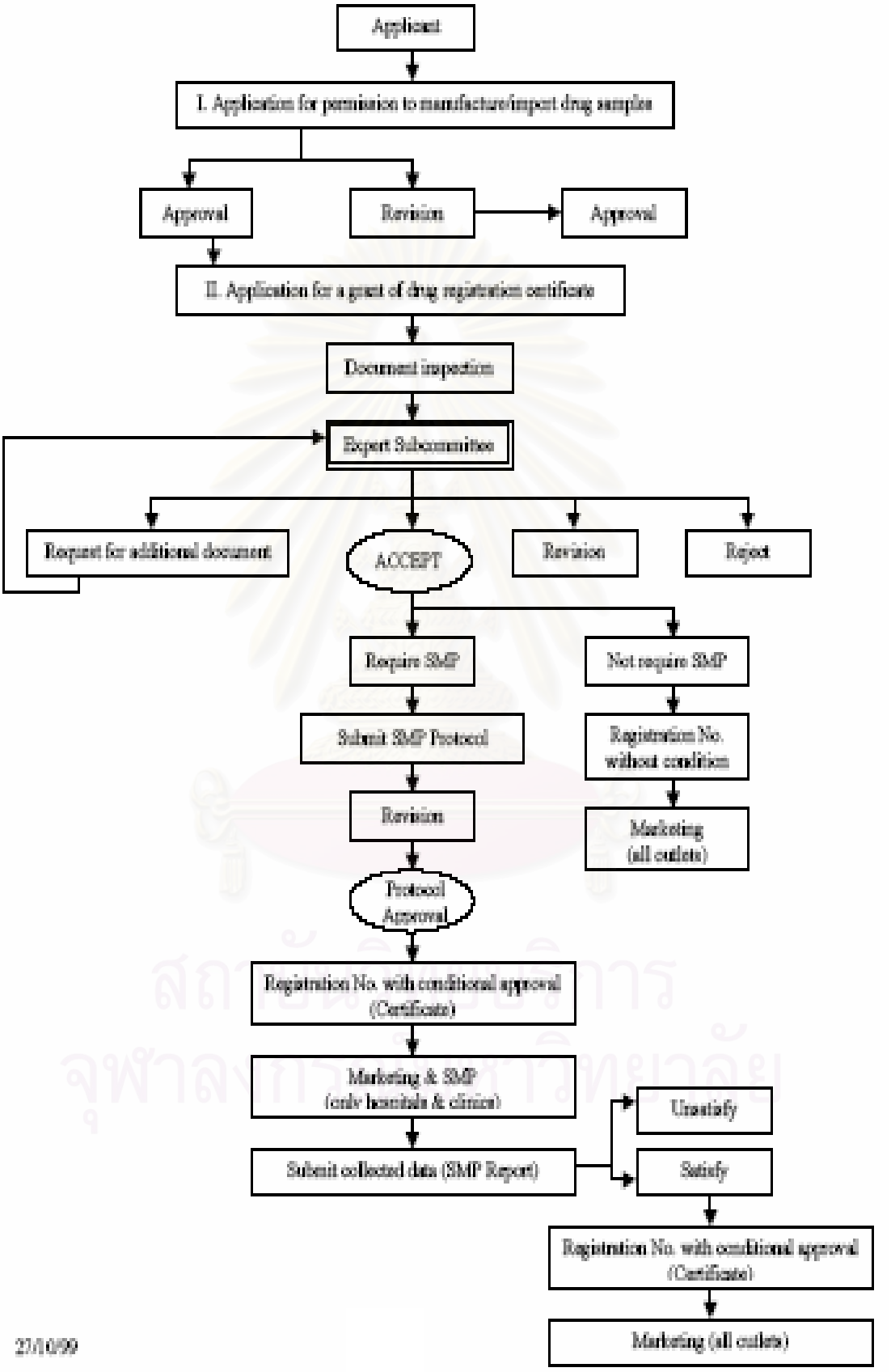

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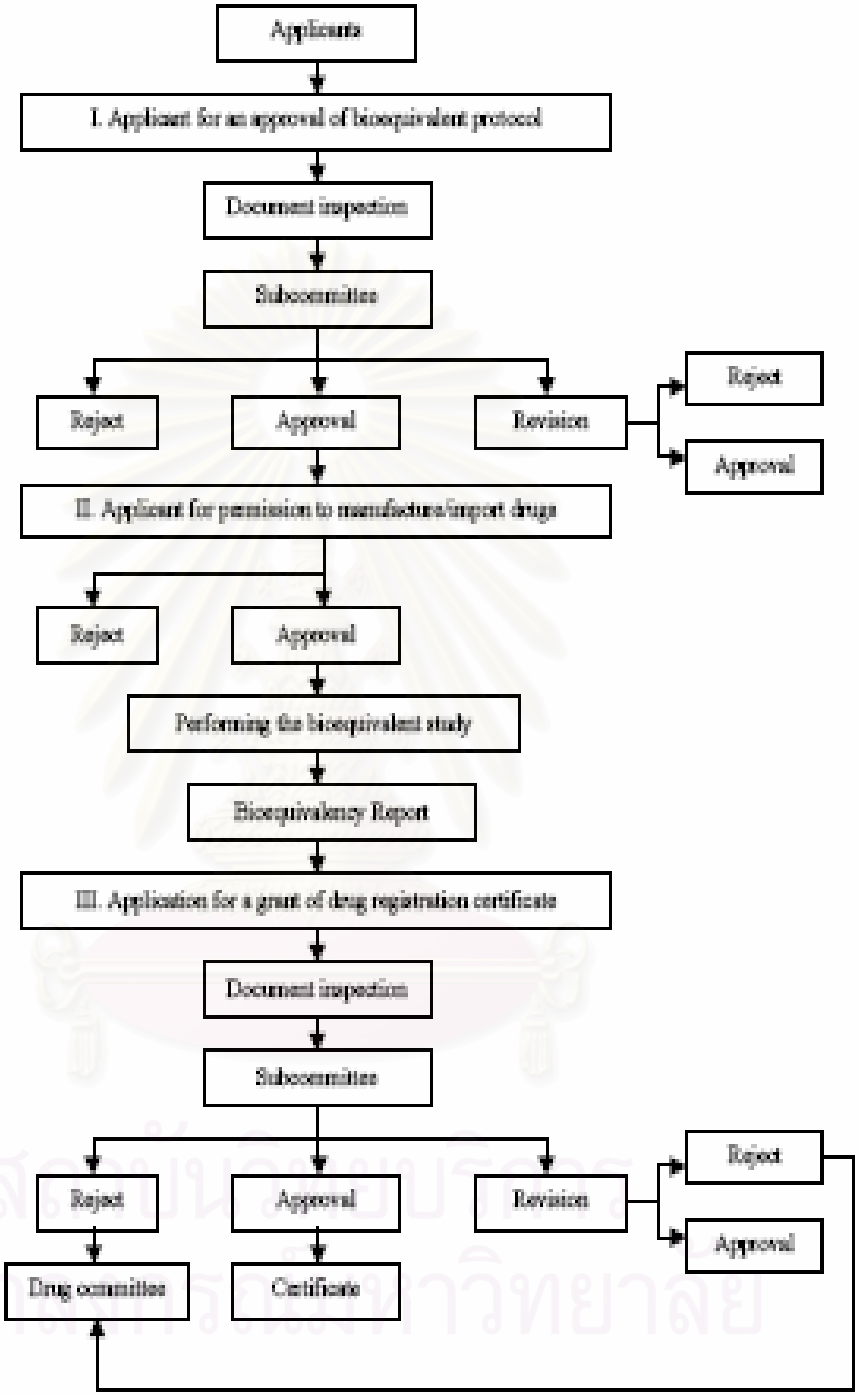
Chart 6 : The registration process of *New Generic Drug*



Data Input for Estimation of Cost Function in Thailand FDA

		Pre-Marketing					Post-Marketing					Other					Unit Price of Input			Dummy Variable		
year	Cost	Cost-Pre	Q11	Q12	No.F	No.L	Cost-Post	Q21	Q22	No.F	No.L	Cost Other	Q31	Q32	No.F	No.L	Pf	PL	Pr	d1	d2	d3
1980	17804400	6,043,500	7444	6130	11	25	4,369,300	12779	37697	9	26	7391600	170	2	3	218	137700	62775	0.080	0	0	0
1981	30063460	7,337,500	9153	6278	13	28	5,445,600	11496	44416	11	29	17280360	219	3	3	245	137700	62775	0.085	0	0	0
1982	42398700	9,861,500	11083	7266	13	28	7,146,900	15819	46782	11	29	25390300	324	4	3	251	160540	73157	0.090	0	0	0
1983	30507800	12,630,300	12915	8967	13	29	8,554,100	15963	38616	11	30	9323400	375	2	3	258	160540	73157	0.087	0	0	0
1984	30145600	13,533,700	9964	5671	16	34	9,356,400	18012	27509	13	35	7255500	401	2	3	304	160540	73157	0.089	0	0	0
1985	36486000	18,041,800	9929	6726	16	34	10,282,600	23899	42483	13	36	8161600	400	2	4	306	159315	73088	0.088	0	0	0
1986	38270100	18,382,500	11389	6765	16	35	10,791,800	13610	32684	13	37	9095800	334.1	2	8	311	151749	114808	0.067	0	0	0
1987	39011100	19,397,769	13023	6856	16	35	11,387,831	13926	37323	13	37	8225500	329.3	2	8	305	151749	114808	0.055	0	0	0
1988	41947000	20,150,887	11945	6008	17	36	12,533,453	13611	44209	14	37	9262660	335	2	8	316	151749	114808	0.056	0	0	0
1989	52104754	25,788,864	14696	6496	17	37	16,040,164	18097	56457	14	39	10275726	340.1	2	10	324	191167	138281	0.072	0	0	0
1990	68938700	31,062,066	11697	5594	18	38	24,221,193	17485	52341	15	39	13655441	354.3	3	11	331	224753	152702	0.087	0	0	0
1991	78865966	39,608,570	11769	6079	19	40	24,998,868	16550	68150	16	42	14258528	356.6	3	13	351	224753	152702	0.091	0	0	0
1992	135194903	65,233,383	12988	22485	19	42	25,776,542	4245	23336	16	44	44184978	1002	4	20	360	282913	187970	0.066	1	0	0
1993	171274571	51,542,959	13790	28049	19	42	27,170,149	2628	19807	16	44	92561463	908	14	22	355	282913	187970	0.058	1	0	0
1994	195349449	55,509,288	10931	20131	19	42	17,057,544	1573	25807	16	44	122782617	512	9	23	347	282913	187970	0.049	1	0	0
1995	253544269	61,305,576	11183	22980	20	42	17,742,768	5052	20630	16	44	174495925	443	11	22	359	379160	242909	0.050	1	0	0
1996	236923417	68,245,812	10027	17858	20	43	20,385,190	4735	6168	17	45	148292415	712	15	26	361	379160	242909	0.050	1	0	0
1997	393562865	70,904,816	16412	16007	20	43	15,339,750	8882	12196	17	45	307318299	81	20	26	361	379160	242909	0.050	1	1	0
1998	467047172	79,485,909	8118	14545	20	43	14,073,451	4254	8052	17	45	373487812	1357	22	27	360	379160	242909	0.049	1	1	0
1999	418138750	80,153,765	5491	8941	20	44	12,306,490	4525	18397	17	45	325678495	1476	20	25	368	347639	228712	0.040	1	1	0
2000	445590923	79,516,836	16033	39879	23	51	17,648,926	4383	17687	19	53	348425161	393	20	24	431	347639	228831	0.027	1	1	0
2001	451190755	87,249,675	15500	35335	23	51	19,241,532	5312	17151	19	53	344699548	418	25	28	450	347639	228902	0.020	1	1	0
2002	445144621	82,497,536	14132	57131	23	51	21,058,679	4543	44632	19	53	341588406	987	24	29	421	347639	229836	0.017	1	1	0
2003	484040792	55,328,206	18562	65129	24	52	78,639,968	6312	370240	20	54	350072618	650	20	30	483	347639	239657	0.011	1	1	1
2004	506429000	60,222,000	21223	82793	24	52	136,211,000	5357	574012	20	54	309996000	294	57	33	501	372681	281876	0.008	1	1	1
2005	689279000	111,490,000	22975	64382	24	52	313,582,000	6913	863909	20	54	264207000	403	69	33	518	391390	293816	0.008	1	1	1

Data Bases of Output in Pre-Marketing System

	Pre-Marketing in Product groups								therapuetic	nontherapeutic	Weight		
year	Food	Drug	Med DV	Cosmetic	Narcotic	Toxic	Import	Total	D+N+M	F+C+T+I	70%	30%	total
1980	1490	6747		1544	667	99		10547	7414	3133	5189.8	939.9	6129.7
1981	1594	6029		1667	1504	89		10883	7533	3350	5273.1	1005	6278.1
1982	1020	6654		2425	2176	172		12447	8830	3617	6181	1085.1	7266.1
1983	1994	8788		1860	2327	101		15070	11115	3955	7780.5	1186.5	8967
1984	985	5365		1152	1771	115		9388	7136	2252	4995.2	675.6	5670.8
1985	1049	6344		1154	2281	91		10919	8625	2294	6037.5	688.2	6725.7
1986	1444	6052		1158	2460	88		11202	8512	2690	5958.4	807	6765.4
1987	1841	5830		1146	2646	89		11552	8476	3076	5933.2	922.8	6856
1988	2219	4591		1481	2350	131		10772	6941	3831	4858.7	1149.3	6008
1989	2571	3969		1522	3506	117		11685	7475	4210	5232.5	1263	6495.5
1990	2704	3768		1532	2271	318		10593	6039	4554	4227.3	1366.2	5593.5
1991	3158	4099		1665	2429	208		11559	6528	5031	4569.6	1509.3	6078.9
1992	8400	12548	2420	17525	5305	1722		47920	20273	27647	14191.1	8294.1	22485.2
1993	7275	15463	2906	22816	8352	1056		57868	26721	31147	18704.7	9344.1	28048.8
1994	8561	14553	845	601	8919	1203		34682	24317	10365	17021.9	3109.5	20131.4
1995	8757	17809	1135	2588	8094	2167		40550	27038	13512	18926.6	4053.6	22980.2
1996	5188	14426	569	1897	7186	686		29952	22181	7771	15526.7	2331.3	17858
1997	3488	8988	1831	2782	8659	1639		27387	19478	7909	13634.6	2372.7	16007.3
1998	12384	6656	1021	2235	6023	1896		30215	13700	16515	9590	4954.5	14544.5
1999	14926	1888	497	617	2820	2116		22864	5205	17659	3643.5	5297.7	8941.2
2000	22450	30190	2552	14508	6764	3792		80256	39506	40750	27654.2	12225	39879.2
2001	20476	22819	3073	16945	7046	3506		73865	32938	40927	23056.6	12278.1	35334.7
2002	50142	34405	3171	35943	5114	4743		133518	42690	90828	29883	27248.4	57131.4
2003	52476	32629	5049	31514	3244	4002	33619	162533	40922	121611	28645.4	36483.3	65128.7
2004	86910	41188	5212	25079	3351	4316	43585	209641	49751	159890	34825.7	47967	82792.7
2005	56118	22961	4508	35286	980	2213	54608	176674	28449	148225	19914.3	44467.5	64381.8

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Position Held :

Year	Position
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