ROLE OF WHO IN NATIONAL DRUG POLICY DEVELOPMENT THAILAND

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1. BACKGROUND INFORMATION AND PROBLEMS

Drugs are essential elements for treating diseases which will bear effect upon health of the population. In time of distress and war drugs are also essential weapons to maintain security within the nation. National Drug Policy is thus widely recognized as a critical integral part of national health policy which is, in turn, interacted and bears effect upon the national economic and social systems.

Problems inherant in the drug system prior inception of the National Drug Policy

1.1 Wastage resulted from over utilization of drugs

Based on a nationwide survey made during 1979-1981 annual drug consumption had experienced an increasing trend from Baht 6,500 million in 1979 to Baht 7,800 and 7,900 million in 1980 and 1981 respectively. The figures were estimated to represent almost 80% of national health expenditure during the corresponding period and reflected the problem of over utilization of drugs in the national drug system whereby the people had to bear sizable burden.

1.2 Problems in reference to domestic drug manufacturing

Thailand has not achieved self reliance in domestic drug manufacturing as the process is largely dependent upon imported raw materials. About 95% of raw materials being used in the country's nearly 200 drug manufacturing plants are imported from overseas.

The ratio of locally produced drugs and the imported drugs which was 75:25 for the period 1974-1979 has remained imbalanced and reflected highly infavorable trade deficit. The underlying causes were contemplated to be lack of appropriate technology and state-of-the-art, inadequate expertise in pharmaceutical research and development including lack of domestic base on raw material manufacturing particularly in view of those which are important drug ingredients.

1.3 Problems concerning inappropriate distribution of drugs

Based on a study made by FDA's Technical Division in 1980, the ratio of drug consumption between the people who live in metropolitan areas and rural areas 6:1 while the urban population accounted for only 18 per cent of the total population. This reflected inequity concerning the opportunity of the people to have access to essential drugs and inappropriate distribution of drugs. However the study took note that majority of the people indulge in self-care through purchasing drugs from drugstores whenever they fall ill.

Two nationwide health behavior surveys jointly conducted by the Ministry of Public Health and Mahidol University's Institute for Population and Social Research in 1970 and 1979 indicated that the percentage of the Thai people who purchased drug at drugstores to treat themselves when ill were 51.4 and 42.3 per cent respectively.

From MOPH's data in 1980, there were 14,586 drugstores throughout the country. Of these 3,500 (24.2%) were located in Bangkok metropolitan area while at the provincial level there were only 155 (%) drugstores per province. Distribution of essential drugs produced by the Government Pharmaceutical Organization under the primary health care programme is found to be inadequate. The health volunteers at the village level who constituted essential mechanism for drug distribution were found to face problems in purchasing and procuring essential drugs. This situation had augmented the problem of drug distribution.

2. CHRONOLOGICAL DEVELOPMENT OF NATIONAL DRUG POLICY

2.1 Background

As having reiterated before the advent of 1980's Thailand has faced critical problem in its drugs system particularly in sound distribution of drugs. Most important of all was the inadequacy of essential drugs in rural areas on the one hand and over utilization of drugs in urban areas on the other. Problems of trade deficit and lack of self reliance in domestic drug manufacturing had become issues of public interest. Financial constraints were also felt by the national health service system infrastructure as hospitals and health service centers absorbed 30-40% of their annual budget on drugs and medical supplies while less then a third had to cover all other health development endeavors.

All these problems called for new approaches in health financing to make best use of the limited resources. One approach designated by the government was to reorientate the drug procurement and distribution systems to be more rationale and effective.

Meanwhile one of the important resolutions of the **28th World Health Assembly held in 1975 called for WHO member countries to reinvent or develop their national drug policy focussing on equity and efficiency.** In 1979 WHO/SEAR Regional Committee Meeting reaffirmed the urgent need of WHO member countries in Southeast Asian Region to realize the pressing need for drug policy formulation. All these are important prerequisites and requirements for Thailand to formulate her **National Drug Policy.**

2.2 Process of National Drug Policy formulation

Following policy commitment of the Ministry of Public Health and the basic principles for drug policy formulation as introduced by WHO, the Thai MOPH's on **October 6, 1980, had appointed a Committee for Formulation of the National Drug**

Policy. The Food and Drug Administration and the Health Planning Division were assigned to undertake essential surveys and data collection for drug policy formulation

as an integral part of the 5th National Economic and Social Development Plan (1982-1986). During 1980-1981 studies and data analysis were made in the areas of drug need, drug manufacturing and procurement, drug distribution including pattern of drug utilization in the government health infrastructure throughout the country. In the process of situational studies and research WHO has provided financial and technical inputs from the very beginning. The outcomes of all studies underscored the importance of the problems and their negative impact upon health and the overall economic and social development of the countries.

A series of technical meetings and seminars were held both by the Ministry of Public Health and Mahidol University to mobilize professional and public opinions regarding national drug system and policy formulation, Senior members of the management, university professors, physicians, pharmacists, health and health related professional and representatives from the private pharmaceutical business sector joined in the meetings. All the aforementioned efforts had formed powerful driving forces towards the development of national drug system and policy.

In **April 1981**, the **Ministry of Public Health had proclaimed its National Drug Policy** which was highlighted in the national programme for drug development as an essential component of the 5th Five Year National Economic and Social Development Plan (1982-1986). Under the national programme for drug development there were 3 major projects namely:

(1) Development of Drug Manufacturing
(2) Development of Drug Procurement and Distribution Systems
(3) Development of Research on Drugs and Herbal Medicine

After the 1981 **National Drug Policy** had been implemented for a few years issue of sustainable development became a concern among MOPH's high officials and the National Committee on Drugs which was appointed to oversee the development pertaining to the National Drug Policy. Such concern stemmed from the fact that the National Committee on Drug was appointed by the cabinet and thus liable to change after new appointment of cabinet members. To ensure sustainability of drug policy implementation, the policy was revised in 1993 to incorporate more detailed approaches, activities and responsible agencies for policy implementation.

The contents of the 1981 drug policy and the revised one in 1993 appear in 3.1.2 and 3.1.3.

2.3 Success and constraints of drug policy implementation

2.3.1 Success

National Drug Policy is recognized as the axis for comprehensive development of the national drug system as well as the focal point for intersectoral collaboration. Implementation of the **National Drug Policy** had led to tangible successes in view of drug system development as follows:

(1) development of system and infrastructure for controlling quality of drugs;
(2) development of national essential drug list and drug distribution system;
(3) promotion of domestic drug manufacturing through good manufacturing practice (GMP's), increase production of essential pharmaceutical raw

materials and export of finished drugs in order to achieve a leading role in drug manufacturing at the regional level;

(4) initiated activities for promoting rational use of drugs at different levels e.g. standardization of treatments, publishing a journal for drug prescribers, establishment of drug monitoring center to follow-up side effects which might occur to consumers;

(5) development of herbal and traditional medicines both at primary health care and industrial levels.

2.3.2 Constraints

(1) Sustainability of drug policy implementation as having reiterated, changes in politics have brought about frequent changes of nation drug committee and sub-committee members which often resulted in slowing down of drug development activities. However through revision of the 1981 national drug policy in 1993 with better defined strategies, activities and responsible agencies, drug policy implementation has been sustained quite favorably. An alternative approach for appointing the national drug committee to ensure sustainability is also being contemplated.

(2) Institutional framework as well as intersectoral collaboration mechanism and networking of all concerned sectors are found to be unclear and inadequate for overall drug system development. Eventhough approaches, activities and responsible agencies are defined as an integral part of the revised drug policy, there has not been any effective collaborative plan as well as a sound follow-up and monitoring of the total system.

(3) As a result of political and institutional repercussions as stated above, some high priority programmes are facing problems pertaining to effectiveness and sustainability notably programmes for development of national essential drug list, promotion of rational use of drugs, development of drug information system etc.

(4) As total drug system development particularly in view of pharmaceutical industry depends upon active support and collaboration of other concerned sectors such as Ministry of Industry, Board of Investment and Research Foundation there is a need to mobilize and enhance their role as strategic partners.

(5) Lack of political commitment and strict adherance to individual party's interest has slowed down certain development programmes of high priority as stated.

Strategies for solving the problems included campaigns for building up political commitment and social responsibility in implementing, following up, monitoring and evaluation of the strategies and plan of action as formulated subject to the **National Drug Policy**. Intersectoral collaboration, partnership and network of the drug and drug information systems have also been promoted to ensure effectiveness and sustainability of drug policy implementation. WHO support in the full drug system development shall be discussed in the following section.

3. ROLE OF WHO IN NATIONAL DRUG POLICY DEVELOPMENT

3.1 Inception and Successive Development of National Drug Policy

3.1.1 Inception of National Drug Policy in 1981

Following the resolution of the 28th World Health Assembly held in Geneva in 1975, WHO had urged member countries to be mindful of the need for formulating their own **National Drug Policy** to ensure efficiency, effectiveness and rational use of drugs and a fairer distribution of essential drugs among different groups of population. WHO Southeast Asia Regional Committee Meeting held in 1976 reaffirmed the need for all member countries particularly the developing countries to establish a managerial framework for drug system management to ensure full efficiency. At that time developed as well as developing countries were facing problems of rapidly increasing cost of health expenditure. In Thailand the problem was felt to be strongly related to the drug system as there has been irrational and overuse of drugs, lack of self reliance in domestic drug manufacturing, maldistribution of drugs and inadequate inter-sectoral collaboration in drug system development.

After conducting a detailed situational analysis and bringing the problems to the attention of all concerned sectors, the general public, the press and opinion leaders in related field through a series of technical meetings, seminars and public hearings, the Ministry of Public had formulated and announced the **National Drug Policy** in 1981 as guidelines for intersectoral coöperation in solving the problems inherant in the Thai drug system. In 1982 the cabinet had appointed the National Committee on Drug to serve as collaborative mechanism for drug policy implementation. The committee also undertook advisory and promotive roles in transforming the drug policy into tangible actions by all concerned sectors and organizations.

3.1.2 WHO Approaches/Recommendations for Drug Policy Development in Comparing with the 1981 National Drug Policy of Thailand.

The contents of the first **National Drug Policy** were actually in line of WHO guiding principles for drug policy formulation. There were essentially 5 policy statements as follows:

3.1.2.1 provision of safe and good quality drugs, extensively distributed to all at reasonable price particularly the essential drugs under the primary health care programme;

3.1.2.2 reduce wastages caused by irrational use of drugs through enforcing all public health service centers to adhere to national formular and essential drug lists while promoting the dissemination of comprehensive information concerning drugs and treatment regimens;

3.1.2.3 enhance control of quality, safety and efficacy of drugs by expanding the network for drug analysis and upgrading organization which are responsible for drug standardization, analysis and production of reference substanced;

3.1.2.4 conduct survey of indigenous raw materials available in the country as well as feasibility study in using local resources for domestic bulk drug manufacturing to build up self-reliance;

3.1.2.5 explore intensively the therapeutic potential of "traditional drugs" and herbs for safe and efficacious use, especially in the field of primary health care. Principles and approaches of the 1981 **National Drug Policy** appeared in Annex 1.

3.1.3 Revision of the National Drug Policy in 1993.

As pharmaceutical science and technology have progressed quite rapidly together with the expansion of domestic drug industry, the 1981 drug policy was found inadequate in solving the problems of the country's drug system. After 2-year implementation the National Committee on Drugs appointed a Sub-Committee for Drug Policy Reorientation to undertake a comprehensive review of the salient contents of the drug policy as well as compile and analyse implementation problems in order to revise the policy to be more adequate, updated and appropriate for the changing conditions. The main objective of drug policy reorientation was to enhance rational use of drug and ensure that all areas of drug development endeavors were in line with the changing socio-economic and technological changes with the ultimate goal of building up national self reliance and security in drug procurement and distribution.

The Thai Cabinet endorsed the **revised National Drug Policy in 1993**. The new policy reflected more explicitly the strategies for policy implementation and expanded the policy statements from 5 to 7 items as follows:

3.1.3.1 To make efficacious, safe and good quality drugs available to all at reasonable price through active cooperation and collaboration between the public and private sectors;

3.1.3.2 To rationalize drug utilization, ensuring maximum benefits both in term of efficiency and effectiveness and to reduce losses and wastages in the pharmaceutical supply system;

3.1.3.3 To develop national self reliance in pharmaceutical industries emphasizing pharmaceutical research and development and promote domestic drug manufacturing for export;

3.1.3.4 To promote the development of pharmaceutical raw material manufacturing industry utilizing local resources;

3.1.3.5 To support research and development aiming at exploring the potentials in disease prevention, health promotion and therapeutic efficacies of herbs, herbal medicines and traditional medicines as well as promote safe and efficient use of such products;

3.1.3.6 To promote and encourage usage of national essential drug lists both in the public and private sectors;

3.1.3.7 To increase efficiency of drug management and enforcement of law, regulations and rule of procedures to facilitate consumers protection.

3.2 Role of WHO in National Drug Policy Implementation

3.2.1 Technical Support

3.2.1.1 Support under WHO Drug Action Programme

This programme was initiated by WHO to support member countries in implementing their National Drug Policies particularly in reference to the distribution of essential drugs. WHO envisaged that essential drugs of good quality and reasonable price could be distributed to all. To achieve this target WHO has formulated guilding principles for publicizing drug policy, strategies as well as need-driven, evidence-based and action oriented approaches whereby each individual country could follow to ensure effective management of their pharmacutical supplies. The programme structure covered 6 essential areas as follows:

(1) **National Drug Policy** Process and Monitoring

(2) Health Economics and Drug Financing

(3) Access Drug Management and National Supply Strategies

(4) Rational Use of Drugs

(5) Traditional Medicines

(6) Regulation and Quality Assurance Capacity

3.2.1.2 Technical Cooperation among ASEAN Countries in Pharmaceuticals

This regional programme covered the esential areas of drug quality control and development of national drug system. It was subdivided into 4 phases

Phase I-II: 1982-1986
Phase III: 1987-1991
Phase IV: 1992-1996

During Phase I-II 6 ASEAN countries namely Brunei, Indonesia, Malaysia, Philippines, Singapore and Thailand received financial support from UNDP and Technical support from WHO. As UNDP support was terminated in 1991 towards the end of Phase IV, WHO continued to support 2 activities under WHO Drug Action Programme on Essential Drugs and Vaccines (EDV), namely :

- Production and Utilization of Regional Reference Substances
- Standardization, Quality Control and Utilization of Herbal Medicine

During the 4 phases all ASEAN countries had participated in joint activities which yield tangible outputs as follows :

(1) Guideline for Good Manufacturing Practices : GMP, 1985

(2) Guideline/Manual on Good Hospital Pharmacy Practices and Management, 1990

(3) Manual on Peripheral Drug Supply Management, 1988

(4) Manual on Drug Evaluation, 1990

(5) Video Tape on Proper Use of Medicine, 1990

(6) Manual for Cultivation, Production and Utilization of Herbal Medicine in Primary Health Care, 1990

(7) Standardized Monographs on Herbal Medicines, 1993

(8) ASEAN Reference Substances (totalling 80 substances endorsed in 1993)

(9) Guideline for ASEAN Good Laboratory Practices, 1993

(10) GMP Guideline for Herbal Medicinal Products, 1993

Of the above items, the Thai FDA had acted as focal point of development in (7) (8) and (10).

3.2.2 Financial Support

During 1989-1995 WHO had provided financial support in implementing the **National Drug Policy** particularly in reference to essential drugs under 8 sub-projects as follows :

3.2.2.1 Strengthening of Drug Information Center

3.2.2.2 Strengthening of Drug Evaluation Registration and Re-evaluation in Thailand

3.2.2.3 Study on Feasibility and Influencing Factors on Drug Pricing Control in Thailand

3.2.2.4 Establishing and Strengthening of Control System for Pharmaceutical Raw Materials in Thailand

3.2.2.5 Drug Quality Control and GMP

3.2.2.6 Strengthening and Development of Drug Management and Rational Drug Selection at Central and Peripheral Levels

3.2.2.7 Quantification of Drug Requirements

3.2.2.8 Drug Utilization Evaluation (DUE) Programme in General/Regional Hospitals.

The outputs from the above mentioned sub-projects could be summarized as follows :

(1) Health manpower development.

Technical personnel and undertaken training, study tour as well as meetings and seminars in pharmaceutical sciences and technologies both within the country and overseas.

(2) Production of technical documents

- Drug Bulletin
- Guidelines for Drug Quality Control
- GMP Guidelines
- Manual for Drug Utilization Evaluation in Hospitals.

(3) Seminar/Workshop on Re-evaluation of Cough and Cold Remedies has been organized.

(4) Development of Computer Software for Quantification of Drug Requirements.

(5) Research on Drug Utilization Evaluation (DUE) Programme in 6 Regional/General Hospitals.

(6) Development of strategies for increasing effectiveness of PTC (Pharmacy and Therapeutic Committee).

In addition during 1996-1997 WHO had provided continuing financial assistance to several essential projects namely :

(1) Project for Extension of Good Manufacturing Practices

(2) Research Projects for Evaluating Essential Drug Policy Implementation Process and Effectiveness and for Development of Policy Information System

(3) Development of **National Drug Policy** Information Dissemination Project with particular reference on promotion of essential drugs.

WHO technical and financial support as having reiterated has contributed immensely in the development of **National Drug Policy** and the comprehensive drug supply system.

4. WHO ASSISTANCE IN EVALUATION OF NATIONAL DRUG POLICY IMPLEMENTATION

Since 1986 the Ministry of Public Health, under close collaboration of WHO, has undertaken 3 major evaluation of **National Drug Policy** implementation as follows:

4.1 First Evaluation of Drug Action Programme in 1986

This first evaluation was conducted jointly by MOPH's technical team and representatives from WHO/HQ and WHO/SEARO during November 24 - December 12, 1986. The objective of this evaluation study was to review the progress of drug action programme with particularly reference to provision of essential drugs at primary health care level. The method of study included consultative meeting, interview concerned managers and personnel as well as data collection at Lumpang and Nakhon Ratchasima provinces.

Five areas of drug action programme were investigated namely drug supply and availability, reduction of wastage, quality assurance, use of indigenous raw material and promotion and utilization of herbal medicine. The results of the evaluation are as follows.

4.1.1 In the area of drug supply and availability, about half of the villages (26,000 out of 50,000) in Thailand have established drug cooperatives where essential drugs are available for sale at low price to villagers who are shareholders. However, village health volunteers (VHV's) who are responsible for the drug cooperatives do not have enough knowledge on drugs and other household remedies and thus have limited role in drug information dissemination.

4.1.2 In an effort for reducing wastage caused by irrational use of drug, the 1981 national essential drug list was enforced to be used by MOPH's hospitals under the direction that they have to use no less than 80% of their drug budget to purchase the essential drugs. After the 1983 cabinet resolution other government hospitals like those under the jurisdiction of the Ministry of University Affairs, Ministry of Interior, etc., were designated to use 60% of their drug budget to purchase essential drugs.

To ensure rational use of drugs it was stipulated that drug purchasing plan be made by all hospitals and health service center at the provincial level to be collated by the provincial public health offices and then forwarded to the MOPH's in Bangkok to facilitate overall planning, procurement, production and distribution of drugs within the public sector. Standard pricing of essential drugs were set and enforced to be used in both the public and private sectors. Drug information center was established to monitor adverse drug reactions with regular publication of prescribers' journal, data sheets and drug bulletin. Provincial hospital drug therapeutic committees were also established with standard treatment guidelines which helped increasing cost-effectiveness of drug treatment.

4.1.3 Quality assurance activities have been strengthened through :

(1) assisting local drug manufacturers in upgrading their manufacturing and quality control procedures by organizing training programmes in GMP's (Good Manufacturing Practices);

(2) increase the scope of quality control sample testing of pharmaceutical products, raw materials, pharmaceutical aids, narcotics and psychotropics;

(3) development of reference substances;

(4) development of Thai Pharmacopoeia;

(5) setting up regional drug laboratories in 5 out of 15 regions;

(6) increasing the workforce of pharmacists in provincial public health offices, provincial and community hospitals for enforcement of drug regulatory control and inspection as well as building up an effective collaboration network of quality control laboratories and drug management.

4.1.4 Usage of indigeneous raw materials have been promoted and supported through conducting research and development to test national potential for essential drug production which will foster national self reliance. Domestic pharmaceutical industries were requested for increasing their capital investment in research and development under close cooperation with interested academic circle.

4.1.5 Usage and promotion of herbal medicine

Knowledge and information about medicinal plants and their usage were disseminated among health personnel and the general public while a comprehensive collection and cultivation of essential herbs was promoted and demonstrated within the compound of hospitals, district health offices, health centres and the village recreational ground. In certain community hospitals selected medicinal plants were produced into appropriate dosage forms for actual patient's treatments.

Major recommendations made in the first evaluation of **National Drug Policy** Implementation appear as follows :

(1) strengthening of the village health volunteer's (VHV's) role in drug education and proper management of essential drugs sold at their respective village cooperatives;

(2) strengthening coordination at central, regional and peripheral levels in drug management to save costs and enhance rational use of drugs;

(3) reinvent procedures for drug registration with well established technical criteria to ensure efficacy and quality of drugs while upgrading and enforcing regulatory control through inspection of pharmacies, drugstores and other drug sale outlets to prevent unauthorized sale of drugs;

(4) conduct comprehensive drug utilization review at all hospitals and health service centers particularly in the areas of selection, quantification and usage in order to forecast drug requirements more accurately while revise current treatment manuals and develop standard treatment regimens to save cost;

(5) develop a uniform computerized system for drug procurement inventory control and distribution to be used by all hospitals and health service centers while monitoring prices of drugs through market surveillance and price negotiations;

(6) strengthen drug quality assurance through promoting GMP in both the public and private drug manufacturing facilities and introduce drug importers to use WHO Certification Scheme for Pharmaceutical Products in place of free sale certificates;

(7) strengthen manpower development to promote rational use of drug in all health care professions, improve the frug management course and develop simple training modules on drug management and therapeutics for training field personnel;

(8) strengthen overall national health information system and indicators for monitoring and evaluation of **National Drug Policy** implementation in critical areas such as access of essential drugs in vulnerable target groups;

(9) strengthen drug information dissemination activities and evaluate usage of Prescriber's Journal, Drug Bulletin and data sheets being used.

4.2 Second Evaluation of the National Drug Policy Implementation in 1992

In December 1992, representative from Drug Action Programme of WHO/HQ and WHO/SEARO and FDA's Technical Division had joint in evaluating the progress of 7 drug development projects under WHO's assistance namely,

Project No.1: Strengthening Drug Information Centre

Project No.2: Strengthening of Drug Evaluation, Registration and Reevaluation

Project No.3: Study on Feasibility and Influencing Factors on Drug Pricing Control in Thailand

Project No.4: Strengthening of controlling System for Pharmaceutical Raw Materials

Project No.5: Drug Quality Control and GMP

Project No.6: Strengthening and Development of Drug Management and Rational Drug Selection at Central and Peripheral Levels

Project No.7: Quantification of Drug Requirements

Results of the evaluation could be essentially divided into 2 parts as follows :

1. **Project No.1 :** Strengthening Drug Information Centre which involved many concerned agencies was studied in detail particularly in information system development and networking. Among critical problems were lack of coordination and cooperation in system development and in the process of data collection and analysis which had resulted in diversity of the drug information system, difficulties in system linkages, overlapping in data collection and analysis, incomplete as well as unnecessary accumulation of data.
2. **Projects No.2-7** which were in the process of operation had progressed quite favorably and timely. The problem which needed due consideration was that the overseas' training programmes in the projects were found to be too short and not tailored to meet real needs of the trainees.

The underlying causes of the above mentioned problems were found to be lack of clear and easy understanding strategies for overall data collection and management, lack of network and focal point for drug information, limitations in terms of staffs' potential and budget.

WHO's Consultant, Mr.Hetgke had proposed two models of drug information systems namely,

(1) Central Database Concept featuring a centralized system with only one information centre where all network sub-systems are individually connected,

(2) Virtual Database Concept or decentralized system whereby each individual agency manages its own system but has access to data of other agencies through information indexing and access mechanism.

Based upon the recommendations, FDA's had developed a preliminary workplan for integration of drug information systems with MOPH's Provincial Hospital and Rural Health Divisions and Chulalongkorn University as pioneer group for this undertaking.

However in actual implementation of the workplan, all concerned agencies could not undertake a real concerted effort to integrate the drug information system due to lack of preparedness in term of well established computer infrastructure. The first stage was to indulge in internal system development and establish linkages wherever possible.

Since 1994, FDA has allocated roughly Baht 50 million of its budget for establishing Executive Information System (EIS) and databases for consumers' protection in 6 essential areas (drugs, narcotic substances, medical equipment, cosmetics,

food and toxic substances). At present the systems are under operation and internal linkage has been made between FDA and the Department of Medical Sciences.

4.3 Third Evaluation of National Drug Policy Implementation in 1997.

Being designated as Regional Programme/Project Coordinator on essential drug (Thai Action Programme on Essential Drug : THA/EDV/001/VD), FDA was requested by WHO to take part in evaluating the outcome of the programme in the 1994-1995 biennium. Guiding principles for evaluation were developed by WHO/SEAR and technical consultant was provided by Dr.Hans V. Hogerzeil from the Regional Office.

The outcome stated time constraint and sustainability of the programme which has to be renewed every 2 years. The quality of operational research protocol and innovative interventions were found to be somewhat inferior whereas the need for WHO consultants or temporary advisors are still felt by local counterparts to ensure success of their respective programme/projects. The areas which needed to be sustained and strengthened were periodic evaluation and reorientation of the **National Drug Policy** and promotion of rational use of drugs.

Overall observations made by the evaluation team appear as follows :

(1) The structure of national drug policy is quite adequate in view of legal control of drugs as well as selection and registration of drugs;

(2) Decentralized system is being used in drug procurement and distribution;

(3) There has been no explicit measure for pricing control;

(4) Problem pertaining to direct purchase of drugs from pharmacies, drugstores or other outlets is yet to be addressed in the **National Drug Policy**;

(5) Existing drug information system needed to be upgraded to serve as database for policy and plan formulation.

4.4 Development of Indicators for National Drug Policy Implementation

The World Health Organization Action Programme on Essential Drugs, under close collaboration of Harvard School of Public Health and Swedish Karolinska Institute, had supported a comparative study of **National Drug Policies** in 12 countries namely Bulgaria, Chad, Colombia, Ghana, India, Mali, Philippines, Sri Lanka, Thai, Vietnam, Zambia and Zimbabwe. On the part of Thailand, WHO country programme budget for the biennium 1995-1996 under PICT/HSD (Programme Implementation Coordinating Team-Health Service Development) was allocated to conduct the Comparative Analysis of National Health Policy based on the Thai experience.

4.4.1 Overall Objectives of the Programme

The overall objectives of the comparative study was to evaluate the outcome of health policy implementation in all 12 participating countries with a view to identify strengths, weaknesses and political dimention behind policy inception and implementation. A set of indicators were developed to purpose comparative analysis and appropriate strategies will be recommended for future operations at the country and international level.

The specific objectives of the Thai study in response to the major project were divided as follows :

(1) Utilizing WHO indicators as aforementioned to study the structure, process and outcome of **National Drug Policy** Implementation;

(2) Utilizing political mapping principle to study the process of policy formulation and implementation with particular reference to the policy for enforcing usage of generic name of drugs.

The two studies would help in identifying appropriate recommendations for improving the process of policy formulation and implementation to be more effective.

4.4.2 Research Tools and Methodologies

Following WHO manual entitled "Indicators for Monitoring National Drug Policies" (WHO/DAP/94.12), the standardized NDP indicators and political mapping principle were used as research tools in studying the total structure, process and outcome of **National Drug Policy** formulation and implementation.

Of the 129 standard indicators designated by WHO the Thai research team selected 81 relevant indicators while 83 country - specific outcome indicators added were used in the study. Investigation methodologies included indepth interview of concerned persons, survey of drug utilization in hospitals and pharmacies.

4.4.3 Outcome of the Thai Study

4.4.3.1 NDP Indicator Study

Five aspects emphasized as result of the comprehensive study are as follows :

(1) Legal control in drug registration and selection

Thailand was found to have quite favorable structure and mechanism for leagl control and monitoring of drug registration and selection. All related Royal Decrees and Ministerial Declarations have stipulated clearly the authorities of the

National Drug Committee and the FDA as well as indemnities for legal violations. However there has been no measure for controlling the number of registered drugs which was as high as 29,461 formulars in 1995. This has been an important underlying cause for irrational use of drugs in Thailand.

(2) Drug procurement and distribution

There have been multiple systems in drug procurement and distribution. Both public and private hospitals could place order directly form local pharmaceutical compaines. In some provinces group purchases were indulged by provincial and district hospitals to have better bargain.

(3) Drug pricing

Even though **National Drug Policy** calls for management drug pricing to be fairer for consumers as one of its high priority objective, in practice the only outcome achieved was to set up the standard pricing for the national essential drugs.

(4) Drug utilization

Many outcome indicators designated that Thailand still faced severe problem of irrational use of drugs which need immediate attention.

(5) Drug and overall health information system

In the process of compiling background indicators the researchers came across the problems in obtaining reliable indicators such as infant mortality rate, maternal mortality rate, statistics concerning health manpower, total drug expenditure, etc.

Based on the aforementioned observations 5 recommendations were made by the study team as follows :

(a) **Information system for policy formulation**

Existing data essential for drug and overall health policy formulation were found inadequate and outdated. It was recommended that the system be upgraded and to increase quality, accuracy, timeliness and capability in prompt retrieval.

(b) **Policy implementation**

Appropriate strategies for following up and evaluating the effectiveness of policy implementation should be formulated and put forth into regular and continuing operations.

(c) **Decentralization of authority**

The central health administration particularly the FDA should render full support to the provincial public health offices both in terms of technical and financial support with explicite framework of decentralized authorities to speed up actual decentralization.

(d) **Drug utilization**

As there have been multiple underlying causes for irrational use of drugs such as quality and reliability of drug information and publicity, qualification of drug procurers, prescribers and providers, there is a need for accurate information and effective dissemination as well as training for all concerned personnel with particular emphasis on professional ethics.

(e) **Forward planning**

To keep pace with rapid growth in international pharmaceutical development, it was recommended that national policy concerning drug patent and drug pricing control be formulated in due course.

4.4.3.2 Study of drug policy implementation process through political mapping principle with special reference to usage of generic name in drug labelling and advertising.

Since Thailand has developed the 1981 **National Drug** in 1993, one of the salient principles which was reflected in the policy was the utmost attempt for enforcing usage of generic name of drugs to ensure rational, efficient and effective use of drugs as well as reduce unnecessary costs involved in procurement.

During 1992-1993 a number of concerned organizations had exercised their role as opinion leaders, promoting the enforcement of the policy for utilizing the generic name of drugs. As a result the Health Minister had endorsed the **Ministerial Declaration No.439/1994 stipulating that generic name of drugs be used in place of trade name in drug labelling and advertising by April 15, 1994.** The process of policy implementation in this particular case involved large number of stakeholders and there have been socio-economic, commercial and political factors affecting various steps of policy implementation. The study team thus decided to use this experience as a case study.

(1) **Research Tools and Methodologies**

Apart from indepth interview with key actors or stakeholders who participated in the process of this specific policy implementation, **"political mapping"** method was used in analysing the overall process on a step-by-step basis as follows :

(a) sequences in policy formulation

(b) position mapping

(c) stakeholder analysis

(d) policy network mapping

(e) transition assessment

(f) strategies for change

(2) **Findings from the Study**

(a) Policy formulation

With extensive public awareness and agreements from all concerned public and private sectors including NGO's and political commitment of the Health Minister, FDA had formulated the policy for enforcing usage of generic name of drugs. In this process, public hearing was first initiated to gain popular support of the undertaking.

(b) Policy implementation

After the ministerial declaration stipulated the use of generic name of drugs in labelling and advertising in place of trade name was put in force on April 15, 1994, FDA then ordered that all pharmacies and drugstores cleared all drugs labelled by trade names out of the market. The order was protested by the Association of Pharmaceutical Manufacturers and Association of Drugstore Owners. FDA and representatives of the 2 associations had proposed the Council of State to review whether the enforcement of the ministerial declaration was justified in reference to the **Royal Decree on Drug.** The Council of State finally held that the declaration could not be enforced.

It could be observed that the process of change needs concerted effort and commitment from all concerned sectors particularly where there are vested interests among stakeholders.

To undertake regular evaluation, WHO had provided assistance under 1996-1997 biennium for the Faculty of Pharmacy of Chulalongkorn University, FDA and Provincial Hospital Division to jointly implement the project, **"Evaluating Essential Drug Policy Implementation, Process, Effectiveness and Development of Policy Information System"** in following up drug policy implementation.

5. SUMMARY OF WHO ROLE IN NATIONAL DRUG POLICY DEVELOPMENT

Since 1975 WHO has promoted the member states to develop National Drug Policies whereby the member states have, in turn, requested for WHO technical assistance in the following areas :

- guideline for national drug policy formulation, research and development, legal control, management and monitoring drug usage within the country;
- recommendations on selection of essential drug list to meet country base health needs at reasonable price;
- education and training for manpower development both in the field of pharmaceutical sciences and technology for further promotion of research, production, evaluation and management of prophylactic and therapeutic substances.

In response to the request, WHO has provided continuing assistance to member states including Thailand in 3 major areas as follows :

- guiding principles, relevant data and information for drug policy formulation, policy implementation as well as monitoring and evaluation;
- financial and technical assistance for implementing drug development projects in Thailand;
- support the government health manpower development to ensure effective implementation of the national drug policy and dispatch WHO technical consultants and experts as may be requested.

Since the inception of the first **National Drug Policy** in 1981 Thailand has successfully implemented the policy to a considerable extend but there is still a need to undertake progressive step of operations to ensure sustainable development in the following areas :

(1) access of essential drugs with quality, standard and safety by all under equity consideration;

(2) rational use and prescription of drugs;

(3) efficient and effective drug monitoring system;

(4) development of the managerial process for effective drug policy implementation to ensure that objectives of the policy will be met.

All the four areas of development do not only rely upon the role of the government but also depend upon active participation of the public sector, communities, concerned, professional organizations, NGO's the mass media, etc. As development models could not be transferred directly from country to country while any individual country alone could not undertake comprehensive pharmaceutical development in isolation, WHO assistances and its role as mediator at the country, regional and global levels are deemed highly essential for future development of national drug policy. Among the priority areas are :

(1) Technical support for further development of action-oriented research which will help obtaine practical models for drug system development or effective approaches for problem solving. Such research should be directed toward active collaboration of all sectors in the society and community for sustainable development which are mindful in country-specific socio-economic, political, cultural conditions as well as level of progress in science and technology;

(2) Technical and financial assistance for further development of national drug information system to ensure that there are adequate and reliable data for total drug system management;

(3) Promotion of technical collaboration, exchange of experiences, ideas as well as information concerning national drug system at the community and regional levels.

" Effective drug policy formulation and implementation

Is contingent upon effective intersectoral collaboration

With human right and equity in mind

We could do our best for mankind "

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Annex 1

Principles and Approach of 1981 National Drug Policy

1. Safe and good quality drug will be made available in adequate quantities at reasonable prices all along the supply lines. The logistics of supply including the planning and budgeting for the supplies required, procurement or manufacture, storage, distribution and control will be streamlines. G.P.O.'s production capacity as well as that of the private sector will be stepped up and the possibility of manufacturing bulk drugs vital to the country will be investigated. A reserve stock of raw materials and finished drugs, covering two months requirements will be maintained to meet sudden or unforeseen demands.

2. To avoid wastage, rational prescription of drugs will be promoted through stricter adherence to the National Formulary, which will be updated, and the specially compiled "Essential Lists". A journal on the lines of the Prescriber's Journal of the U.K. will also be published to disseminate to the medical profession comprehensive information about drugs and treatment regimens.

3. The facilities and manpower available for the Drug Analysis Laboratory in Bangkok and its regional laboratories will be augmented so that a continuous surveillance can be kept over the quality of drugs moving in the country, especially in the peripheral areas. Special attention will be paid to the development of adequate capacity for testing biological and immunological products. Advice on matters relating to drug standards and analysis and shall be responsible for the preparation and supply of national reference standards and substances.

4. The non-restrictive import policy operating in Thailand provides little motivation for the indigenous drug industry to develop the manufacture of basic pharmaceutical chemicals used by it for processing formulations. However, no country can afford to be permanently and totally dependent on imports. In Thailand's case, the availability of a wide range of raw materials of agricultural, marine, mineral, plant, animal and synthetic origin justified the need for harnessing the scientific manpower available in the country for research aimed at producing bulk drugs. Steps will be taken to develop these activities by bringing together the research agencies, the health profession and academic institutions.

5. The therapeutic potential of Traditional Drugs will be explored on an intensified scale, particularly for the treatment of diseases that are prevalent in rural areas. The drugs that appear promising in preliminary trials will be subjected to further systematical studies. Standardization of stable dosage forms will constitute the third stage of the study.