Chapter III

Overview of the Thai Food and Drug Administration

This chapter aims to view some background for understanding the role and functions of the Thai FDA on health consumer protection as well as its cost and output structure during the past 20 years.

3.1 Role of governments on health consumer protection

One of the most familiar role of governments is the regulation on the behavior of firms and individuals. What governments do, how much they spend, and how they obtain the means to finance their functions reflect political interaction of citizens. Government power is used through the functions to establish rules that regulate the social interaction among individuals and group of people. Through political interaction, citizens agree that governments may interfere in guaranty all citizen protection of their rights to equal opportunity.

Using the power of the state to regulate private choices is the most direct way for governments to exercise power. One of the categories of government regulatory activities is social regulation that is an attempt to use government authority to regulate private actions to achieve goals that result in collective benefits to all citizens. Regulation imposes costs on those who are regulated by forcing them to undertake actions on which they would not promise. Governments attempt to prevent undue control of prices in markets by limiting monopolistic power and by trying to prevent collusion among sellers who keep prices high to increase their profits. The power of

governments are also used to control the quality and kinds of goods and services sold in markets.

Paternalism is the belief that government power should be used to guide and correct individual choices, implying that individuals are not capable of evaluating their own welfare. This philosophy is used to justify the banning of certain harmful products, which individuals may wish to use if they were free to choose. Governments always interfere supposedly on the consumer's behalf. Many people believe that government supply of information can improve consumers' choices, presuming the information provided by governments to be more accurate than what is available to individuals.

Law and consumer protection are inter-linked and inter-dependent to achieve the goals of a good healthy society. The government uses laws and regulations as a tool for implementing consumer protection activities. For example, the Food Act and Drug Act were promulgated due to the principles that food and medicine are very much parts of fundamental right to health of every human being. The citizens have a right to quality health care, treatment and medication regardless of race, religion, social status and ability to pay. Right to public health is very much vital and every state has a sacred duty to ensure reasonably liveable condition of life for entire citizens in all circumstances. Fundamental rights and directive principles of state policy are two important wheels in establishing the egalitarian social order and health care. It is true that scientific and technological developments globally have created new problems of public health and medical care and, therefore, they need to be redressed.

3.2 Health consumer protection in Thailand

Public health sector has continuously expanded and developed. New technologies have been introduced, many health products have been created, and public communications have been adopted as means to improve people's consumption behavior. Because people are the determinants of success in development, the eighth National Economic and Social Development Plan (1997-2001) has been adjusted and changed in concepts, directions, and processes of the country's development, from focusing on economic development to people or human development.

Focusing on the development of people, it is inevitable to change the existing development process which separated developmental sectors into different areas or fields, to an integrated or systematic development of different factors. This type of development has set two main directions. One is the development of people's physical, mental, and intellectual potentiality in order to have a good quality life and to be effective part of the development processes. Another one is the development of people's environments including to families, communities, economics, social, culture, environment and natural resources, which will lead to sustainable development.

According to this development goal, the integrated public health development has been emphasized in two areas. First is focusing on the impacts of health problems which is related to the economy, society, culture, social values, behavior, and environment. Second is focusing on people's health and sanitation by encouraging them to gain more knowledge on health care and disease prevention. Taking care of

themselves and their families should be introduced when they suffer from uncomplicated diseases.

In order to make the public health development be in accordance with the country's development goal and to achieve the desired Thai society in the future, strategic planning was determined as a framework for development. Health consumer protection has been one of the strategies which consisted of operating ways as follows:

1) Reinforce the government's supervision and administration to promote the usage and consumption of high quality, safe, and effective health-related products which are of reasonable price.

2) Develop the mechanism of independent organizations to improve the standard quality of both public and private hospitals as well as clinics; promote the dissemination of information on standard quality and fee for services so as to support the complete market mechanism for consumer protection on services.

3) Promote private organizations' participation in system research, examination and analysis, dissemination of information, and various campaigns for consumer protection by allocating the budget for technical data and information; relax strict control and rigid official regulations that may be obstacles to the development.

The health consumer protection is one of the programmes under the public health development in the national economic and social development plan. Its objectives are to ensure people to be able to receive health services and health products which are of high quality, safe and effective. Quality control and

surveillance are given particular emphasis. The health consumer protection programme consists of three sub-programmes and thirteen work plans which are taking charge by the following organizations:

1. Office of Food and Drug Administration
2. Department of medical sciences
3. Office of permanent secretary for public health
4. Department of medical services
5. Government pharmaceutical organization

3.3 Authorities and functions of the Thai Food and Drug Administration

Office of Food and Drug Administration (FDA) is an agency within the Public Health Service. Major roles and responsibilities of the Thai FDA are quality standard control and monitoring of manufacturers, importers, and sellers of health-related products. The authorities and functions of the Thai FDA are confined to the scope of eight Acts, namely:

1. Drug Act 1967 (B.E. 2510), 2nd revision 1975 (B.E. 2518), 3rd revision 1979 (B.E. 2522), 4th revision 1985 (B.E. 2538) and 5th revision 1987 (B.E. 2530)
2. Food Act 1979 (B.E. 2522)
3. Cosmetic Act 1992 (B.E. 2535)
4. Narcotic Act 1979 (B.E. 2522), 2nd revision 1985 (B.E. 2528) and 3rd revision 1987 (B.E. 2530)

5. Psychotropic Substances Act 1975 (B.E. 2518), 2nd revision 1985 (B.E. 2528) and 3rd revision 1992 (B.E. 2535)

6. Volatile Substances Act 1990 (B.E. 2533)

7. Medical Devices Act 1988 (B.E. 2531)

8. Hazardous Substances Act 1992 (B.E. 2535)

In addition, the authoritative scopes of the FDA also expand to 6 international conventions:

1. Single Convention on Narcotic Drugs 1961, commentary on the protocol amending at Geneva on March 25, 1972

2. Convention on Psychotropic Substances 1971

3. Code of Conduct on Distribution and Use of Pesticides 1990

4. London Guidelines for Exchange of Information on Chemicals in International Trade, amended 1989

5. Convention on the Control of Transboundary Movement of Hazardous Waste.

6. United Nation Convention against Illicit traffic in Narcotic Drugs and Psychotropic Substances 1988

Administration of the Acts and Conventions is performed through eight committees, appointed by the Minister of Public Health. These committees are on drug, food, cosmetic, narcotic, psychotropic substances, prevention of volatile substances, medical device and hazardous substances. Three additional national

committees are appointed by the Cabinet to develop policy and promote technological development on food, drug and chemical safety.

In addition to the roles and responsibilities in accordance with the laws and regulations, the FDA also plays important roles on public education, information services, promotion and up-grading of quality standards of manufacturers and exporters. Proceeding directions towards these roles are:

1. Pre-marketing control of health products and household hazardous substances. This part deals mainly on issuances of notifications, setting up quality standards, inspection and examining before approval and granting of licences for business operation and registration certificates of controlled products.

2. Post-marketing monitoring

Monitoring and inspection of manufacturers, stores, markets, supermarkets, sampling products for testings and re-evaluation of the approved products whether they conform to the proclaimed quality and safety.

3. Surveillance of health products

Safety of products were monitored. Watching for unforeseen hazards, abuse , or complaints concerned undesirable uses were handled according to the laws.

4. Public education and dissemination of information

Education and information are the effective means to achieve the goal of consumer protection. These were done through various media, such as radio,

television, newspapers, magazines, posters, stickers, and handouts. In addition, training, meeting and seminar programmes were occasionally organized. Campaigns and exhibitions were also organized at schools, shopping malls, villages, districts, etc. to deliver essential information to the public.

5. Promotion of technological development, researches and quality improvement through cooperation with other entities. FDA plays the supportive roles on research development and technology transfer, cooperatively and collaboratively carried out with universities and concerned private agencies. Funds for researches were allocated. Advices and recommendations on either technological development or sources of getting assistance are provided for the requesting operators. Various means including its authorities on enforcement of Good Manufacturing Practice (GMP) have been used to upgrade the local industries.

To carry out the mandate of consumer protection, the Thai FDA covers its authorities upon the whole country's regulated businesses.

1) Inspections and legal sanctions

The staff member of FDA, as investigators and inspectors, visit health product facilities routinely, seeing that products are made right and labeled truthfully. As part of their inspections, they collect domestic and imported product samples for laboratory examination or for label checks.

If a company is found violating any of the laws that FDA enforces, FDA can encourage the firm to voluntarily correct the problem or to recall a faulty product

from the market. A recall is generally the fastest and most effective way to protect the public from an unsafe product.

When a company cannot or will not correct a public health problem with one of its products voluntarily. FDA has legal sanctions it can bring to bear. The agency can go to court in order to force a company to stop selling a product and to have items already produced seized and destroyed. When warranted, criminal penalties-including prison sentences-are sought against manufacturers, importers and distributors. In addition, import shipments are also detained at the port of entry because the goods appear to be unacceptable.

2) Scientific expertise

The scientific evidence is needed to back up FDA's legal cases. FDA collaborates with Department of medical sciences to analyze samples in order to see whether products are contaminated with illegal substances. Some test results are reviewed and submitted by companies to seek agency approval of products such as drugs, food additives, coloring agents, etc.

Assessing risks and weighing risks against benefits is at the core of FDA's duties. By ensuring that products and producers meet certain standards, FDA protects consumers and enables them to know what they are buying.

In deciding whether to approve new formulary of products, FDA does not itself do research, but rather examines the results of studies done by the manufacturer.

The agency must determine that the new products produce the benefits it is supposed to without causing side effects that would outweigh those benefits.

3) Product safety

Another major FDA mission is to guarantee the safety and wholesomeness of products. Samples are tested to see if any hazardous substances are presented in unacceptable amounts. If contaminants are identified, FDA takes corrective action.

The food supply is also protected as FDA sees that medicated feeds and other drugs given to animals raised for food are not threatening to the consumer's health.

Medical devices are classified and regulated according to their degree of risk to the public. Devices that are life-supporting, life-sustaining or implanted, such as pacemakers, must receive agency approval before they can be marketed.

Cosmetic safety also comes under FDA's jurisdiction. The agency can have unsafe cosmetics removed from the market. The dyes and other additives used in drugs, foods and cosmetics also are subject to FDA responsibilities. The agency must review and approve these chemicals before they can be used.

FDA's scrutiny does not end when a kind of products is approved for marketing. In addition, FDA also collects and analyzes reports on product safety after they have been put on the market to monitor for any unexpected adverse reactions.

Since 1992, some extents of FDA authorities have been delegated to all provincial health offices. They work in close collaboration with the FDA, particularly on safety monitoring and post-marketing surveillance of health products, within their own boundaries.

3.4 Cost and output structure of the Thai FDA

Before studying cost determinants of FDA, the general statistic of cost and output components should be assessed. The data was drawn from annually previous reports of the Thai FDA during the period 1980-1999.

3.4.1 Total costs of the Thai FDA

Figure 3.1 presents the total costs of the Thai FDA. The budgets, allocated for provincial health offices on health consumer protection activities, were excluded. The budgets allocated on the average in each year were around 17.1% of total costs. It was found that the total costs have been increasing sharply at the growth rate on the average of 19%, particularly during 1989-1994 that were the economic booming periods and the price of land was very high. In 1998, the total cost swung up very sharply from the cost of education and information provided to the public via mass communication media such as radio and television programmes (about 154 million bahts). It increased from the year 1997 (about 80 million bahts) 92.5%. In 1999, the total cost declined from the government budget limitation, resulted from the economic crisis of the whole country.

The percentage of capital stock in the total cost components is illustrated in figure 3.1a. Building, cars, computer system and land were included on the average of 4.6%, 0.6%, 7.0% and 19.3% respectively. It indicated that land cost tend to be one-fifth proportion in the components.

Figure 3.1b and 3.1c denote the percentage of labor expenses in the total cost components during 1980-1989 and 1990-1999 respectively. It is observed that the component of labor expenditures was a large proportion (55.5%) at the period 1980-1989, but declined to 32.5% during 1990-1999 according to the government policy on personnel quantity limitation.

3.4.2 Total costs of pre and post-marketing activities

This study conceptualized only pre and post-marketing activities of the Thai FDA.

The percentage of costs of pre and post-marketing activities in total cost components are shown in figure 3.2. The proportion of pre-marketing cost is 41.2% and the proportion of post-marketing cost is 18.3%. It can be remarked that pre-marketing activities used more capital inputs, such as land, building, than post-marketing activities, when post-marketing activities used capital, such as cars, more than pre-marketing activities. Hence, capital cost allocation for each activity is due to the actual amount of capital inputs consumed.

Figure 3.2a and 3.2b show the total costs of pre and post-marketing activities respectively. The data exhibits that the total costs of pre-marketing activities (C1) increased at the rate 26.8% during the period 1983-1992 and then fluctuated. The total costs of post-marketing activities (C2) also increased sharply during 1987-1991 at the rate 28.6%, but declined continuously since 1992. The sudden change in cost structure was notable after the year 1992 due to the decentralization policy, from which some extents of authorities were delegated to provincial health offices.

3.4.3 Unit price of labor factor input

Figure 3.3 presents unit price of labor factor input. The data shows that prices of labors have been increasing sharply, particularly since 1989. The growth rate is about 9.6% each year. However, the ratio of wage rates and total costs declined from 0.2% in the year 1980 to 0.06% during the period 1991-1990, due to personnel limitation policy.

3.4.4 Outputs of the Thai FDA

There are a lot of FDA output categories recorded in the annual reports. This study, however, conceived only the outputs of pre and post-marketing activities which were employed in the cost functions.

The outputs of pre-marketing activities (Q_1) are presented by figure 3.4 and the outputs that shows subsets of Q_1 as amount of premises and warehouses licentiousness (Q_{11}), products registration (Q_{12}), and others such as labels or

advertisement and information control (Q_{13}) are presented by figure 3.4.1, 3.4.2 and 3.4.3 respectively. Q_{11}, Q_{12} and Q_{13} are the raw data got from the sum of the whole outputs of each products controlled. Q_1 are the adjusted outputs, got from the sum amount of weighted sub-outputs. In the same way, figure 3.5 presents the outputs of post-marketing activities (Q_2). Amount of premises inspection (Q_{21}), products inspection (Q_{22}) and labels or inserted documents in accordance with information and advertisement inspection (Q_{23}) are presented by figure 3.5.1, 3.5.2 and 3.5.3 respectively. Q_{21}, Q_{22} and Q_{23} are also the raw data and Q_2 are the adjusted outputs.

It can be observed that there has been a tremendous change in Q_1 and Q_2 since 1992. In that year, medical device control division was established, and it caused more jobs and certainly more outputs. At the same time, FDA deconcentrated some jobs, especially some post-marketing activities, to provincial health offices. This made the outputs of post-marketing activities suddenly fall down and the outputs of pre-marketing activities run up sharply due to the sudden change in task structure and adaptation of its role to be a supervisor of the provincial staff. In addition, more interrelationship between central and local organization have been created.

From the subset data of Q_1 and Q_2, some interesting remarks should be discussed, particularly Q_{12}, Q_{21} and Q_{22}. In general, the important tasks or activities of FDA concentrate in products and premises control. It is believed that when the government guarantees the quality and safety of products, people will be protected. If the premises, either manufacturers, distributors or stores, are guaranteed, we are also ensuring the quality and safety of products. It can be seen from figure 3.4.2 that Q_{12} (product registration) have been declining during the years before 1990, but after that

they have been increasing continuously. This can be explained from the sharp rise in economic growth during that time, push a great amount of new products registered and launched in the market. In contrast, premises and products inspection (Q_{21} and Q_{22}) returned downward rapidly after 1992 because of the deconcentration of some tasks to provincial health offices in accordance with the changed role. However, the fluctuation and inconsistency of other sub-outputs as Q_{11}, Q_{13} and Q_{23} cannot be explained by any reasons, except the doubtful management capability or it might be the characteristic of Thai bureaucratic system that did not have effective evaluation among the governmental agencies.

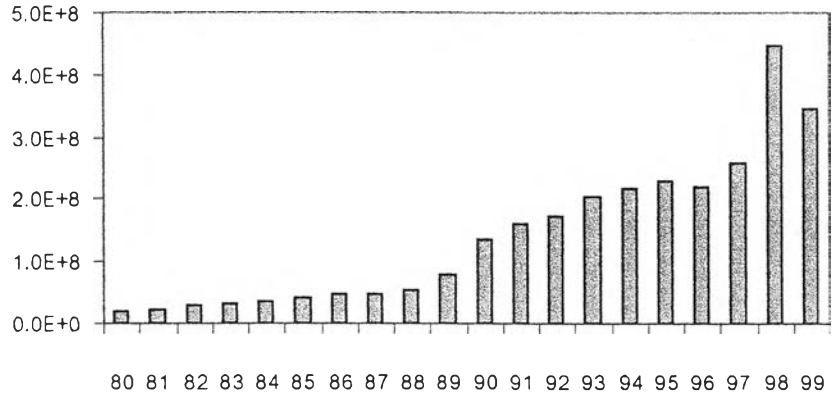

Figure 3.1 Total costs (TC) of the Thai FDA, by year 1980-1999.

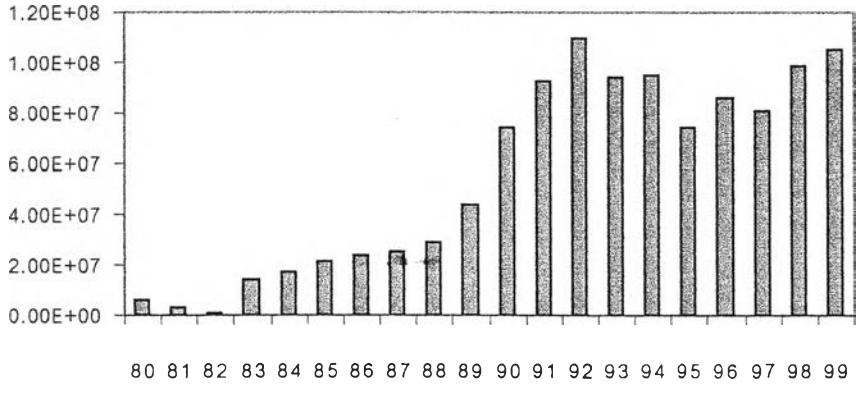

Figure 3.2a Costs of pre-marketing activities (C1), by year 1980-1999.

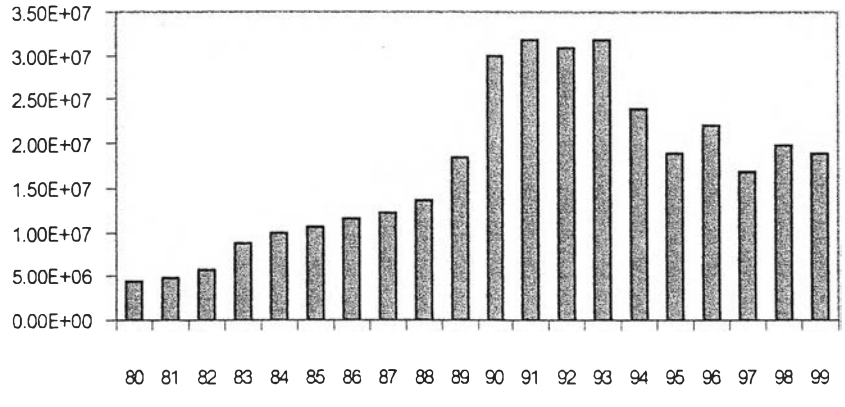

Figure 3.2b Costs of post-marketing activities (C2), by year 1980-1999.

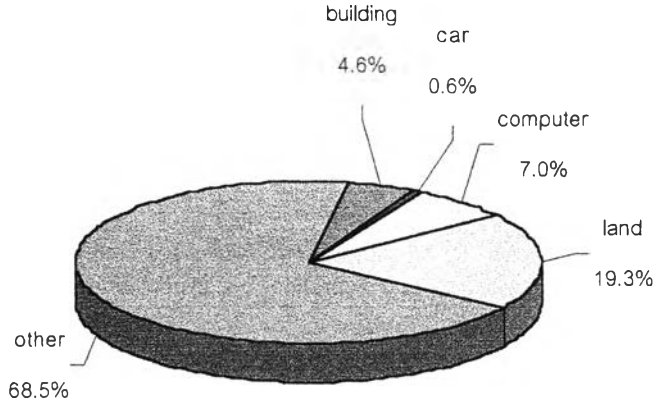

Figure 3.1a Percentage of capital assets in the total cost components.

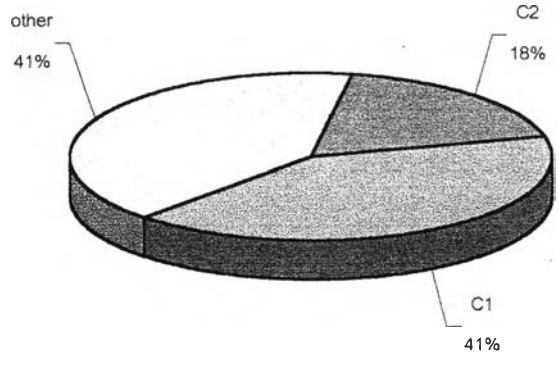

Figure 3.2 Percentage of the costs of pre-marketing (C1) and costs of post-marketing activities (C2) in the total cost components.

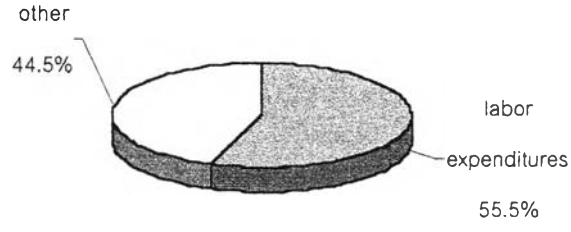

Figure 3.1b Percentage of labor expenditures in the total cost components, by year 1980-1989.

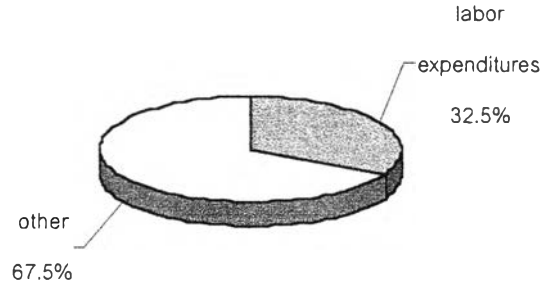

Figure 3.1c Percentage of labor expenditures in the total cost components, by year 1990-1999.

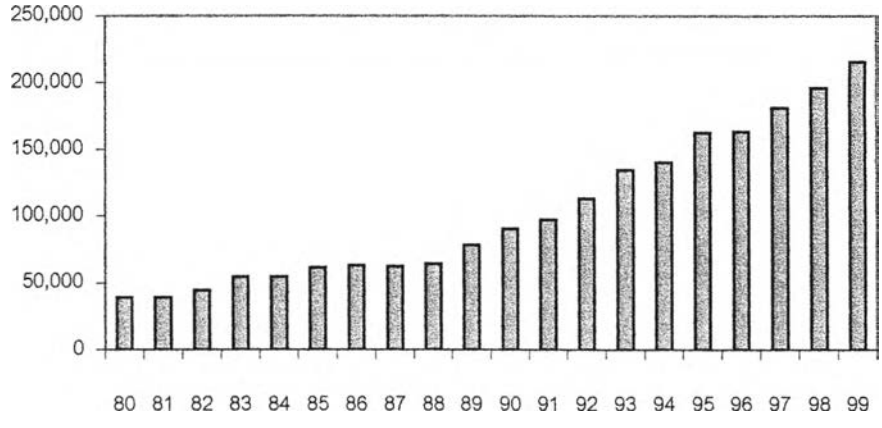

Figure 3.3 Unit prices of labor input (PL), by year 1980-1999.

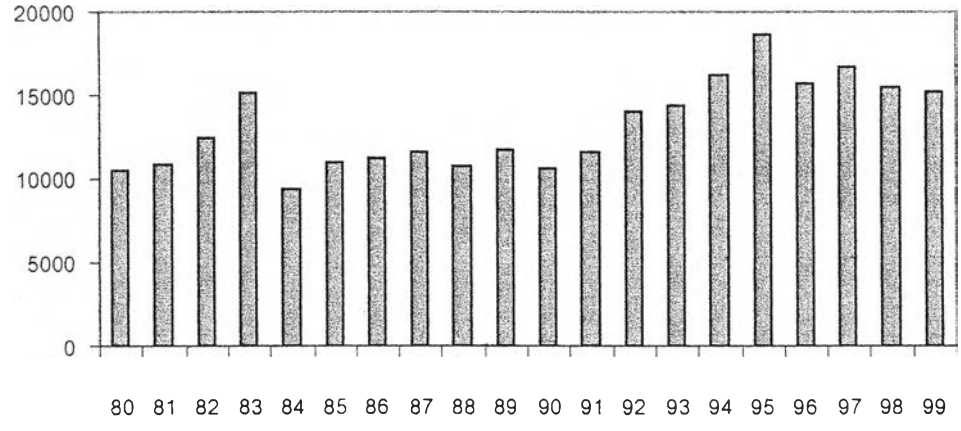

Figure 3.4 Outputs of pre-marketing activities (Q1), by year 1980-1999.

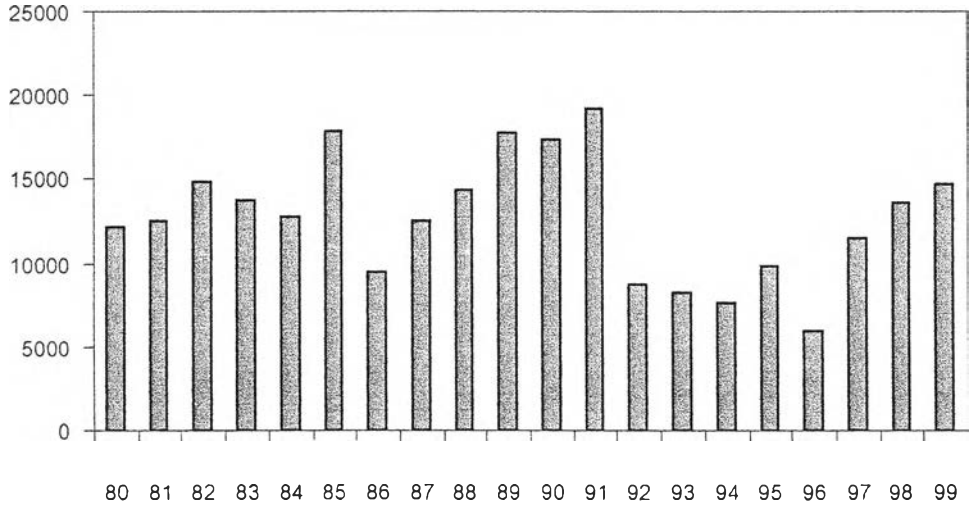

Figure 3.5 Outputs of post-marketing activities (Q2), by year 1980-1999.

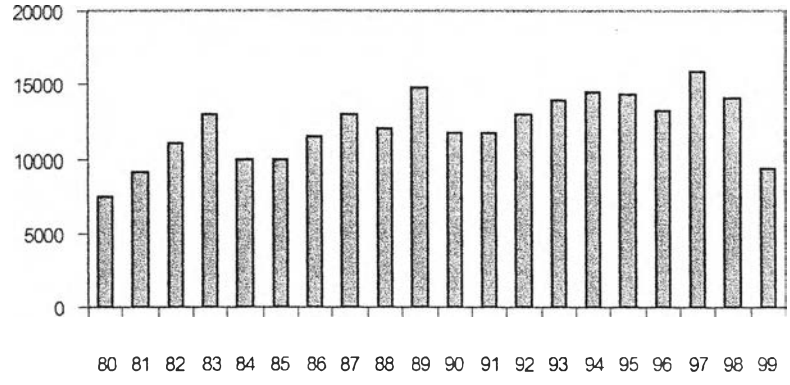

Figure 3.4.1 Amounts of premise and warehouse licentiousnesses (Q11), by year 1980-1999.

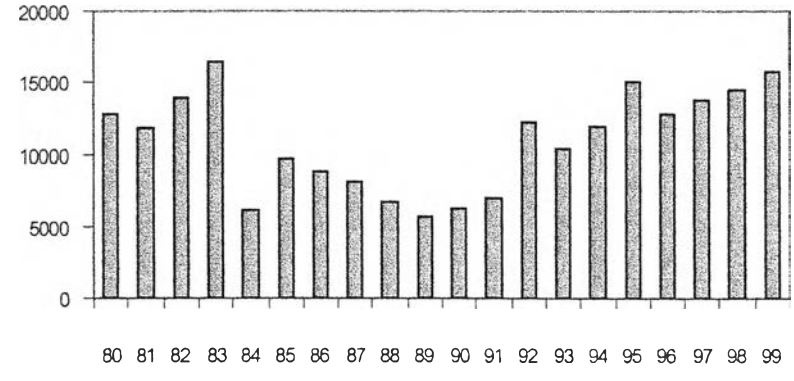

Figure 3.4.2 Amounts of product registrations (Q12), by year 1980-1999.

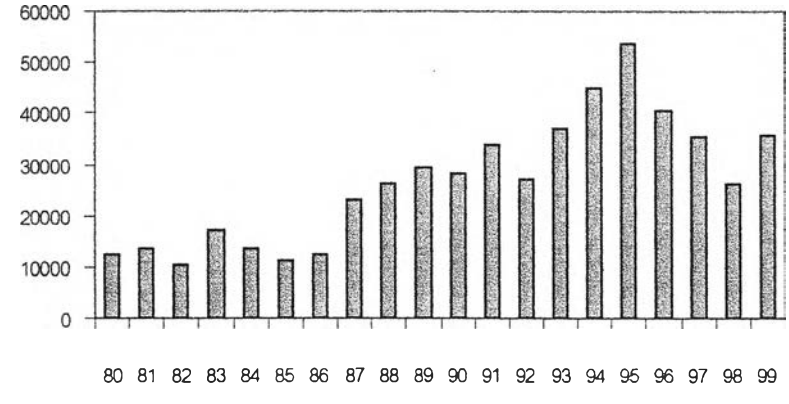

Figure 3.4.3 Amounts of other products of pre-marketing activities (Q13), by year 1980-1999.

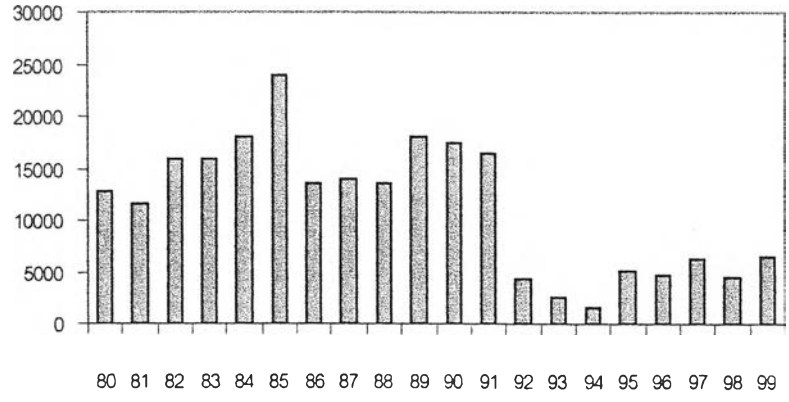

Figure 3.5.1 Amounts of premise and warehouse inspections (Q21), by year 1980-1999.

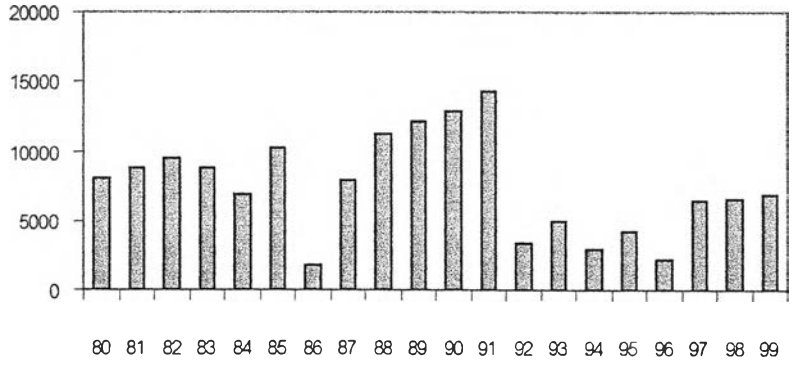

Figure 3.5.2 Amounts of product inspections (Q22), by year 1980-1999.

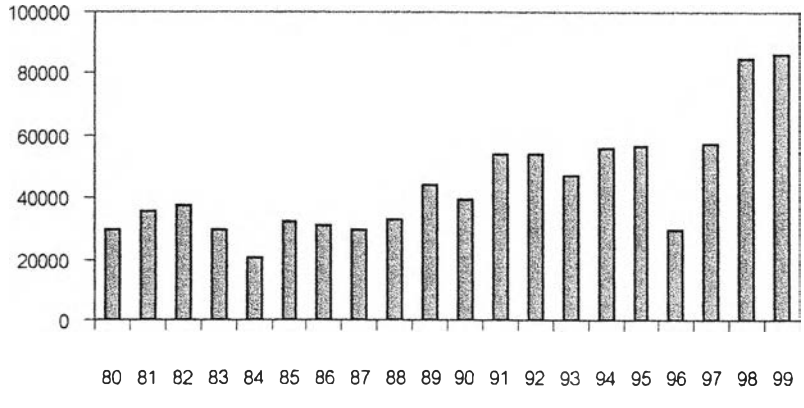

Figure 3.5.3 Amounts of other products of post-marketing activities (Q23), by year 1980-1999.