Chapter I

Introduction

Statement of the Problem.

Pharmaceuticals are central elements in health care system. For many conditions they are the only, for others they are the cheapest and most effective form of treatment. In the third world countries, pharmaceuticals are relatively even more important, and sometimes account for as much as one quarter or one-third of health expenditure.

Almost all countries, including newly industrialized and developing countries have a drug industry of some kind or other, which caters for a part of the nation's needs. This is generally not only the result of deliberate policy, but also rendered possible by a number of significant industry features.

Pharmaceuticals may be divided horizontally into two broad groups according to the patent status.

The first group are generic or multisource drugs, off-patent products made by more than one company, and available on prescription or over-the-

counter (OTC). They may be sold under brand-names or under their generic names. Price competition is often severe and profit margins low.

The second group, and the most important concern are on-patent drugs which are sold on prescription. Products of this type are responsible for the spectacular growth of the pharmaceutical industry since the 1930s, and are the ultimate source of prosperity not merely for the innovative company, but also for the generic sector as well. Competition is by the development of new drug research and development . Given patent protection, successful firms are, in principle, able to earn large returns. The investment required is high, however, only a limited number of firms are able to participate (OECD, 1980).

Competition in the first group also has an indirect but important influence on the innovation of considerable value, which is why they are still worth being produced after patent protection has been expired. The extent to which the original innovator can retain a market after his patent ends must obviously affect his cash flow and his ability to invest in research and development.

The structure of a market refers to such characteristics as seller concentration, barriers to entry for new firms, conditions for demand, and buyer concentration. Seller concentration can have a significant impact on a market in terms of the product supplied side and the nature of competition among the leading firms. It is usually measured by the concentration ratio, that is the share of sales accounted for by a small number (usually four to eight) of the largest sellers. In a typical oligopoly situation, the dominant sellers will be reluctant to provoke retaliation by cutting prices; instead, they compete primarily through product differentiation and promotional activities. Seller concentration is closely linked to the barrier to entry of new firms.

Generally, the higher the degree of concentration, the more difficulty it is for new firms to penetrate the market. This might be due to the production economies of scale, product differentiation accompanied by substantial promotion, or a combination of these (Koch, 1980). The pharmaceutical industry, despite its fragmentation, does show some of the characteristics of concentration described above particularly in the production of bulk drugs and in certain therapeutic markets. In addition, its structure is further influenced by the particular nature of consumer demand: in the proprietary sector, drugs are advertised directly to the consuming public and do not require a prescription - the consumer himself makes the buying decision. In the ethical sector, where a prescription is required, the buying decision is made for the consumer by a physician. Since the latter may be insensitive to or uniformed with price differences, his decisions can be influenced to a great extent by the drug manufacturers who are often the sale source of information on new drugs (UNCTC, 1980).

In Thailand, the pharmaceutical industry still remains an infantile pharmaceutical importing, compounding, packaging industry. Research and development which is the main element of a real drug industry, is still in the primary stage of production virtually non-existing ultimately finished product. Antibiotic drugs are the first ten leading pharmacological groups of drugs distributed in the market. It is found that the market share of antibiotic is the largest, comprising about 31 percent of the total drugs value for import and local production distributed to the consumers. (see Tables 1.1 and 1.2)

Table 1.1: Production of Major Pharmaceutical Products, 1992

Pharmacological Group	Output Value (Million Bahts)	% Share
1. Antibiotics	2,470.90	31.73%
2. Neuro-muscular System	2,145.99	27.56%
3. Dermatological	1,145.23	14.71%
4. Respiratory System	1,209.95	13.22%
5. Alimentary System	995.31	12.78%
Total	7,967.38	100.00%

Source: The Food andDrug Administration

Table 1.2: Imports of Major Pharmaceutical Products, 1992

Pharmacological Group	Output Value (Million Bahts)	% Share
1. Antibiotics	1,119.33	31.31%
2. Allergy & Immune System	959.08	26.82%
3. Cardio-vascular System	721.2	20.17%
4. Other Chemotherapeutic	430.71	12.05%
5. Neuro-muscular System	344.99	9.65%
Total	3,575.31	100.00%

Source: Same as Table1.1

Like other drug producers, the antibiotic drug producers can be classified into two types, branded-drug firms and generic-drug firms. The pricing behavior of antibiotic drug firms in Thailand is interesting. There exist quite significant difference in the price of antibiotic drugs. The high price are mostly of branded drugs, produced by MNCs. On the contrary, the low price are those generic drugs which mostly produced by local drug firms. Questions relating to the "domestic" structure of the industry are especially important to policy makers. A conventional way of looking at the industry's structure is in terms of the market share attributable to a predetermined

number of firms. Several alternative expressions but the most popular one is the concentration ratio which is used in this study.

Therefore, it is worth examining the market structure and pricing policy of the two types of antibiotic drugs and assessing how much the consumer can gain from money saved by consuming generic drugs instead of branded drugs and the consequence of that gain.

Objectives and Scope.

The overall objective of this study is to examine the nature of market structure and pricing policy of the branded and generic antibiotic drugs in Thailand and consequently assess the potential gain for money saved from replacing branded drugs with generic drugs.

Specifically, the study aims at examining the followings :

1. the market structure of antibiotic drugs industry,
2. the pricing policy of the branded drug firms and generic drug firms and,
3. the amount of money saved if generic drugs are encouraged to substitute the branded drugs.

The term "antibiotic drugs" in this study refers to 5 groups as follows :

1. Penicillin
2. Cephalosporin & Combinations.
3. Tetracycline,Chloramphenicol & Combinations.
4. Macrolides, Fluoroquinolones, Trimethoprim & Combinations.
5. Aminoglycosides & Others.

The emphasis is on general modern drugs, human drugs which include tablets or capsules and injections.

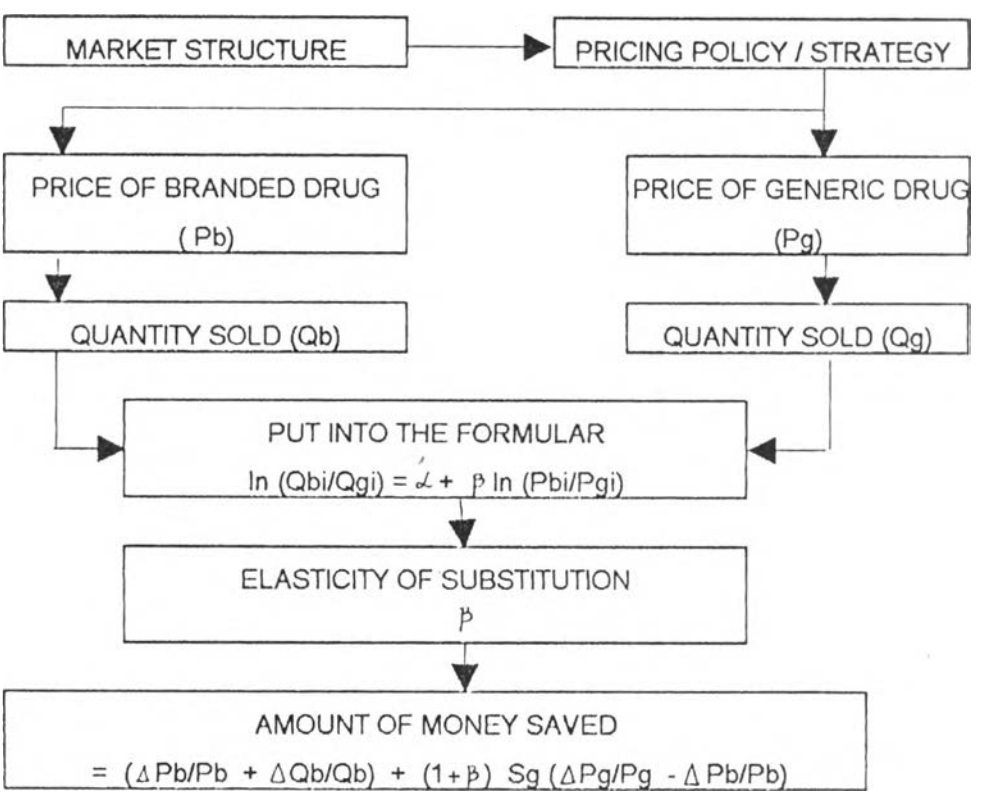
Methodology.

1. Definition

Generic drug firm, which is called in Thailand a local made drug firm, is referred to the firm that produces off-patent drugs.

Branded drug firm, which is called in Thailand an original drug firm, is the firm that is the first that produces anyone type of the drugs.

2. Conceptual Framework



3. Tools / Methods Used

To accomplish the above objectives, the antibiotic drugs are classified according to their pharmacological action and data availability into 5 groups. They are 1) Penicillin, 2) Cephalosporin&Combinations, 3) Tetracycline, Chloramphenicol&Combinations,4)Macrolides,Fluoroquinolones, Trimethoprim & Combinations and 5) Aminoglycosides & Others.

This study use the following tools to analyze each of the pharmacological groups :

a) Assumption

1) Pattern of antibiotic drugs treatment is constant.
2) Drugs are totally sold at the end of the year or drug stock is nil.
3) Quality of the generic drugs equal to the branded drugs.

b) Identification the market structure

Market share / concentration index is used as an indicator to identify the market structure of branded drugs and generic drugs, using the output value representing the market share as follows:

1) Market Size (MS) = Total output value
2) Market Growth Rate (GR)

This study defined the growth of market as a percentage change of this year industry's total production from that of the previous year. That is,

$GR_i = (\Delta TS_{i(t)} / T_{i(t-1)}) * 100$

Where : GR_i = Growth of industry i

$TS_{i,T}$ = Total output value of industry i in year T ; T = t, t-1

3) Concentration Ratio (CR) ; using the four - firm - sales - concentration ratio, defined as

$$CR_4 = \sum_{i=1}^{4} s_i / S * 100$$

Where : CR_4 = Four - firm concentration ratio

s_i = Output value of the largest i^{th} firms; i = 1,2,3,4

S = Industry 's total production or output value

Remark :

1)In calculating the values of the above 1)-3) items, this study use the Weighted Average Price (P), shown by the formula:

$$P = \sum_{i=1}^{n} P_i Q_i / \sum_{i=1}^{n} Q_i$$

Where : P_i = Wholesale price per unit of output of firm i

Q_i = Quantity sold of firm i

$P_i Q_i$ = Total output value of firm i

n = The number of firms

2) Apart from using concentration ratio as an indicator or index for determing the market structure, there exist other indices as well. Since 1950 there have been efforts to develop a "summary" or "comprehensive" index of market structure. The aim of these is to contain all the relevant features of the structure of the market in just one variable. This would widen the focus from the leading firms only and would embrace all the firms in the market. Besides, it is earily manageable since it requires data only on the market's total size and the summed size of a few leading-firm group. Several of the "summary" indexes are given as follows :

(a) The Hirschman - Herfindahl index sums the squares of all the market shares. This weights the larger firms particularly strongly.

(b) The Rosenbluth index is based on the rank of each firm as well as its market share. This gives more weight to the numbers and importance of small firms, for those who consider such "fringe" firms important.

(c) The Entropy index offers still another weighting among the shares of all firms.

Several studies have found, not surprisingly, that the various measures are highly correlated when applied to actual industries. The concentration ratio, however, remains the best all-purpose measure of the degree of competition (Shephard, 1985). Therefore, the analysis of the market structure in this study is based on the four firm concentration ratio.

c) Difference in pricing policy / strategy

From the given market structure, this study attempts to identify pricing policy in order to see how price is determined in each group (both branded drug and generic drug firms) and whether the firms have their pricing policy in either one or more of the followings:

1) The uniform pricing or performing price discrimination.
2) Non - collusive, quasi - collusive or collusive pricing.
3) Elaborate on the main government policies which have had significant impacts on the operation of the firms.

d) Amount of money saved from the substitution of branded drugs by generic drugs.

Type of substitution is firstly identified, whether prefect or imperfect substitution, by using elasticity of substitution between the two types of drugs. Considering total private consumption as a single household, it has to consume some commodities , under limited budget, categorized into food, non-food and drugs with their prices are market determined. Consumers will try to maximize their utility. Hence, price play the important role in private consumption because it determine the demand. Both price and relative price of indifference goods also implies the degree of substitution between different supply of goods.

The Constant Elasticity of Substitution (CES) demand function applied in this study is derived from the basic model of demand for products distinguished by place of production (Armington, 1969). If the purchasing

power of the consumer is a given by the amount Y (for budget), the problem posed will be that of maximizing a utility function.

Max U (drug, food, non - food,...)

Subject to $Y = \sum_{i=1}^{n} P_i Q_i$

Since the consumers have to pay for one amount of drugs from the previous maximized utility. Hypothetical consumers choose only two types of drugs; generic and branded drugs, independent marginal rate of substitution from other goods. The prices of both types are market determined. Thus they are exogenous. Consumers will try to minimize their cost of buying drugs by deciding to consume the optimum amount of generic and branded drugs to come up with the minimized expenditure. Therefore, consumer must allocate their limited budgets so as to meet the optimum Q

$$\text{Min } P_g Q_g + P_b Q_b = B \text{ ----------(1)}$$

$$\text{Subject to } Q = Q(Qg,Qb) \text{----------(2)}$$

Where $\bar{Q}$ = total drug consumption

g = generic drug

b = branded drug

B = expenditure for drug consumption = PQ

P_g, P_b = price of generic and branded drugs

Lagrangean function of this optimization model is

$$\mathcal{L} = P_g Q_g + P_b Q_b + \lambda(\bar{Q} - Q(Qg,Qb)) \text{--(3)}$$

The first - order condition, lead to the following set of simultaneous equations :

$\partial \mathcal{L}/\partial Q_g = P_g - \lambda^* \partial Q/\partial Q_g = 0$

$\partial \mathcal{L}/\partial Q_b = P_b - \lambda^* \partial Q/\partial Q_b = 0$

$\partial \mathcal{L}/\partial \lambda = \overline{Q} - Q(Qg,Qb) = 0$

From which, it follows that

$P_g = \lambda(\partial Q/\partial Q_g)$----------(4)

$P_b = \lambda(\partial Q/\partial Q_b)$----------(5)

$\overline{Q} = Q(Qg,Qb)$----------(6)

Assume that Q is the homogeneous function of degree one. By the Euler's Theorem, we can express in the form

$\overline{Q} = Q_g(\partial Q/\partial Q_g) + Q_b(\partial Q/\partial Q_b)$------(7)

Substituing (4) and (5) into (7), we can finally tranform into

$\lambda\overline{Q} = P_gQ_g + P_bQ_b$----------(8)

$\lambda = (P_gQ_g + P_bQ_b)/\overline{Q}$----------(9)

From (1); $P\overline{Q} = P_gQ_g + P_bQ_b$----------(10)

Divide (10) by (9), it get

$\lambda /P = 1$

$\lambda = P$

Therefore, Langrange's multiplier (λ) is equivalent to the aggregate price (P) of generic drugs and branded drugs.

To simplify the Product Demand Functions, introduce the assumptions that (a) elasticity of substitution in each market is constant and

(b) the elasticity of substitution between any two products competing in a market is the same as that between any other pair of products competing in the same market . Thus we get the constant - elasticity - of substitution (CES) functions, which have the general form as

$$Q = A(a_1\bar{Q}_g^{r} + a_2\bar{Q}_b^{r})^{-1/r} \text{----------(11)}$$

Where

A = Efficiency parameter or shifted function parameter

a_1, a_2 = Distribution parameter of Q_g and Q_b

r = Substitution parameter which can be shown as $(1/\sigma) - 1$ where σ is constant elasticity of substitution

From (7) and (10) its first - order partial derivatives are

$$\partial Q/\partial Q_g = A(-1/r)[a_1\bar{Q}_g^{r} + a_2\bar{Q}_b^{r}]^{(-1/r)-1}\ a_1(-r)\bar{Q}_g^{r-1}$$

$$= a_1 Q\bar{Q}_g^{(r+1)}(a_1\bar{Q}_g^{r} + a_2\bar{Q}_b^{r})^{-1} \text{------(12)}$$

$$\partial Q/\partial Q_b = A(-1/r)[a_1\bar{Q}_g^{r} + a_2\bar{Q}_b^{r}]^{(-1/r)}\ a_1(-r)\bar{Q}_b^{r-1}$$

$$= a_2 Q\bar{Q}_b^{(r+1)}(a_1\bar{Q}_g^{r} + a_2\bar{Q}_b^{r})^{-1} \text{-----(13)}$$

Substituting $\partial Q/\partial Q_g$ and $\partial Q/\partial Q_b$ from (12) and (13) into (4) and (5)

$P_g = \lambda[a_1 Q Q_g^{-(r+1)} * (a_1 Q_g^{-r} + a_2 Q_b^{-r})^{-1}]$ ---------(14)

$P_b = \lambda[a_1 Q Q_b^{-(r+1)} * (a_1 Q_g^{-r} + a_2 Q_b^{-r})^{-1}]$ ---------(15)

From (4.1) ; $Q_g^{r+1} = \lambda\, a_1 Q (a_1 Q_g^{-r} + a_2 Q_b^{-r})^{-1}\, P_g^{-1}$ --------(16)

From (5.1) ; $Q_b^{r+1} = \lambda\, a_2 Q (a_1 Q_g^{-r} + a_2 Q_b^{-r})^{-1}\, P_b^{-1}$ --------(17)

$(Q_g/Q_b)^{r+1} = (a_1/a_2)*(P_b/P_g)$

$Q_b/Q_g = [(a_1/a_2)*(P_g/P_b)]^{1/r+1}$

$Q_b/Q_g = (a_2/a_1)^{\sigma} * (P_g/P_b)^{\sigma}$

When $\sigma = 1/(r+1)$;

$\ln (Q_b / Q_g) = \sigma \ln (a_2 / a_1) + \sigma \ln(P_g / P_b)$

$= \sigma \ln (a_2 / a_1) - \sigma \ln (P_b/P_g)$

$\ln (Q_b / Q_g) = \alpha + \beta \ln (P_b/P_g)$-------(18)

Where $\alpha = \sigma \ln (a_2/a_1)$= Constant

$\beta = -\sigma$ = Elasticity of Substitution

The amount of money saved is calculated by using elasticity of substitution between branded and generic drugs. The amount of money saved can be shown in the form ;

$$\Delta(P_bQ_b+P_gQ_g) = \Delta P_bQ_b + \Delta P_gQ_g$$

$$\frac{\Delta(P_bQ_b+P_gQ_g)}{P_bQ_b+P_gQ_g} = \frac{P_bQ_b}{P_bQ_b+P_gQ_g} * \frac{\Delta P_bQ_b}{P_bQ_b} + \frac{P_gQ_g}{P_bQ_b+P_gQ_g} * \frac{\Delta P_gQ_g}{P_gQ_g}$$

$$= S_b * \frac{\Delta P_bQ_b}{P_bQ_b} + S_g * \frac{\Delta P_gQ_g}{P_gQ_g}$$

Where S_b = Share of branded drugs in term of output value

S_g = Share of generic drugs in term of output value

$$\frac{\Delta(P_bQ_b+P_gQ_g)}{P_bQ_b+P_gQ_g} = (1-S_g)\left[\frac{P_b\Delta Q_b}{P_bQ_b} + \frac{Q_b\Delta P_b}{P_bQ_b}\right] + S_g\left[\frac{P_g\Delta Q_g}{P_gQ_g} + \frac{Q_g\Delta P_g}{P_gQ_g}\right]$$

$$= (1-S_g)\left[\frac{P_bQ_b}{P_bQ_b}\cdot\frac{\Delta Q_b}{Q_b} + \frac{Q_bP_b}{P_bQ_b}\cdot\frac{\Delta P_b}{P_b}\right] + S_g\left[\frac{P_gQ_g}{P_gQ_g}\cdot\frac{\Delta Q_g}{Q_g} + \frac{Q_gP_g}{P_gQ_g}\cdot\frac{\Delta P_g}{P_g}\right]$$

$$= (1-S_g)\left[\frac{\Delta P_b}{P_b} + \frac{\Delta Q_b}{Q_b}\right] + S_g\left[\frac{\Delta P_g}{P_g} + \frac{\Delta Q_g}{Q_g}\right]$$

$$= \frac{[\Delta P_b+\Delta Q_b]}{P_b\ Q_b} - \frac{S_g\,\Delta P_b}{P_b} - \frac{S_g\,\Delta Q_b}{Q_b} + \frac{S_g\,\Delta P_g}{P_g} + \frac{S_g\,\Delta Q_g}{Q_g}$$

$$= \frac{[\Delta P_b+\Delta Q_b]}{P_b\ Q_b} + S_g\left[\frac{\Delta P_g}{P_g} - \frac{\Delta P_b}{P_b}\right] + S_g\left[\frac{\Delta Q_g}{Q_g} - \frac{\Delta Q_b}{Q_b}\right]$$

$$= \frac{[\Delta P_b+\Delta Q_b]}{P_b\ Q_b} + S_g\left[\frac{\Delta P_g}{P_g} - \frac{\Delta P_b}{P_b}\right] - S_g * \beta\left[\frac{\Delta P_b}{P_b} - \frac{\Delta P_g}{P_g}\right]$$

$$= \frac{[\Delta P_b+\Delta Q_b]}{P_b\ Q_b} + S_g\left[\frac{\Delta P_g}{P_g} - \frac{\Delta P_b}{P_b}\right] + S_g * \beta\left[\frac{\Delta P_g}{P_g} - \frac{\Delta P_b}{P_b}\right]$$

$$\frac{\Delta(P_bQ_b+P_gQ_g)}{P_bQ_b+P_gQ_g} = \frac{[\Delta P_b}{P_b}\frac{+\Delta Q_b]}{Q_b} + (1+\beta)S_g\frac{[\Delta P_g}{P_g} - \frac{\Delta P_b]}{P_b} \text{----------(19)}$$

4. Data Collection

The data employed for the analysis of this study are both primary and secondary data. Primary data are obtained from interviews with the firms of both types, academics, government officials concerned and other knowledgeable people especially those from pharmaceutical association e.g. Pharmaceutical Product Association (PPA), Thai Pharmaceutical Manufacturing Association (TPMA) and the Government Pharmaceutical Organization (GPO). Primary data are required to supplement the understanding about pricing policy

Secondary data, using time series data from 1990 - 1993, are obtained from several resources: quantity sell profile from the Food and Drug Administration, the Ministry of Public Health; the description of drug manufacturer profile from the Ministry of Industry and the price profile from the Infopharma Media Services Ltd. (IMS). Multistage sampling techniques used in selecting the sample. In the first stage, antibiotic drugs are stratified into 5 subgroups according to their pharmacological effect and the availability of data. Then, simple random sampling method with 10 percent of sample size for each group is applied to randomize type of drugs into 5 groups (both tablets or capsules and injections). Altogether 10 items of drugs in the 5 subgroups are sampled as follows ;

1) Penicillin, sampling 1 from 14 items. The sample obtained is cloxacillin capsule.

2) Cephalosporins, sampling 2 from 16 items. The sample obtained are cephalexin capsule and cefsulodin injection.

3) Tetracyclines & Chloramphenicols, sampling 2 from 16 items. The sample obtained are tetracycline capsule and thiamphenicol injection.

4) Macrolides, Fluoroquinolones, Trimethoprim & Combinations, sampling 3 from 26 items. The sample obtained are pefloxacin capsule, pefloxacin injection and spiramycin injection.

5) Aminoglycosides & Others, sampling 2 from 24 items. The sample obtained are amikacin injection and aztreonam injection.

All the sample of generic drugs are GMP granted products. This study has its limitation in term of information to investigate. The secondary data obtained are small which contain data for only 4 years. In order to carry out the survey, a list of drug firms was obtained from the Ministry of Industry. It was found that there were 129 drug manufacturing firms in this study. The number of firms in each sub-group of antibiotic drugs are given in Table 1.3. The survey was conducted during January and February 1995 by distributing questionnaires to all of the firms in this study and followed by in-depth interviews only some of them committed to be interviewed.

Table 1.3: Number of Antibiotic Drug Manufacturers, 1990-1993

	Branded Drug Firms	Generic Drug Firms	Total Drug Firms
Cloxacillin capsule	1	31	32
Cephalexin capsule	3	7	10
Cefsulodin capsule	1	-	1
Tetracycline capsule	3	65	68
Thiamphenicol injection	-	1	1
Pefloxacin tablet	1	1	2
Pefloxacin injection	1	1	2
Spiramycin injection	1	-	1
Amikacin injection	1	10	11
Aztreonam injection	1	-	1
Total	13	116	129

Source: Drug Control Division, FDA

5. The Data Obtained.

The survey is separated into two aspects, the quantitative data and in-depth interview (qualitative data). The quantitative data is conducted by interviewing the drug manufacturers. The questionnaire is categorized into two sections; a) Pricing policy of antibiotic drugs in each firm.

b) The impact of government policy on the firm's activities.

The response rate was only 7 firms from 129 firms or about 5 percent of the copies sent out. Since the response rate was very low, redistributed

of the questionnaires and followed by phone were tried. As a result, the response rate increased by 2 percent. The in-depth interview or qualitative data was conducted. The academics, government officials concerned, staff of PPA, TPMA and IMS were interviewed. The questionnaires is categorized into three sections;

a) The information system,
b) The problem of pharmaceutical industry and
c) The guideline for policy maker to encourage this industry.

However, there are some limitations encountered during this study. Those limitations could be grouped as follows:

a) This study is a case study on the antibiotic drugs. Therefore, the implications of this study can not be applied to the other groups of drugs.

b) The availability of data: the information of actual output from FDA is severely limited. The output unit of drug is different among the firms. Also, it might be under reported due to tax reason and confidential of the firms.

c) The reliability of data: the case that the respondents could provide information in the quantitative survey, the answers obtained were much unreliable and the response rate was very low . It may lead to the problem of the inaccuracy of the data. Hence, the author did not analyze the part of quantitative data obtained from this survey. Only the in-depth interview that has been used for detailed information about the industry as a whole.

Possible Benefits.

It is hope that the study would provide some guidelines for policy makers to consider about the role played by the branded drug firms and the generic drug firms. If the government wants the generic drug firm to contribute more to the society, the government could establish some measures to encourage the activities of generic drug firms, the utilization of generic drugs and to control the price and quality of generic drugs so that the consumers as a whole will gain more in terms of spending of their money to buy the antibiotic drugs.

Organization of the Study.

There are five chapters in this study. Chapter I is the introduction, presenting the problem, the objectives, the theoretical framework and the methodology as well as data sources. Chapter II presents an overview of the pharmaceutical industry including a review of literature. Chapter III analyses the antibiotic drugs industry emphasizing on the manufacturers of drugs in terms of market structure and pricing policy. Chapter IV presents the empirical results emphasizing on the substitution mechanisms and potential gain from the substitution. Finally, the last chapter provides conclusions and some policy implications.