CHAPTER 2

PHARMACEUTICAL INDUSTRY IN THAILAND

Pharmaceutical industry in Thailand has been actively developed over the past 10 years. In 1995 the value of pharmaceutical products at wholesale price was 25,097 million Baht. The value of drugs produced in the country was 15,821 million Baht and the value of imported drugs was 9,276 million Bath. As shown in Table 2.1,the growth rate of the sales of local manufactured drugs versus the imported drugs from 1987 to 1995 increased every year.

The factors that supported the growth of pharmaceutical industry in this period (from 1987 to 1995) were the following :

1. The economic status of Thailand.
2. Higher education leading to better improving income.
3. The structure of people's working place changing from the agricultural sector to the industrial sector and moving from rural to city environment.
4. The pattern of illness changing from infectious diseases to chronic diseases, leading to increased demand for drugs.
5. A high profit of the pharmaceutical industry during the previous 2-3 years, which increased competition .

Table 2.1 shows the proportion of local drugs value and imported drugs value. It is noted that both values are increasing every year while the proportion of local manufactured drugs to imported drugs fall down from 69 :31 in 1987 to 63 : 37 in 1995.

Table 2.1 Value of Local Manfactured Drugs and Imported Drugs in Thailand,1987-1995

(Wholesale price)

Year	Local Manufactured Drug (million Baht)	% Growth	Imported Drug (million Baht)	% Growth	Total (million Baht)	% Growth	Local Manufactured : Import
1987	5,145.15	-	2,325.43	-	7,470.58	-	69 : 31
1988	6,708.85	30.39	2,570.98	10.56	9,279.83	24.21	72 : 28
1989	8,372.85	24.80	3,307.60	28.65	11,680.45	25.87	72 : 28
1990	8,886.02	6.13	3,449.08	4.28	12,335.10	5.60	72 : 28
1991	9,657.54	8.68	4,216.41	22.25	13,873.95	12.48	70 : 30
1992	10,696.54	10.76	4,682.61	11.06	15,379.15	10.85	70 : 30
1993	11,831.03	10.61	5,075.31	8.39	16,906.34	9.93	70 : 30
1994	12,969.68	9.62	6,086.63	19.93	19,056.31	12.72	69 : 31
1995	15,820.87	21.98	9,276.47	52.41	25,097.34	31.70	63 : 37

Source : Drug Control Division, FDA

2.1 Nature of the Pharmaceutical Industry

Pharmaceutical products, including drugs and vaccine, are a key element of health care services. In many cases they are the most powerful weapons in the battle against disease. Demand for pharmaceutical products seem to be associated with the increase in population, increase in population means an increase consumption in the country.

In 1995,the total value of drug consumption in Thailand was around 22,697 million Baht in wholesale value equivalent. The value of drug consumption was shown in Table 2.2. The growth rate of drug consumption increases every year by 5 % to 28%. The unequal increasing rate are linked to the differences in public health plannings each year, the pattern of illness, the public health status and sales promotion due to launching new products in the drug markets. It also depends on the economic situation at that time, the population income per capita and the GDP growth.

In the past, the pharmaceutical industry in Thailand had been classified as "traditional" or "modern" according to the nature of materials and the product formula. Traditional medicines comprise purely botanical raw materials while others are mixtures of botanicals and inorganic salts compounded to traditional formulae and are freshly prepared by the shop owner for a specific patient and diseases. Modern drug manufacturing has developed during the year 1940-1941 through the Government Pharmaceutical Laboratories, the first pharmaceutical factory in Thailand, which became GPO in 1966. Later the number of private pharmaceutical firms increased. The growth rate of the number of private pharmaceutical manufacturers is shown in Table 2.3.

Table 2.2 Value of Drug Consumption in Thailand, 1987-1992

Year	Local Production (A) (million Baht)	Import (B) (million Baht)	Export (C) (million Baht)	Total Consumption A+B-C (million Baht)	% Growth of Total Consumption
1987	5,145.75	2,325.43	330.9	7,140.28	-
1988	6,708.85	2,570.98	545.1	8,734.73	22.33
1989	8,372.85	3,307.60	480.8	11,209.65	28.33
1990	8,886.02	3,449.08	604.1	11,731.00	4.65
1991	9,657.54	4,216.41	784.8	13,089.15	11.58
1992	10,696.55	4,682.61	920.3	14,458.86	10.46
1993	11,831.03	5,075.31	1,500.00	15,406.34	6.55
1994	12,964.68	6,086.63	n.a.	n.a.	n.a.
1995	15,820.87	9,276.47	2,400.00	22,697.34	n.a.

Sources : 1) Thai Customs Department

2) Drug Control Division

3) TPMA

Table 2.3 Number of Pharmaceutical Manufacturers in Thailand

Year	Manufacturers	Received GMP	%Received GMP
1989	191	58	30.37
1990	188	79	42.02
1991	184	95	51.63
1992	180	105	58.33
1993	180	112	62.22
1994	178	115	64.61
1995	179	122	68.16
1996	172	126	73.26

Source : Drug Control Division , FDA

In May, 1996 the Food and Drug Administration (FDA) reported that there were in Thailand 480 pharmaceutical importers and 172 drug manufacturers, which were drug-formulators or repackaging agents, 4,723 modern drugstores and 5,147 ready packed modern drugstores as shown in Table 2.4. Most of local manufacturers are locally owned approximately 85%. Another 26 firms are joint ventures with Multinational Corporations (MNCs).

The number of pharmaceutical firms operating at each time varies because of new firms entering the market and old firms going out. One of the factors leading firms to close their business is that they must operate under the manufacturing guildelines, Good Manufacturing Practice (GMP) which usually require high cost of operation. Those which can operate under these GMP guidelines can receive the GMP's certificate from FDA to guarantee their product qualities. Table 2.3 also shows the number of awarded GMP manufacturers. The figure confirms the diminishing of pharmaceutical factories. Another factor to that is the severity of market competition.

2.2 Production of Pharmaceutical Products.

According to Sepulveda and Meneses (1980) the pharmaceutical production can be divided into a number of stages:

1. Precursors, as substances based on natural resources, are transformed into chemicals which as such have no known pharmaceutical activity but are the base of production of active principles.

2. Raw Materials, which represents pharmaceutically active principles prepared on the basis of precursors ; this type of production is conventionally called manufacturing.

Table 2.4 Number of Modern Drugstores in Thailand

Year	Drugstores	Ready Packed
1986	3339	5361
1987	3450	5385
1988	3533	5351
1989	3697	5560
1990	3697	5553
1991	3679	5533
1992	4221	5607
1993	4471	5342
1994	4487	5321
1995	4539	5190
1996	4723	5147

Source : Drug Control Division , FDA

3. Dosage Forms , which represents active substances duly presented and fractional for clinical use ; this phase of production is conventionally called formulation.

4. Finished Products , which represent dosage form duly packed for entering the market. (Repackaging from the bulk into small package.)

According to Balasubramaniam (1983), the pharmaceutical production is divided into 3 stages as following:

1. Formulation of dosage forms from raw materials.

2. Production of raw materials from chemical intermediates. fermentation, plants and animal sources.

3. Production of chemical intermediates from basic chemicals.

Balasubramaniam also stated that the technology for formulation is relatively simple. Capital investment needed is low and economies of scale are not very critical. On the other hand technology for the production of raw materials and chemical intermediate needed is very high , and economies of scales are very critical. Therefore, only few countries can establish vertically integrated pharmaceutical industries starting from basic chemical industry in upstream and move into downstream activities. Most of the firms in Thailand produce drugs in individual trade names which are usually patent expired. The production activity is downstream. This means that the production started by using raw materials and active principles to compound in various forms according to the pharmacopeia in simple to moderate technology. Capital investment can be approximately not more than 10 million Baht for establishment of formulation plant capable of production some dosage forms. Hence, the number of pharmaceutical companies increased to reach the peak of 191 firms in 1989 and

declined in later to 172 firms in 1996 because of the strict control of GMP guidelines by the FDA. For the upstream activity in pharmaceutical field, there were a few manufacturers of raw materials comparable to the formulators, only 10 firms among 179 firms in Thailand as shown in Table 2.5. This kind of production requires high technology and large investment. As a consequence, there is an attempt of the government to encourage foreign investors by offering attractive incentives in the form of tax reductions or tax holiday in the first five years of operation. The simplest kind of production is repackaging of imported bulk finished products or medical chemicals by dividing from bulk into small package with labeling in brand name for sales. This requires even less technology and investment. As for equipment and machinery, about half are locally made as most of them are semi-automatic and do not require high technology.

Due to a large number of pharmaceutical firms in the country, it is unnecessary to keep large stocks of pharmaceutical products at one time. So pharmaceutical plants are operating at about 30-40% of their full capacity in 1984 (Thailand Business, 1984). In addition the purchasing procurement of MOPH requiring the public sector to buy the pharmaceutical products from GPO, limited the volume of private production. A study on production capacity by Kwanjai Rattanarojsakul (1986) found that the local firms and GPO produce at about 61 % and 80 % of their production capacity, respectively.

Table 2.5 Manufacturers of Pharmaceutical Raw Materials in Thailand, 1995

Manufacturer	Raw Material
1.T.S.Polyproducts	Aluminium hydroxide compressed gel
	Magnesium hydroxide compressed gel
2.Pure Chem	Sorbitol
3.Rhone-Poulenc Thai Industries	Aspirin
	Acetic acid
	Paracetamol
4.United Pharma Antibiotics Industries (UPA)	Amoxycillin
	Cloxacillin
	Ampicillin
5.Srimuang Industries	Saccharin
6.Lupin Chemicals (Thailand)	Trimetroprim
	Pyrazinamide
	Rifampicin
	Erythromycin
	- stearate
	- estolate
	- ethylsuccinate
7.PP.Laboratories	Aluminium hydroxide compressed gel
8.Thai Meiji Pharmaceutical	Kanamycin sulfate (sterile)
	Gentamicin sulfate (sterile)
9.Olic (Thailand)	Aluminium hydroxice compressed gel

Table 2.5 (continued)

Manufacturer	Raw Material
10.GPO	Aluminium hydroxide compressed gel Alcohol (absolute) Sodium Chloride Anaesthetic Ether Manesium hydroxide Dextrose monohydrate Dextrose anhydrous

Note : Numbers 7-10 are the factories produce both finished products and raw materials.

Source : Drug Control Division, FDA

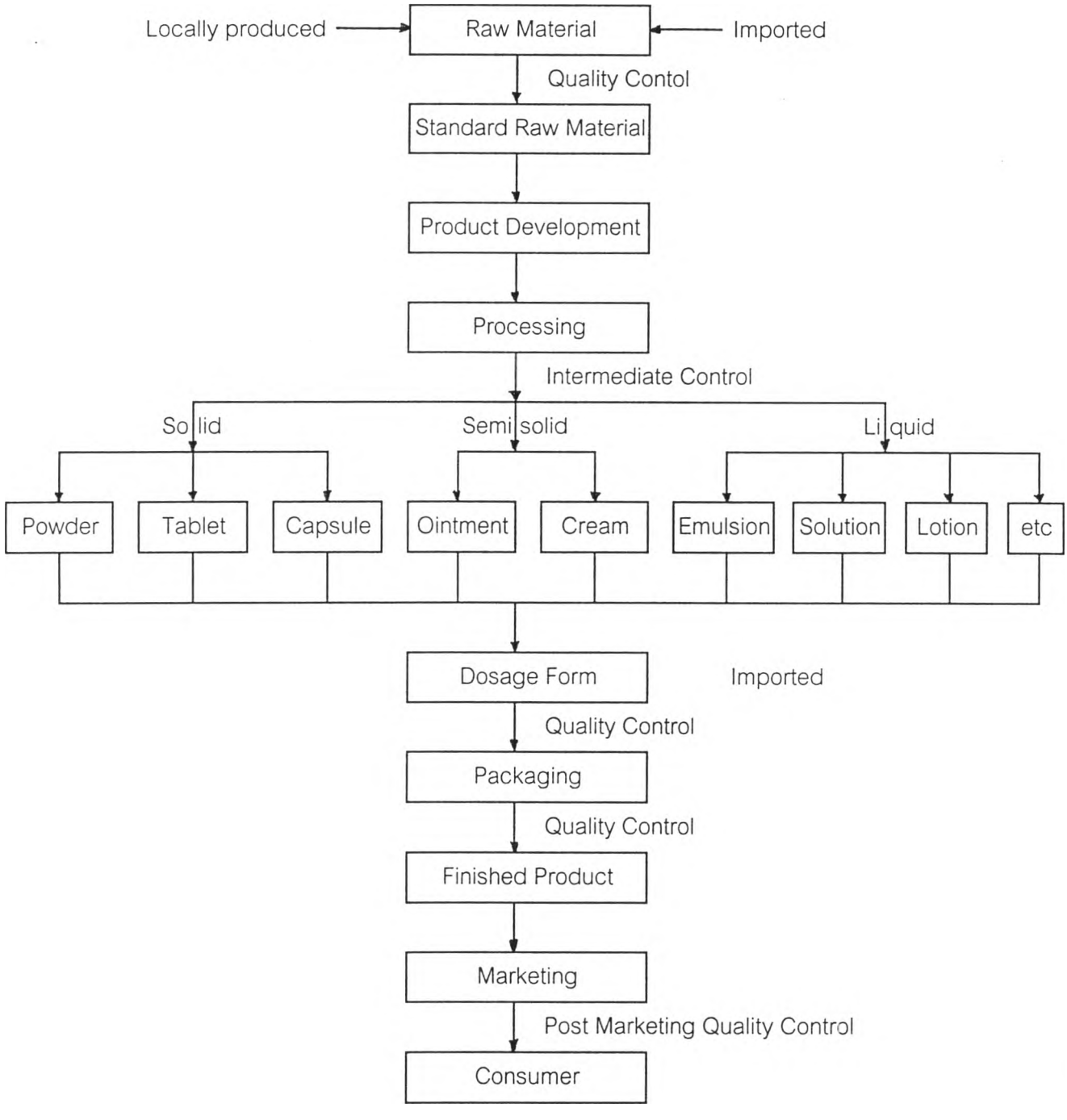
Nowadays GPO uses its full capacity in some sections. However it is still not enough to supply some products from to the public sector. GPO has a limited budget to buy new machines with higher capacity. GPO has to purchase some products from the private firms (about 38 % annually). It can be said that the potential capacity of the GPO is lower than that the potential of the local firms and the MNCs because of the limited budget and space to expand the production. The private pharmaceutical firms can extend their production into the pharmaceutical market especially through the drugstores and private hospitals.

The Production Process

The Production of medicines is the process of compounding the pharmaceutical substances according to the formulation in the pharmacopoeia of BP , BPC , USP and NF to become standard finished products for curing illness or injuries.They come in different dosage forms such as powder , tablet , capsule , ointment , cream , emulsion , solution , lotion , mixture , etc. The quality control which developed to the quality assurance ensures the quality at every stage from the raw material used in processing to the final processing under the guidelines of GMP , ISO-9000 , etc. The process in the pharmaceutical production is shown in Figure 2.1

Raw materials used in the production are both locally produced and imported. Those need to pass the quality control before processing. Moreover, the finished products in any dosage forms can be imported, pass

Figure 2.1 The Pharmaceutical Production Process



Source: Kwanjai Rattanarojsakul,(1986)

the quality control process, get into the packaging process and be supplied to the consumers. After the drugs are distributed on the market, sampling test is necessary for post marketing quality control in order to assure the quality of drugs. Most of pharmaceutical materials used are imported from other countries (around 90-95%) , mostly form Europe and USA , because of the limitation in high capital investment and technology and the adequate specialists or experts. So there are a few new firms emerging in the past two decades. Mostly could only produce the MNCs. The government tried to promote the industrial investment in Thailand in his attempt to support self-reliance. There are now more manufacturers up to 10 manufacturers including the GPO both Thai owned manufacturers and joint venture companies. Presently, the demand for some imported pharmaceutical materials has declined especially for antibiotic chemicals, which have higher cost such as gentamicin, amoxycillin, cloxacillin which can not be produced in the country. These led to the decrease of the value of imported material.

2.3 Distribution of Pharmaceutical Products

Drugs are purchased by a limited group of consumers (patients) with a particular disease or health problem. Therefore, methods of drug distribution vary from those for other goods. Some drugs are distributed directly to the customers while others are distributed through public and private health care services. The proportions of total sales handled by each distribution outlet are different.

Imported or locally produced drug are distributed through six channels according to Thai Drug System by HSRI in 1993 which is shown in Figure 2.2 as the following:

1.Drugstores/Pharmacies.

The most important channel of drug distribution in Thai drug market is drugstores. There are 3 types of drugstores :

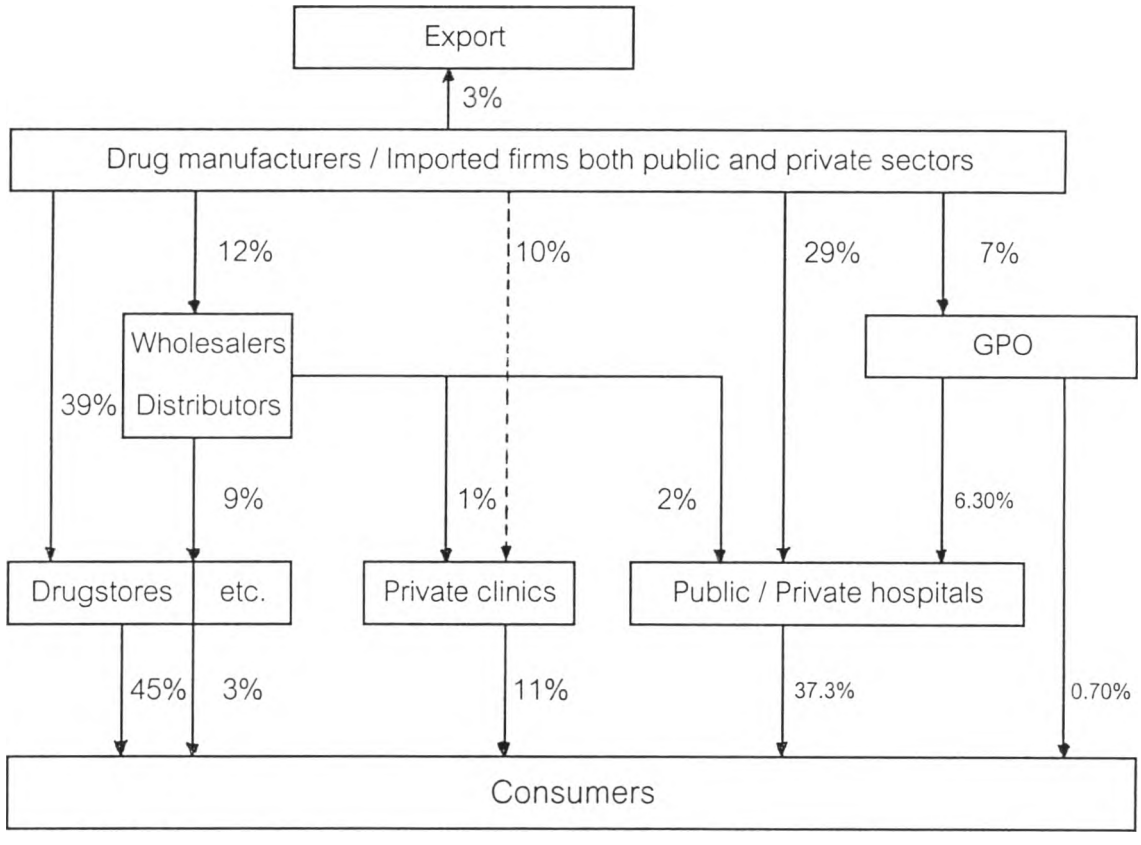
a.Modern drugstores (Pharmacies) sell pharmaceutical compounds including those considered "dangerous drugs","restricted drugs" or prescription drugs. There must be a pharmacist in the drugstore all the time. In practice it is generally not the case. There are 4,723 modern drugstores, out of which 2,262 drugstores are in Bangkok. The remainders 2,461 are scattered in the regional areas.

b.Modern drugstores sell only ready-packed of non-dangerous drugs, (unrestricted drugs called Over-the-counter (OTC)) There are 5,147 ready-packed drugstores, of which 710 are in Bangkok and of 4,437 are in the regional areas.

c.Traditional drugstores sell traditional drugs produced from herbs, animal organs or natural minerals. Most of these drugstores are in the region area. Only 395 drugstores out of total 2,249 drugstores in Thailand are in Bangkok.

In addition ,there are approximately 300,000 village groceries that also sell household remedies.

Figure 2.2 Proportion of Drug Distribution in Thailand in 1992



Notes : 1) etc. means items not included in the distribution are, for example, gloceries, mobile sales.

2) 0.7% (GPO) means sales through retails, private clinics.

3) Percentage shown was estimated number of IMS

Sources : 1) Thai Drug System by HSRI (1993)

2) The Infopharma Media Services (IMS)

Around 45% of medicines are dispensed through drugstores and another 3% via groceries. 48 % of drugs dispensed to the public comes from direct purchase, 39% through both public and private sectors and 9% through wholesalers or distributors.

To a considerable extent the self-medications is dependent on purchasing power or ability to pay. Most available drugs bought are antibiotics, analgesics, antipyretics, cold remedies and vitamins. Therefore, drugstores play the most important role in distributing drug to consumers.

2. Public and Private Hospitals.

Today this channel is more popular among patients because of higher education of the population, more information, and better reliability of medical practitioners. Moreover, both public and private health sectors in last decade have expanded vigorously due to the economic growth of country. This is true mainly for the big cities or urban area with large numbers of public and private health care services. For the distance rural areas there is still utilization of self-medication. As a consequence, the distribution of drugs through hospitals is lower than through drugstores.

From Figure 2.2, the public and private hospitals purchase 29% of the total value of drugs manufactured. They imported from private companies because of prompt delivery and good services. They purchased through GPO for 6.3% and from wholesalers' distributors for 2%.

3. Private Clinics

This drug distribution outlet is welcome by patients both in urban and rural areas. Because of the convenience provided by doctors it can save the time in transportation, waiting and services. Total services can be completely finished in

not more than half an hour starting from examination, but till receiving the drugs and have more time to consult with the doctors. Another reason is to generate close relationships between doctors and patients. The distribution to consumers by private's clinics represents 11%. Private clinics get 10% directly from drug manufacturers and imported agents and 1% from wholesalers or distributors.

4.Wholesalers/Distributors

12% of drugs distributed through wholesalers or distributors who in turn sell to drugstores (9%), 1% to private clinics and 2% to hospitals. Some drug firms employ the services of a distributor or wholesaler who gets paid on the base of fee for service. Terms of payment and discount vary due to the benefit in marketing cash flow. Some are given 30 to 45 days for delivery, some are allowed 60 days. Pharmaceutical firms also offer different dispensing discount rates, depending on term of payment and quantity purchased. For sales directly to hospitals and clinics drug firms can get paid in 3 to 6 months. This is why pharmaceutical firms use wholesalers as distribution outlets.

5. Exportor

The number of export value of pharmaceutical products manufactured locally and imported is quite low as indicated in Table 2.6. During 1987-1995 the average export value was 7.3% of the drug manufacturing value. According to Figure 2.2, the export value is only 3% of the value of drug manufactured and imported in both public and private sectors. The customers are the neighboring countries. The trend is increasing especially in the market like Sri-Lanka, Middle East, Africa and Indochina.

Table 2.6 Value of Exported Drugs in Thailand , 1987-1995

Year	Exported Value (million Baht)	% Growth	Value of Manufactured Drugs (million Baht)	Proportion to Value of Manufactured Drugs
1987	330.9	-	5,145.75	6.43%
1988	545.1	64.73	6,708.85	8.13%
1989	480.8	-11.80	8,372.85	5.74%
1990	604.1	25.64	8,886.02	6.80%
1991	784.8	29.91	9,657.54	8.13%
1992	920.3	17.27	10,696.54	8.60%
1993	1500	12	11,831.03	12.68%
1994	n.a.	n.a.	12,969.68	n.a.
1995	2400	n.a.	15,820.87	15.17%
			average	7.30%

Sources : **1)** Thai Customs Department, Ministry of Finance.

2) Drug Centrol Division, FDA

3) The Government Pharmaceutical Organization, Annual Report. 1996

6. GPO

It is noted that the drugs produced and imported in Thailand and distributed through GPO in only 7%. 6.3% of total value is sold to the public and private hospitals. Another 0.7% is sold directly to customers via retailers (Figure 2.2).