# THAI DRUG SYSTEM

## *A situation analysis for further development*

by

Technical working group for analysis
of the Thai drug system

supported by

Thailand Health Research Institute,
(THRI/NEBT with the support of the Rockefeller Foundation )
Thai Food and Drug Administrations,
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# Foreword

In 1993, it was estimated that overall drug consumption for Thai people amounted to 50 billion Baht (2 billion USD) at retail price. This is approximately 35% of the total health expenditure, then was 140 billion Baht. Drug expenditure has been increasing at a rate higher than health expenditure and national economic growth. Abundant evidences reveal that there are irrational use of drugs at all levels, from self-prescription in the community to prescription by specialists in medical schools. Irrational use of drugs is an example of one of the biggest problems challenging public health administrators and policy makers, that is the problem of inefficient use of limited health resources. Only through knowledge-based health system that rational use of drugs, and efficient use of limited health resources can be achieved.

On the other hand, Thai traditional medicines, and Thai drug industry, are becoming more and more important components of our developing health system and growing economy. Drug export, 1.5 billion Baht in wholesale value in 1993, accounted for 5-6% of the total drug sales. Local industry shared about two-third of the total drug sales. Essential information is needed for policy recommendations and development of strategies towards more self-reliance as well as more competitive drug industry.

Although technical information is essential, it can partly or totally be imported. Information on the drug system, on the contrary are locally specific, and can only be created through health system research. The **Technical working group for analysis of the Thai drug system**, designated by the Thailand Health Research Institute (THRI/NEBT) with the support of the Rockefeller Foundation, the Thai FDA, and the Health Systems Research Institute , spent 12 months, recruiting more than 70

experts from all parts of the Thai health system, i.e. universities, Ministry of Public Health, and the industry, to carry out this study. The results of this study were presented in a two-days national workshop involving more than 400 participants from all concerned parties.

This study is the first attempt of its kind to comprehensively review the situation of the Thai drug system, and give recommendations for reform. Only summary of essential findings and recommendations, extracted from the much more detailed Thai version, are published in English.

We are grateful to and would like to thank all experts in the working groups and participants of the workshop without whose valuable technical contribution, this study will not have been finished. We hope that the results and recommendations will benefit all parties, especially the Thai people.

Finally, we should add that this comprehensive study is carried out not to give negative criticism, but to acknowledge what is, and give constructive recommendations for reformation of the Thai drug system.

**Thailand Health Research Institute**
**(THRI/NEBT)**

**Food and Drug Administration**
**(Thai FDA)**

**Health Systems Research Institute**
**(HSRI)**

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# Executive Summary

## Current situation and problems pertaining to the Thai drug system

1. It is estimated that in 1993 overall drug consumption per annum for Thai people amounted to approximately 27,000 million Baht at wholesale price or 50,000 million Baht at retail price.

2. The expenditure on drug consumption is increasing at a rate higher than those of the health expenditure and the GNP growth. There are ample evidences of irrational drug consumption from community level i.e. self-medication, to tertiary care level. Factors underlying such problems are as follows :
   - 2.1 Unethical drug promotion.
   - 2.2 Too many drug formularies, of which includes a large number of inappropriate ones.
   - 2.3 The prevailing culture of practice in curative care service and drug prescription. It is a common practice that Thai medical doctors, after examining the patients and diagnosing the diseases, will prescribe and sell drugs. Meanwhile, drugs are also sold and prescribed by pharmacists and dispensers at drugstores. These lead to both irrational drug prescribing and selling.
   - 2.4 Inefficient regulatory and monitoring system especially in regard to drug distribution, drug prescription, and drug utilization
   - 2.5 Inadequacy of health personnel's competency and other essential facilities for carrying out efficient health

services.

3. Out of the total number of 184 pharmaceutical manufacturers in Thailand, 174 are producing finished products, only 10 are producing 25 different kinds of raw materials. The proportion of locally produced drugs as compared imported ones experienced a downward trend from 76 : 24 in 1987 to 65 : 35 in 1993.

   Despite the improving quality of locally munufactured drugs, substandard drugs (based on active ingredients) still approximate 11% of the overall output. The rate of substandard drugs produced by Non-GMP factories is three folds higher than that of the factories with GMP.

   It is envisaged that the inception of regional market such as AFTA (ASEAN FREE TRADE AREA) the opening of Indochina countries's market and the promulgation of the Patent Act for protection of intellectual properties, will affect the domestic drug industry particularly in the aspect of severe competition. Meanwhile there is an increasing opportunity for export.

4. Legislative and regulatory authorities as well as the related infrastructure, although fairly well developed are still inefficient and somewhat redundant focussing mainly on strict control. Other supportive mechanism and measures for promoting and strengthening the drug system development i.e.the formulation of the National Drug Policy, research on rational use of drugs, etc., are found to be scattered and inadequate. Such activities are limited and often without adequate resource support.

5. The revival and development of body of knowledge regarding traditional medicine is found to be inadequate for its successful usage.

   Consequently, microbial contaminations, as well as illegal mixing of modern drugs in traditional medicine are among serious problems, affecting consumer's health. Eventhough there is an increasing trend for research and development in traditional medicine aiming at large scale manufacturing e.g. through the Government Pharmacentical Organization. The efforts are fairly limited and often not achieving the full cycle of R&D, and international marketing.

6. The drug information system (DIS) is not fully developed and thus needs to be further upgraded for the purpose of monitoring and decision making on the part of consumers, and all concerned medical professions.

## Recommendations for drug system development

1. The Government should accord a strong political commitment in promotion of drug system development in order to achieve equitable accessibility of safe, good quality, and effective drugs, as well as to promote self-reliance and export.

2. Improve and strengthen concerned government organizations and legislative bodies as well as their infrastructures related to the drug system both to exercise the needed control as well as to promote its sustainable development. The infrastructure for implementing National Drug Policy should specifically be strengthened.

3. All relevent agencies should collectively strengthen their activities, particularly concerning the following :

3.1 Drug re-evaluation should be carried out more efficiently and on a continual basis. Only those having scientific evidences on safety, efficacy and quality could be accepted.

3.2 Promotion of rational drug use should be enforced e.g. utilization of drugs in the national essential drug list by generic names, as well as intensive monitoring on unethical drug promotion.

3.3 Intensive monitoring of drug procurement and distribution procedures for the public and private sectors should be undertaken.

3.4 Improve and strengthen organizational structures to facilitate domestic drug manufacturing particularly in regard to registration procedure, research and development, GMP (Good Manufacturing Practice), and development of a Trust Fund to support R&D.

3.5 Formulate strategic plan for gradual reorientation of the prevailing practice concerning drug prescription in an effort to reduce drug selling by doctors at their private clinics or hospitals as well as drug prescribing by pharmacists and drugstores.

3.6 Develop effective and updated drug information system which allow timely and easy access of accurate information for both consumers and concerned medical

professions.

3.7 Actively promote further development of Thai traditional and herbal medicine emphasizing the whole process of R&D, large scale industrial production, and international marketing.

# Thai Drug System : A Situation Analysis for Further Development

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## 1. Background

Problems, solving strategies, technologies, information, and business in connection with the Thai drug system have experienced a rapid change during the past decade. Attempts to compile and review all relevant information so as to identify prevailing problems, propose direction and strategies for tackling them as well as to further develop the drug system, are deemed highly essential. These undertakings would then facilitate the development of National Drug Policy, promotion of rational drug use and domestic drug manufacturing, national self-reliance in drug supply, promotion and development of traditional and herbal medicine as well as expansion of oversea's market.

The National Epidemiology Board (presently known as THRI : Thailand Health Research Institute under the National Health Foundation) has funded a project entitled, "Analysis of Thai Drug System." The project's activities were undertaken by a working group appointed to study and analyse the Thai drug system since March 1993. Specific ad hoc task forces were also appointed to elaborate eight thematic issues namely, drug selection, development of drug industry, drug procurement and distribution, drug utilization, national drug policy, drug information system, drug legislation and organizational structures, and finally herbal

and traditional medicine.

This paper is prepared in the context of the concluding remarks and recommendations made by the eight ad hoc working groups.

## 2. Linkages between drug system and other related systems

The Thai drug system are closely connected with two other systems namely : (Figure 1)

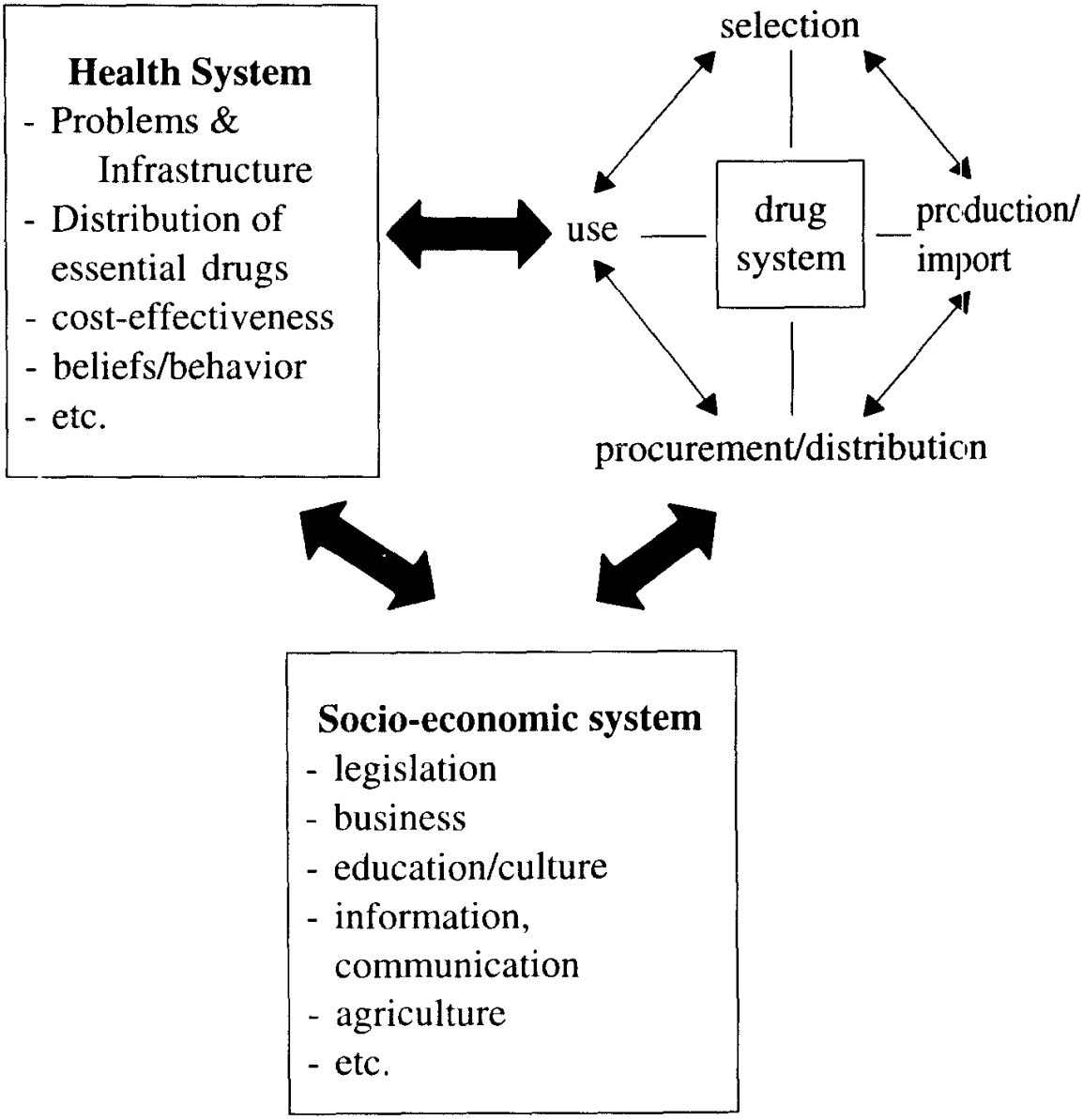


**Figure 1** *Linkages between drug system and other related systems*

### 2.1 Health system

This is the fundamental system which encompasses major drug users particularly government hospitals and health centers. Consideration must be given to rationalization of drug use in relation to health problems and level of care as well as to ensure full coverage and equitable distribution of essential drugs.

### 2.2 Socio-economic system

Taking into account its sub-systems for instance, legislative system, business system, socio-cultural and educational system etc. their influence upon drug production, procurement and distribution as well as other aspects of R&D needs not be underscored.

As for the linkages with other related systems this study attempts to illustrate only key issues of significant importance during the course of discussion.

## 3. Drug selection system

It is clear from the beginning that the responsibility to ensure safety and efficacy of a drug is primarily vested upon drug manufacturers or importers. In addition, all drugs to be used in the country are obliged to meet criteria and standards established by Thai FDA for quality, safety, and efficacy. Following the national policy for rationalizing drug use, the National Essential Drug List (NEDL) was developed, comprising essential drugs which are cost-effective and widely used to tackle major health problems. This list is enforced to be used by government hospitals and health centers. However drugstores and consumers as well as health professionals as a whole still play important roles in drug selection, especially in private health facilities.

Crucial issues to be taken into consideration :

### 3.1 Number of drug products available in the country

By the end of 1993, approximately 30,000 products have been registered for use in Thailand. They can be categorized into three major groups as follows :

| | | |
|---|---|---|
| (1) drugs according to Drug Act comprising | 28,800 | formularies, |
| - modern drugs for human use | 22,777 | formularies |
| - modern drugs for veterinary use | 2,280 | formularies |
| - traditional drugs | 3,820 | formularies |
| (2) psychotropic substances | 462 | formularies |
| (3) narcotics | 199 | formularies |

In addition, there are additional items of drugs produced by GPO (Government Pharmaceutical Organization), Thai Red-Cross, and public health institutions whereby registration requirements are exempted.

This situation when compared with other countries worldwide, very few countries have registered more drug formularies than in Thailand.

On the other hand, developed countries like those within the European Community have relatively fewer number of registered drugs-only around thousands of products.

Among ASEAN countries Thailand has the largest number of registered drugs.

Of those 30,000 formularies, approximately 2,000 active ingredients are included. It is noteworthy that in the national essential drug list only 348 active ingredients are regarded as necessary for the Thai health service system.

### *3.1.1 Factors influencing the number of drug formularies in the country*

*(1) Patent Act*

The Patent Act B.E.2522(1979) protected only the process of drug manufacturing not the product itself. Consequently raw materials could be imported to produce drugs and then sold as Generic products, e.g.

| | | |
|---|---|---|
| antiulcer, **Cimetidine** | 220 | products |
| anti-inflammatory, **Piroxicam** | 179 | products |

*(2) A large number of drug manufacturers/importers*

By the year 1994, there are 184 drug factories and 496 importers. It is perhaps not surprising, in view of the intensity of product competition, that a large number of similar drugs are registered.

*(3) Lifelong valid of drug registration with low registration fee and without charge for maintenance of regislation*

*certificate*

Previously, according to the Drug Act, drug registration needed revision every five years. After the 1983 revision of the said Act, drug registration became lifelong certificates. Registration fee costs only 2,500 Baht (100 USD) per formulary which is very low. Besides, there is no cost incurred in maintaining a certificate for any drug registered. This results in certain numbers of registered drugs not actually be produced or distributed due to various reasons e.g.low profit, low volume of sale, etc.

A recent drug marketing survey undertaken by IMS found that only one-third of registered drugs (10,000 out of total 30,000) are available in the market.

Nevertheless, registration is liable to be withdrawn in case actual manufacturing or import have not occurred for 2 successive years. Through intensive review actions, registered drugs are thereby reduced to only 16,700 formularies by early 1994.

*(4) Availability of Inappropriate drugs*

A number of registered drugs are found to be inappropriate and are currently being re-evaluated e.g.,

- Up to 1,977 brands, with 36 combination formulars, of antitussive for paediatric use are available, some have cough suppressants in combination with expectorants.

- Combination drugs constitute up to 31% of the total registered drugs. Eventhough most of them contain not more than 4 active ingredients it is found that one of them contains as many as 31 active ingredients.

*(5) Registration of similar drug or drug with same strength*

Regulation under the Drug Act rules that similar

drugs in terms of ingredients or strength, and delivery system, should they appear in different color and/or shape, even if from the same manufacturer, separate registration number will be given. This leads to unnecessary increase of drug registration numbers.

### *3.1.2 Effect of too many drugs*

There are both advantages and disadvantages of having too many drugs.

***Disadvantages :***

(a) Overconsumption of drugs via self-medication and irrational prescribing is prompted by very active drug promotion due to high market competition. Vast variety of brand names may lead to drug name mix-ups and drug abuse. Besides, habitual consumption might occur in some categories of drugs.

(b) Increase burden of overall drug management i.e., registration, control of quality, advertisement, sale, inventory, and drug utilization.

(c) With too many drugs, it is obviously difficult in disseminating drug information to physicians, pharmacists, nurses, health personnel, as well as the general public.

(d) Difficulties in identification of drug by its appearance since there are a large number of drugs with more or less the same appearance.

***Advantages :***

With a wide variety of drugs available in the market, one would expect a more active competition in product quality and price which are beneficial for consumers. However, there should also be other prerequisites i.e. efficient quality assurance and appropriate information for consumers, physicians and pharmacists, as a tool to make the right decision in consuming, prescribing or dispensing drugs.

### 3.2 Drug registration

In principle, drug registration must take into account the balance between safety and efficacy.

In case of new drugs which cover new chemical entities, new indications, new combinations, or new delivery systems, if approval is to be made, there is a requirement for 2-year safety monitoring clearance prior to an unconditional approval. During the period of 2-year SMP (safety monitoring program) or untill obtaining an unconditional approval, these new drugs can be marketed only to health facilities manned by physicians. Thereafter, generic products will be allowed to register with requirement for bioequivalence study.

Formerly, drug registration procedure was not well developed, leading to the aforementioned problems of inappropriate drug items. To tackle these problems, there is a need for efficient drug re-evaluation programme.

Another remaining problem is that there is yet no regulation controlling the use of chemicals as raw materials.

***Orphan drugs***

There exists a group of specific drugs that nobody wants to register neither for production or import owing to low benefit or unfavorable business opportunity. They are the so-called **"Orphan drug"**. Developed countries, in general, often stipulate laws or regulations promoting and strengthening R&D, production, and import of such drugs.

Subcommittee on the orphan drugs, appointed by the National Drug Committee have studied the basic data and reported that there are, at the beginning, 43 orphan drugs, 8 of which will be voluntarily imported, and 2 of which will be produced by GPO and Faculty of Pharmacy, Silapakorn University. The FDA will facilitate registration process and exemption of import duty.

### 3.3 National Essential Drug List (NEDL)

As previously reiterated, the National Eessential Drug list was formulated to solve the problem of increasing expenditure on drug consumption, limitation of health budget, inappropriate prescription and irrational drug use. It was adopted first as the List of Essential Formularies for the Department of Medical Services in 1972 and further developed into the NEDL in 1982.

In 1993, the NEDL consisted of 348 essential drugs, totalling 390 items. This more or less corresponded with the WHO list which designated 284 principle drugs and 50 supplementary drugs.

Drug procurement criteria using NEDL is also established for public hospitals. In the MOPH hospitals, 80% of the budget for drug procurement must be used to purchase essential drugs. As for other public hospitals, the purchase of drugs in NEDL should be at least 60% of the drug budget.

In addition, under the 1990 Social Security Act, medical and health services both of the private and public sectors are indirectly obliged to use the NEDL as their minimum standard drug list.

It could be said that the application of NEDL has helped to achieve rational use of drug. It also help strengthening other relevant activities e.g., drug procurement, IE&C on drug, as well as drug production and import. The development of NEDL is indeed the core of the whole drug system development.

***Problems concerning the application of NEDL :***

***3.3.1 NEDL is not updated.*** The NEDL was revised with major changes only once since 1982, despite 4 minor revisions for amendments and supplements.

***3.3.2 Lack of cost-effectiveness data for NEDL development.*** Study in this aspect should be advocated and health economists should be represented in the subcommittee for NEDL

development.

### *3.3.3 Breach of procurement regulation.*

In 1992, it was reported that 50, 60 and 80 percent of the drug budgets were used by regional, provincial, and community hospitals of the MOPH respectively to purchase essential drugs. This is contradict to the 80% procurement regulation.

The reason of breaching as occurred in some regional and provincial hospitals are due to the fact that the NEDL is outdating and there is no strict monitoring and control system on drug procurement.

## 3.4 Drug selection for health service institutions

In general there are Pharmaceutical and Therapeutic Committees-PTC appointed to undertake this task for health service institutions in the public sector.

Due to the fact that there are various vested interests in drug purchasing, lack of strict monitoring and control system as well as public scrutinization, a number of health institutions carry out this task by no means of PTC's.

Meanwhile, large private hospitals prefer to use original drugs rather than generic ones. This situation may be opposite in small private hospitals and clinics.

Drug selection or prescription at drugstores is generally based on local problems and consumers' decision.

## 3.5 Household remedies

This is a category of safe and effective drugs that the consumers can purchase by themselves without any prescriptions by physicians or supervision by pharmacists. Sales of these drugs need no license. At present, there are 42 formularies (modern drugs) and 28 formularies (traditional drugs) designated as household remedies.

Problems facing are unpopularity of the products among both consumers and producers, weakness of public relations as well as shortage of drugs. Most of them are produced by the GPO. They are not popular for private manufacturers due to official restriction on the specific name, dose, pattern and labelling.

### 3.6 Trend of number of drug products

Considering the existing situation and direction of drug system development in the country, it is postulated that there will be a decreasing trend in the number of drug products based on the following reasons :

3.6.1 There has been a continual effort towards re-evaluation of currently registered drugs as well as strengthening of drug monitoring and surveillance e.g.,

(a) caffeine withdrawal from analgesic and cold remedies.
(b) ephedrine withdrawal from all kinds of drugs.
(c) dipyrone withdrawal from combination drugs e.g. dipyrone in cold remedies for paediatric use, dipyrone in smooth muscle relaxant.
(d) withdrawal of some inappropriate anti-emetic for pregnancy.
(e) re-evaluation of cough and cold remedies, including antidiarrhoea.
(f) withdrawal of drugs without any report on production/import for 2 successive years.

3.6.2 New drug approval procedures delay generic product registration.

3.6.3 When the Patent Act B.E. 2535 (1993) becomes effective in protecting new drugs for the next 5 to 10 years, generic

registration will face with difficulties. They will have to wait at least 8 to 10 years after the approval of the original or until the patent of the original comes to an end.

3.6.4 There is a tendency to conform with the recommendation regarding the use of only one registered number for similar drug products with equal strength manufactured by the same company whereby their color and/or shape are different.

3.6.5 There is a gradual increase of coverage of health insurance under the Social Security Act and other existing insurance systems. This results in more extensive use of essential drugs.

Up to a certain point, cost-effectiveness of new drug will be taken into consideration in the registration procedure. Alternatively, price negotiation may have to be settled with the FDA or health Insurance Fund prior to their approval.

To that end, registered drugs, NEDL, or list of drugs use in health facilities should be very similar. This is the situation prevailing in developed countries.

**3.7 Recommendations for improvement of drug selection procedure at various levels :**

3.7.1 Increase efficiency of drug registration procedure so as to ensure good quality, effective, and safe drug. The time require for registration should also be reduced to help manufacturers and importers save cost. These will improve the standard of drug manufacturing (to be discussed in section 5).

An amendment of Drug Act should be made to raise registration fee and add maintenance charge, aiming at using the additional income for development activities.

3.7.2 Promote research and development particularly in the context of pharmaco-economics e.g. cost effectiveness study, in order to obtain data to support appropriate selection of

essential drugs.

3.7.3 Strengthen the continual drug re-evaluation activities and establish priority for certain classes of drugs especially combination drugs, long-lasting registered drugs, and those of ambiguous efficacy.

3.7.4 Organize one stop service or green channel to facilitate rapid generic product registration.

3.7.5 Promote and strengthen utilization of generic name and more extensive use of essential drugs, including strict monitoring of performance in accordance with procurement regulation and PTC's designations. Public scrutinization should also be encouraged.

3.7.6 Revise and update list of household remedies and motivate private manufacturers to produce them for marketing.

3.7.7 Develop legal measures for controlling pharmaceutical chemicals so as to assure the quality of finished products.

# 4. Drug consumption by Thai people

## 4.1 Drug consumption

A number of studies and reports concluded that in the year 1993,

drug consumption at wholesale price amounted to 27,000 million Baht

drug consumption at retail price amounted to 50,000 million Baht

total health expenditure for the Thai's 140,000 million Baht

It is therefore estimated that per capita expenditure on drugs for Thai people is 450 Baht or 18 USD (at wholesale price), and 840 Baht or 34 USD (at retail price).

The percentage of drug expenditure by total health expenditure is around 35%, which is rather high when compared to the figures of 10% to 20% in developed countries (Figure 2). For USA, the proportion is less than 10%.

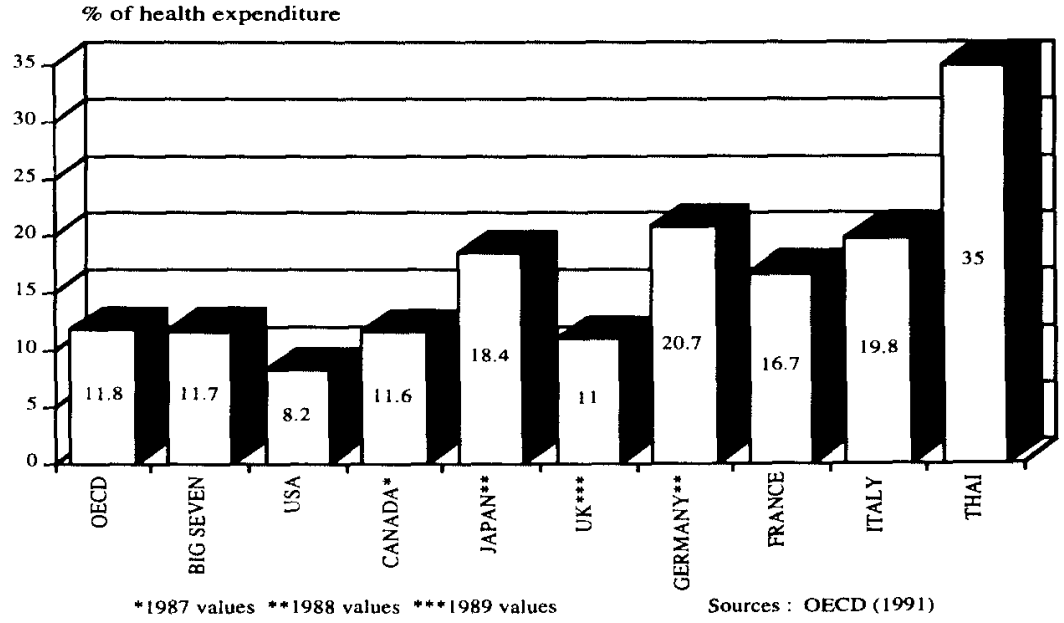


**Figure 2** *Drug expenditure in proportion to health expenditure of OECD countries, 1990*

This may be due to overconsumptiom of drugs on the part of the Thai people. Also, it may be the case that other health expenditures in developed countries e.g. medical service and hospital fee etc., are much higher than those of the Thai's.

Although in real term per capita expenditure on drugs of the Thai's may not be as high as those in developed countries (factors involved are difference in drug prices, drug consumption behavior, etc.), the Thai's figure, when comparing with other ASEAN countries with similar socio-economic conditions for instance, the Philippines - 12 USD, Indonesia - 6 USD, is found to be much higher.

Regarding the rate of increase of the Thai drug expenditure, it is estimated that the rate of increase per annum during the period of 1987-1992 would be around 23%. The growth rate is higher than both the health expenditure (14% per annum) and the GNP growth (8% per annum), (Figure 3).

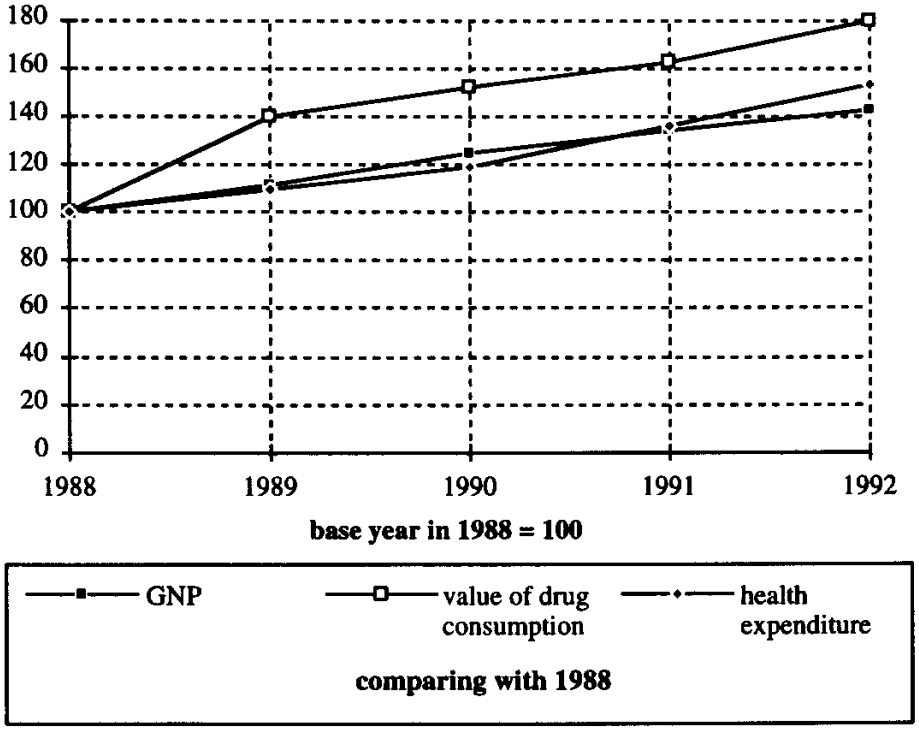


**Figure 3** *Growth of drug consumption vs GNP growth and growth of health expenditure in Thailand*

### 4.2 Rational use of drug

Approximately two-third of drugs is consumed via health professionals i.e. doctors, pharmacists, and other health personnel. The other one-third is consumed through self-medication, advice by relatives, friends or drugstore keepers and through advertisement.

Obviously, there are evidences of overconsumption and irrational use of drugs particularly antibiotics, NSAIDS, analgesic, and cold remedies.

In 1992, there was a lesson learnt at Ramathibodi Hospital Faculty of Medicine, an 800 beds hospital, that the application of a systematic approach in antibiotic monitoring with appropriate guidelines and extensive information dissemination has resulted in 8 million Baht (320,000 USD) annual saving on antibiotic expenses.

One of the critical problems concerning irrational use of drug is the evidence that drugs classified as dangerous, specially controlled group, psychotropics, the so-called Ya-chud (combination of drugs some of which must be prescribed by doctors only), and steroid containing traditional medicine are illegally sold in some village groceries or even in some Village Drug Fund.

### 4.3 Factors involving irrational use and overconsumption of drugs

#### *4.3.1 Drug information*

Inaccurate, imbalance, and misleading information are among key factors influencing overconsumption of drugs.

In 1992 it is estimated that 600 million Baht were spent on drug promotion via various media. These excluded other entertaining expenses i.e. overseas' travel sponsor by pharmaceutical companies, commission on drug purchase, sponsor

for symposia and congress, etc. A figure of more than one billion Baht is believed to have been expended per annum for overall drug promotion. Drug commercials often overclaimed efficacy excluding information on adverse affects, cautions and comparative cost-effectiveness.

On the other hand, educational activities for health professionals and the general public on rational use of drugs are extremely inadequate with very limited resource support.

Drug advertising campaigns often aim towards image building of brand names. It is thus not surprising if an individual chooses to purchase drugs with different brand names at higher price eventhough it contains practically the same chemical contents.

Current drug promotional strategies are inducing extravagance consumption, prescription, and sale. The process include, pricing discount, gadget incentives, free samples, or raffle drawing, etc.

### *4.3.2 Drug procurement procedure*

There are various hidden vested interests under drug procurement in health service institutions. The PTC's approach is efficiently carried out only in some institutions.

Irrational drug purchasing often lead, to irrational drug use particularly expensive drugs.

### *4.3.3 Drug prescription within the health service system*

It is a common practice that the patients are charged by doctors for medical services inclusive of the prescribed drugs. In clinics and hospitals, selling drug is a major source of income.

Meanwhile, neither pharmacists nor storekeepers are supposed to sell or prescribe drugs by themselves. In practice, however, they diagnose, prescribe and sell drugs as well.

This particular culture of the Thai health service system create incentive to over prescribe and dispense drugs.

### *4.3.4 Drug distribution/utilization control system*

The existing control system at all levels, from medical practitioners, drugstores, to village groceries is extremely inadequate.

By July 1993, there are a total of 12,184 drugstores classified into 3 types :

(a) Modern drugstores selling pharmaceutical compounds (including those considered "dangerous") and prescription medicines.

(b) Modern drugstores selling only ready packed non-dangerous drugs (so-called OTC)

(c) Traditional drugstores.

These 3-type of drugstores number 4, 471; 5,365 and 2,348 respectively.

In addition, there are approximately 300,000 village groceries that also sell household remedies. This situation poses a heavy burden for control and monitoring. Eventhough attempts have been made to implement strict control measures, investigations and IE&C compaign, illegal sale of dangerous drugs does exist at all levels.

### *4.3.5 Wide variety of drugs (See 3.1)*

### *4.3.6 Competency of doctors, facilities of health institutions*

Inadequate competency of doctors in diagnosis, lack of facilities and resources in health service institutions and limitation of standard treatment lead to irrational drug use, as well as adverse drug reactions especially in regard to antibiotic

utilization.

### 4.4 Trends of drug consumption in Thailand

It is likely that drug consumption via medical practitioners and through health insurance shemes will be increased. Hopefully this would to lead better control and monitoring of drug utilization, especially when capitation payment is applied to the health insurance system.

Meanwhile irrational drug use, illegal and inappropriate drug sale are likely to remain, especially when purchasing power increases. This is particularly due to incapability of the management in controlling vested interests in drug procurement, extensive drug promotion, quality of the health service system and the medical professions, level of education, knowledge, and understanding on the part of the general public.

### 4.5 Recommendations for promotion of rational drug use

4.5.1 Regular updating of National Drug Policy and Essential Drug List.

4.5.2 Promote and moniter activities carrying out by the PTC's

4.5.3 Regionalize collective bargaining for drug purchasing at the provincial level (pilot projects based on this approach have been proven successful in saving cost and increase quality, and are being replicated in all provinces).

4.5.4 Regulate and enforce the use of generic name in drug labelling, information leaflets and promotional messages.

4.5.5 Development of ethical criteria and monitoring system for controlling drug promotion in

Thailand.

4.5.6 Disseminate information on National Drug Policy, Essential Drug List, and rational drug use to both consumers and concerned medical professions via multi media approach. The said information should also be incorporated into academic curricula of the Schools of Medicine and Pharmacy.

Drug store keepers manager of village drug cooperatives, and village groceries, should be orientated to enhance their roles in providing health education and drug information to the customers.

4.5.7 Promote research studies on drug consumers' behavior at various levels as well as studies on pharmaco-economics and utilize the findings in the development of strategic plan to tackle the problems pertaining to irrational drug use.

4.5.8 Promote utilization of essential drugs both in the public (subject to procurement regulation or voluntary commitment) and private sectors (according to Health Insurance Schemes under the Social Security Act).

4.5.9 Control and monitor drug sale at all levels as well as explore alternative approaches e.g. availability of household remedies in place of dangerous drugs sold in village groceries.

4.5.10 Develop an effective national network for rational drug use to enhance mutual support and cooperation with the international network (INRUD-International Network for Rational Use of Drug).

## 5. Drug Industry

Approximately two-third of drugs presently marketed in Thailand are manufactured in the country. The other one-third constitutes imported drugs.

Raw materials for local drug production are mostly imported.

### 5.1 Number of modern drug manufacturers/importers

At present there are 184 drug factories. Three-fourth of which centered around the Bangkok Metropolitan. Most of them (approx. 85%) are owned by Thai's. There are 26 factories under joint venture with overseas' partners. During the past decade, there has been a decreasing trend in the number of factories due to severity of market competition and intensive enforcement of drug regulatory measures.

There are 10 factories including GPO, producing 25 different kinds of raw materials.

In view of drug import, there are 496 importers.

Despite the achievement of self-reliance in our pharmaceutical needs, the proportion of locally produced drugs as compared to imported ones has shown a decreasing trend from 76 : 24 in 1987 to 65 : 35 in 1993.

### 5.2 Drug quality

Quality of locally produced drugs particularly generic products is a very important factor influencing the feeling of trust and acceptance among consumers and medical practitioners which, in turn, has a direct bearing upon domestic drug production.

In 1991, the Inspection Division of the FDA in collaboration with the Department of Medical Sciences reported a drug sampling survey under the GMP (Good Manufacturing Practice) project that of all locally produced drugs approximately 11.5% is

considered substandard (in regard to active ingredients). Products from GMP factories were found to have less substandard as compare to those of non-GMP factories, 8% as compared to 25% respectively. However, there was very rare cases of fake drugs.

There were a number of dissolution and bioequivalence studies on various kinds of locally produced drugs. Some problems existed, expecially those of anti-inflammatory groups.

Development strategies and approaches for drug quality assurance are stipulated by the Drug Committee under the Drug Act. They appear as follows :

(1) Strengthen and enforce the GMP scheme which has been initiated since 1984. In 1993, 62% (112 factories) of all manufacturers have already received the GMP certificate including the GPO (Government Pharmaceutical Organization). The FDA has planned to meet the target of 100% GMP coverage by the year 1996. Technical, educational, as well as financial strategies were used to speed up implementation. Major obstacles against GMP development are requirements for capital investment, personnel, and technical know-how, and lack of legal measures for GMP enforcement (GMP is still not compulsory).

(2) Following the 1992 ministerial order, drug manufacturers must set up standard and dissolution testing method for 36 drugs as notified by the Minister.

(3) Since 1993, content uniformity testing has been required for drugs containing less than 2 milligram per dosage of active ingredient.

(4) For all imported drugs and 12 locally produced drugs as notified, stability testing is required prior to registration.

(5) Since 1993, bioequivalence study has been required for generic products registration (in case of generics for new drugs).

(6) Intensive controlling and monitoring of drug factories,

especially non-GMP ones.

Hence, there is a trend toward better quality of locally produced drugs. As opportunity for drug export to neighbouring countries and market competition increase manufacturers are forced to enhance their attempts to improve the quality of their products.

### 5.3 Drug research and development

Drug research and development in Thailand are limited to the levels of drug formulary development and study on quality of produced drugs. R&D section were initiated only in 16% of drug factories.

However, there are a number of R&D projects in the public sector especially in the academic institutions and GPO. Among the successful ones are :

- R&D on vaccine for Dengue Hemorrhagic Fever at Mahidol University.
  (Phase II clinical trial has been accomplished, if success, this will be the 1st new drug developed locally)
- R&D on extraction process for **Plaunotol**, an antiulcer drug from a plant, Croton sublyratus Kurz., by Chulalongkorn University.
- R&D on clinical trials of herbal medicines e.g. Andragraphis paniculata, Aloe vera, Ganoderma lucidum by the GPO in cooperation with other academic institutions.

### Problems involving drug R&D

5.3.1 Budget deficiency. R&D activities require heavy investment and high risk is often involved. As pharmaceutical industries in Thailand are of small to medium sizes they cannot afford extensive R&D. It is thus recommended that the Goverment

provide supports to R&D e.g. provision of budgetary subsidy or mobilising resources from drug sale to set up R&D promotion fund. Tax exemption for R&D instruments and other relevant financial strategies are deemed essential.

5.3.2 Shortage of manpower particularly pharmacists, researchers and doctors who are interested in carrying out R&D. According to the regulations set forth by the Royal Thai Government, upon graduation doctors and pharmacists are bound to serve in the civil service for a period of 2-3 years.

5.3.3 Clinical trial studies are limited. Only drugs with certification of free sale from the country of origin can be used in clinical trial study. Without any criteria, standard guidelines or monitoring procedures for clinical trial, current studies are often carried out in collaboration with multinational companies which aim at achieving positive data for drug promotion.

### 5.4 Drug Procurement and Distribution

Through market survey undertaken by the IMS, drugs are distributed through the following channels :

| | |
|---|---|
| Pharmacies | = 40% |
| Hospitals (public + private) | = 43% |
| Private clinics | = 10% |
| GPO outlets | = 2% |
| Others | = 2% |

There are several problems and needs pertaining to drug procurement and distribution :

5.4.1 There is a need to strengthen the PTC's and provincial drug procurement strategies in order to achieve good quality drugs at reasonable prices.

5.4.2 There is a deficiency of information concerning drug market.

5.4.3 Illegal drug distribution is still rampant e.g. the sale of ya-chud (specially prepared combination), dangerous drugs, specially controlled and psychotropic drugs in village groceries and drugstores as well as the sale of these drugs in modern pharmacies while the pharmacist is not on duty.

Weaknesses in drug control system, inadequate education for consumers, and relatively few items of OTC drugs are thought to be major reasons behind this problem.

5.4.4 Overlapping of professional responsibilities regarding the sale of drugs in doctor's clinics and hospitals.

## 5.5 Price Control

Drug pricing in Thailand is controlled through the following mechanisms :

5.5.1 Market mechanism allowing free competition among generics, and competition among drugs under the same category.

5.5.2 Direct price control under the Price fixing and Antitrust Act, enforce by the Ministry of Commerce.

5.5.3 Medium pricing designated for the sale of essential drugs in public facilities.

5.5.4 Patented drug pricing control designated by the Committee on Patented Drug appointed under the 1992 Patent Act.

Nevertheless, it should be noted that drug price index is almost always higher than general consumer price index.

## 5.6 Impact from international economy

### *5.6.1 Agreement on Intellectual Properties*

Thailand amended its Patent Act in 1992 to cover

product as well as process patent. Limited market exclusivity has also been given to pipeline products following the pressures from international drug manufacturers since 1991.

Chances for investment and sales of generic products are decreasing and hence there is a downward trend of consumption of local products as compared to imported ones.

This situation, however, stimulate R&D and improvement of drug quality both in the public and private sector.

### *5.6.2 Free trade agreement*

Pharmaceuticals constitute one of the fast track commodities in the AFTA (ASEAN FREE TRADE AREA) agreement. With the reduction of tariff barrier as well as an increase in the economy of scale and market competition, strengthening of R&D and improvement of drug quality could be expected.

The AFTA agreement may, in the future, develop its working mechanism similar to that of the EC's. In this case harmonization or even centralization of drug market may evolve which will pose a big challenge for the drug regulatory authority.

### *5.6.3 Open up of Indochina countries*

The Indochina countries comprising Myanmar, Vietnam, Laos PDR., and Cambodia including southern China accommodate more than 200 million people. With improving economy and hence purchasing power, they constitute a potential drug market while some of its members will become competitors for drug export in the future.

However, due to weaknesses of the drug regulatory authority in these countries the incidences of drug trafficking are frequently found along the border.

### 5.7 Export of drugs

In 1993, the total value of drug export from Thailand was estimated to be around 1.5 billion Baht, 5-6% of the total drugs produced and imported. The trend is increasing especially in the market like Sri-Lanka, Middle East, Africa, China and Indochina.

However, there are several problems being encountered in drug export e.g.

(1) Delay in registration process.

(2) Current situation regarding quality control of locally produced drugs.

(3) High market competition.

(4) Weaknesses in the economy and drug control system in the trade partner countries.

### 5.8 Future trend of Thai drug industry

(1) There will be fewer number of small scale producers due to pressure from competition, intellectual properties' right agreement and implementation of GMP. In the case that GMP is legally enforced, it is estimated that more than 30 small drug factories may be closed down.

(2) Market competition will be more extensive with increasing opportunity for export. This will help strengthen the Thai drug industry.

(3) There is likely to be a decline in the sales of locally produced drugs.

(4) Domestic drug industry will be upgraded to a higher level in terms of quality and if properly supported in its R&D endeavour, it might be able to develop and market new drugs. Cooperation with research institutes both public and private ones as well as joint venture with foreign drug companies are important factors enhancing the success.

### 5.9 Recommendations for improvement of domestic drug industry

5.9.1 Set up R&D support fund and develop measures for promoting R&D in the private sector.

5.9.2 Increase efficiency of drug registration process, especially for products to be exported.

5.9.3 Establish a green channel to speed up registration of generic products especially after expiration of original drug patent.

5.9.4 Exercise all efforts including legal enforcement to achieve 100% GMP coverage.

5.9.5 Strengthen bilateral and regional collaboration in developing effective drug regulatory system in Indochina countries in order to facilitate drug export.

5.9.6 Gradually increase the requirement for standard prerequisites in several aspects to further improve drug quality.

5.9.7 Support and promote research and networking of information especially on pharmaco-economics in order to obtain accurate figures in regard to drug market, drug price index, and drug utilization.

5.9.8 Improve drug categorization so that more drugs can be sold as OTC's while strictly enforce legal measures against unlawful sale of drugs.

5.9.9 Improve the standard of all types of drugstores and gradually establish a system with appropriate segregation of professional responsibilities.

## 6. Drug information

Drug information is essential as a base for decision-making on the part of consumers, medical professions and drug regulatory authorities. It is thus considered as important as the quality, safety and efficacy of drugs.

Pharmaceutical companies spent about 15% of the drug sale volume to promote their drugs. This included intensive advertisement of drugs. In 1992, they spent approximately 600 million Baht (24 million USD) on drug promotion through newspapers, television and radio broadcasting.

However consumers's education on proper use of drugs is still very limited and uncomparable to the extensive advertisements made by the drug manufacturers. Due to heavy workload, physicians and pharmacists have little time to educate patients or the general public on rational use of drugs.

More than 70% of drug advertisements at provincial radio broadcasting stations contain messages on drug propaganda which are not technically sound and also illegal.

Drug label and package inserts, another important source of information, were also found to give inadequate and incorrect information, and sometimes even too difficult to read.

Information in support of drug control and R&D, although plentiful are scattered and difficult to retrieve. Some information is inadequate especially those on behaviors of consumers, health professionals and drug manufacturers.

**Recommendations for improvement of drug information**

6.1 Drug labelling and packages insert should be reviewed together with drug reevaluation.

6.2 Generic labelling and advertisement should be promoted and enforced.

6.3 Develop national ethical criteria for medicinal promotion with appropriate monitoring system especially by NGO's. Education of the media and drug industry is also needed.

6.4 Strengthen information dissemination on rational use of drug to be integrated in all infrastructures including the mass media, professional bodies, school system as well as nonformal education.

6.5 Networking of scattered information database to acheive easy access and more efficient use.

6.6 Support IE&C research for better information especially on the behaviors of consumers, health professionals, and drug manufacturers.

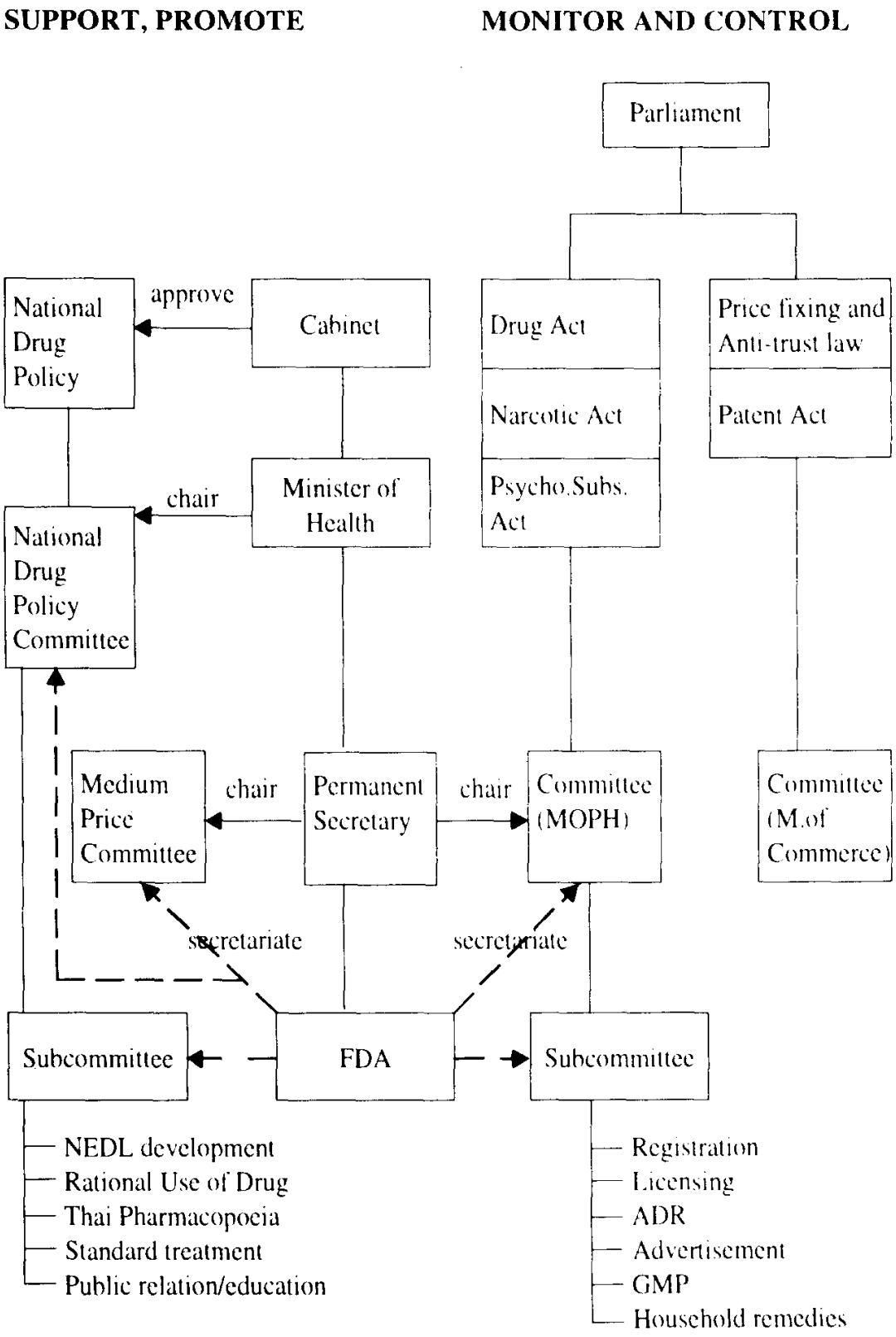


**Figure 4** *Organization structure for drug system*

## 7. Organizational and legislative infrastructure

The organizational and legislative infrastructure of the Thai drug system can be divided in to two parts (Figure 4).

**Monitoring and Control part**

The Thai FDA is responsible for the implementation of drug control under three acts i.e., Drug Act, Narcotic Act, and Psychotropic Substances Act.

It is also responsible for the development of a medium price system under the procurement regulation stipulated by the Office of the Prime Minister.

Office of Permanent Secretary of the Ministry of Health is responsible for enforcement of the Medical Practice Control Act and the Medical Premise Act.

Ministry of Commerce is responsible for the enforcement of Price Fixing and Antitrust Act as well as Patent Act.

Office of the Prime Minister is responsible for Consumer Protection Act and drug procurement regulations.

Professional Councils namely Medical, Pharmacy, Dental and Nursing Councils are responsible for the enforcement of Medical Profession Act, Pharmacy Profession Act, Dental Profession Act, and Nursing Profession Act.

**Supportive and Promotive Part**

The Thai FDA coordinates and supervises activities under the National Drug Policy including the provision of public and professional education.

Office of Permanent Secretary supervises the procurement and distribution of drugs in the health facilities under the Ministry of Health.

Universities and academic institutions particularly the

schools of medicine and pharmacy, apart from being drug users, carry out research on drugs and disseminate drug information.

Certain NGO's participate in promotional activities e.g. TPMA (Thai Pharmaceutical Manufacturer Association - mainly local producers), PPA (Pharmaceutical Producer Association - mainly subsidiaries of multinationals), Drugstore Association, Drug Study Group, Committee for coordination of NGOS on Primary Health Care, etc.

The foresaid organizations are less organized, and weaker in infrastructure than those of the monitoring and control part.

**Recommendations for the development of organizational and legislative infrastructure**

7.1 Strengthen the capacity and efficiency of organizations responsible for development and control of the drug system through :

(a) Partial privatization of FDA and strengthening of its infrastructure responsible for drug registration, inspection and advertisement control as well as public education. A system of self-finance through registration fees as applied in the countries like Sweden and U.K., may be considered for application.

(b) Strengthen the infrastructure supporting the implementation of national drug policy and especially policy on rational use of drug. This include part of FDA, Office of Permanent Secretary Ministry of Public Health, and professional organizations.

7.2 Strengthen NGO's (both for profit and not-for-profit) involvement in the Drug committee and National Drug Policy committee. Promotion and support of self monitoring and control by private for-profit organizations as well as ensuring adequate resources for not-for-profit organizations should be encouraged.

7.3 Improving the legislatures related to drugs, stressing on promotion of rational development of the drug system e.g.,

Create funds for R&D and promotion of drug education, by deducting certain percentage of income from drug sales into these funds

Drug committee should be reviewed and upgraded in its efficiency. If possible, the three Acts relating to drugs should be combined.

# 8. Traditional and Herbal Medicine

There are two approaches for the development of this subsystem. On one hand, attempts are made to develop the process of selection, production/import and distribution of traditional medicine according to the Thai traditional medicine texts, mostly combination drugs. On the other hand, some herbal medicines are developed through scientific studies, mostly single herbs.

## 8.1 Policy

Policy support for the development of traditional and herbal medicine has commenced since the first National Economic Development Plan (started in 1961) and was successively reiterated in every government policy as well as in the two national drug policies. A specific national committee for herbal medicine development was appointed by the cabinet.

## 8.2 The control of traditional medicine industry

Registration is required for locally produced or imported traditional medicines. For locally produced products, registration depends primarily on their compliance to the 4 traditional medicine texts, developed almost 100 years ago.

In 1993, there are 3,820 traditional medicine formularies, 3,254 of which are locally produced. Most of the 649 local producers are in up-country areas while the majority of the 96 importers station in Bangkok.

Most local producers run their small family businesses, many of them are illegal. There are less than 10 factories which could meet the desired standard. The quality of herbs used as raw materials for production still remain a problem starting from selection, planting to collection and preparation.

The Government Pharmaceutical Organization (GPO)

produced 6 herbal medicines while another group of 6 are under R&D.

In 1992, 355 million Baht worth of traditional medicines were produced and imported, amounting to approximately 2% of total drug consumption. Three-fourth of the consumption are out of locally produced drugs. If illegal and household use of traditional and herbal medicines are included, their consumption would account for up to 20% of total drug consumption.

Export of traditional and herbal medicines still remains in a very early stage.

### 8.3 Quality Control

Two leading problems concerning quality are notable namely the microbial contamination, and the incorporation of dangerous modern drugs in traditional medicine especially when they are illegally produced. The most common modern drugs illegally mixed in traditional medicines are corticosteroids, antiinflammatory, antiasthmatics, and antihistamines (appetite stimulant). These dangerous modern drugs are available in drugstores selling western medicine and could be bought without prescription, to mix with traditional medicine.

In 1992, 17-19% of locally produced traditional medicine, were found to have dangerous drug content as compare to 24-37% of microbial contaminations.

Approximately 4% of imported products are found to be contaminated with microbials.

Attempts have been made to standardize and improve the quality of traditional medicine :

8.3.1 Standardize the traditional medicine texts and herbal pharmacopoeia.

8.3.2 Develop GMP standard for local producers which has to be applicable to the household producers.

8.3.3 Reconsider and permit the use of certain modern drugs and equipments for the production of traditional medicines.

### 8.4 Distribution

8.4.1 Through drugstores

There are 2,348 traditional drugstores. However, traditional medicines can also be sold in 4,471 modern pharmacies as well as 5,340 drugstores selling pre-packed nondangerous modern products. Some village groceries also sell traditional medicines.

8.4.2 Through traditional medical doctors both registered and non registered.

8.4.3 Through household use - mostly common herbs.

8.4.4 Through public health facilities - mostly under the primary health care program and through Ayuravedic doctors stationing in 25 district hospitals.

In the process of distribution, overclaims and inappropriate advertisements and promotional activities do exist e.g., a formula of laxative is advertised as a weight reducing drug.

### 8.5 R&D

Many concerned institutes are carrying out R&D concerning traditional medicine eventhough not on a large-scale basis. Market research and research to improve the 4 traditional medicine texts are needed.

### 8.6 Recommendations

Total development of traditional medicine is needed encompassing human resources, body of knowledge, biological selection, plantation, collection, production, efficacy and toxicity, utilization, marketing, and export (Figure 5).

The whole process of development will be acheived through

the cooperation of several committees appointed for specific functions. As resources are limited, support from the government is needed particularly in budget allocation and creation of a specific endowment fund for research and development activities.

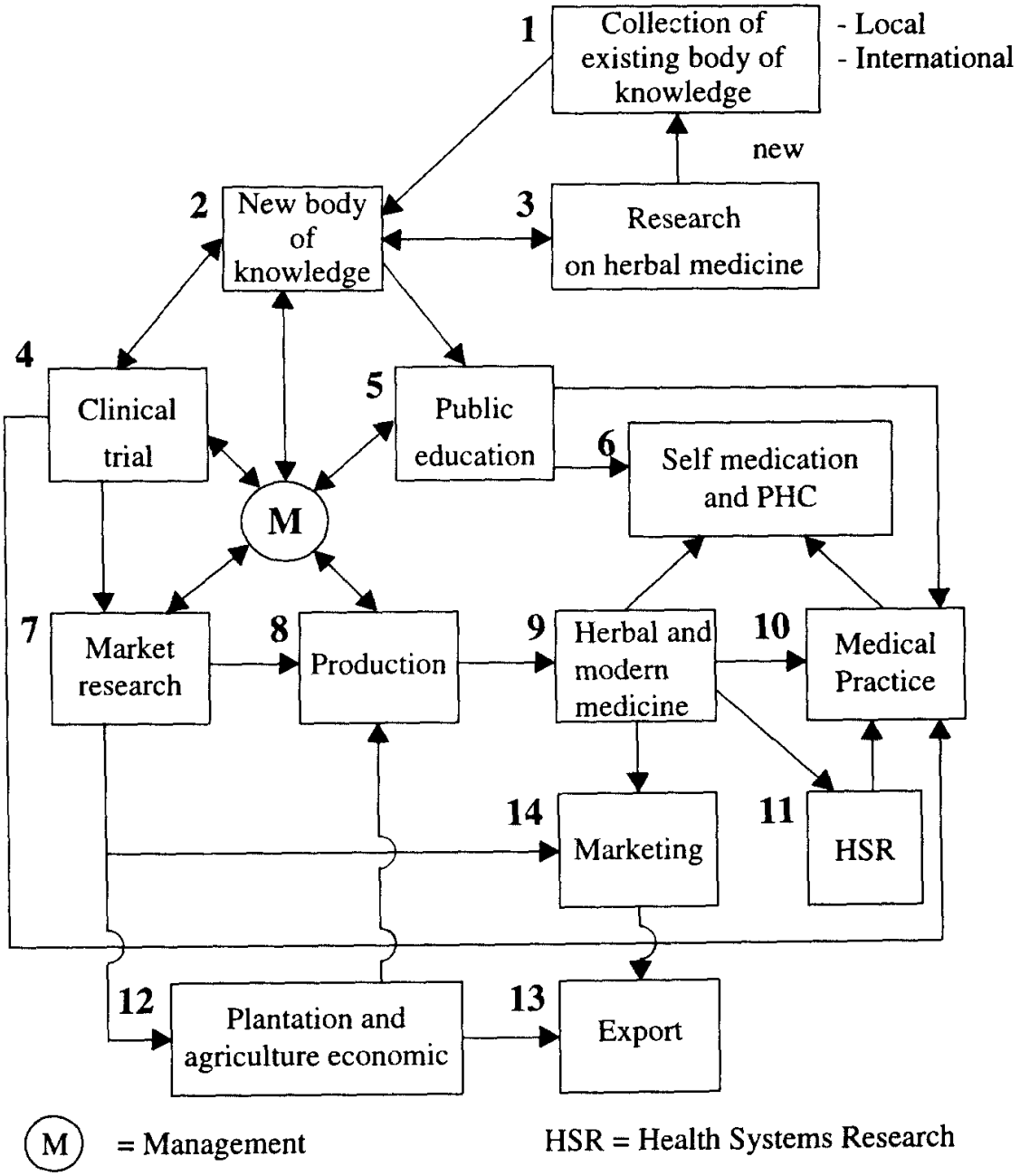


**Figure 5** *Praves Vasi : Strategies for herbal medicine development*

## 9. National Drug Policy

The first national drug policy was developed in 1981 by the national drug policy committee appointed by the cabinet. It aimed at accomplishing availability, accessibility and rational use of good quality essential drugs.

The policy was revised and its second version was approved in 1993. It helped guide total development of the drug system. Major development which followed the implementation of the national drug policy comprised :

9.1 Improvement of drug quality and infrastructure to assure quality control.

9.2 Development of essential drug list which is both the target and the core of drug system development. Availibility of essential drugs especially in the remote areas is also improved.

9.3 Higher production capacity and standard of Thai Drug industry comparable to and even stronger than the neighbouring ASEAN countries. More raw materials are being produced locally with increasing opportunity for drug export.

9.4 Activities in support of rational use of drugs has been extensively strengthened e.g. development of standard treatment guidelines, Prescriber's journal, drug information centre, adverse drug reaction monitoring system, and development of PTC's.

9.5 Traditional and herbal medicines were developed and used both at primary health care and industrial level.

However, there are several constraints needed to be solved :-

**(1) Continuity of activities**

As the national drug policy committee is appointed by the cabinet its term depends on the continuity of the government. To ensure continuity of activities the appointment of the national

drug policy committee should be a requirement under the Drug Act.

Since 1993, with the adoption of the new national drug policy, the roles and responsibilities of each organization involved in the Thai drug system have been well defined so that policy implementation could continue even when the committee was dissolved with the cabinet.

**(2) Infrastructure support**

The infrastructure supporting drug policy implementation is fairly weak with limited internal and external collaboration and networking and no definite plan for monitoring and evaluation.

FDA, being the secretariat of the national drug policy committee, should strengthen its capacity in supporting policy implementation as well as monitoring and evaluation.

**(3) Efficiency of activities**

Due to the constraints as defined in (1) and (2) the efficiency in carrying out activities in persuance of the national drug policy was quite low. The essential drug list is not updated, irrational use of drugs is still widespread, and drug information is scattered and difficult to access.

**(4) Support from concerned organizations**

With the advancement of domestic drug industry, the supportive roles of other related organization e.g., Ministry of Commerce, Ministry of Industry, BOI (Board of Investment), and Ministry of Finance need to be enhanced accordingly.

**(5) Inadequate political commitment**

National compaigns to build up public and political commitment are required.

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