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The State of the Thai National Drug Policy: An Indicator Analysis

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ABSTRACT: This paper reports key concepts and findings of an indicator study of the Thai National Drug Policy. This study is a part of the "Comparative Analysis of National Drug Policies" Project, which was carried out in 12 countries. Eighty-three standardized national drug policy indicators were used to assess the current status of the structure and implementation process of Thai national drug policy and to evaluate the policy performance. These indicators are intended to capture different aspects of a national drug policy and are classified into four categories: background information, structural indicators, process indicators, and outcome indicators. Data were obtained from records and statistics from government and other sources, results of recent surveys of drugstores and hospitals, and interviews with relevant officers. Analysis of the indicator data was based on the structure-process-outcome framework, and addresses five areas: 1) legislation, regulation, selection, and registration; 2) procurement and distribution; 3) price; 4) use; and 5) public health and pharmaceutical system information. The findings suggest that Thailand has a considerably well established policy structure as regard to drug legislation, regulation, registration, and selection. Some lags and discrepancies exist in policy implementation of drug regulation. Pharmaceutical procurement and distribution rely on multiple, and basically decentralized, systems. Pharmaceutical prices are not controlled. Problems of drug use, especially in drugstore sector, call for serious policy intervention.

KEY WORDS: national drug policy, indicators, policy evaluation

INTRODUCTION

The "Comparative Analysis of National Drug Policies" Project was initiated in 1993 to assess the performance of national drug policies in developing countries. It was a joint effort undertaken by the Action Programme on Essential Drugs, World Health Organization (WHO); Harvard School of Public Health, USA; Karolinska Institutet, Sweden; and teams of researchers in 12 countries--Bulgaria, Chad, Colombia, Guinea, India, Mali, Philippines, Sri Lanka, Thailand, Vietnam, Zambia, and Zimbabwe. Results of the country studies were presented in June 1996 in Geneva (1).

The overall project consists of two separate and independent sections: an indicator study of national drug policy and a political mapping study of drug policy process. This

paper reports key concepts and findings of the country study in Thailand, focusing solely on the section on policy indicator study. Eighty-three policy indicators were used to assess the current status of the structure and implementation process of Thai national drug policy and to evaluate the policy performance.

METHOD

This study employed a set of national drug policy (NDP) indicators as research tool. Indicators have been widely used as standard instrument for measuring situations and changes in diverse areas, from measuring the state of national economy to health status, for example. Standardized indicators have also been developed for studying drug utilization patterns in

health facilities and in community (2,3). The standardized nature of indicators makes them a powerful tool for studies that are conducted across settings as well as across time. For example, using national drug policy indicators in a cross-sectional study allows more objective comparison of policy performance across country. Similarly, a standardized set of indicators can be used with a longitudinal research design to evaluate effects of an intervention over a period of time. The main purpose of this study is to describe the state of policy implementation at a particular point in time.

One-hundred and twenty-nine standardized NDP indicators were developed by Drug Action Programme, World Health Organization, as the basis for country application (4). These indicators were designed based on a *Structure-Process-Outcome* framework. The list, therefore, contains structure, process, and outcome indicators, plus a category on background information. The main features of these indicators are described below.

- Background information is intended to provide basic data on the demographic, health, economic, and pharmaceutical contexts in which drug policy is being formulated and implemented. Indicators included in this category are general population and economic data, health status and health system information, and drug sector information. They are quantitative, aggregate data used to assess country situation. Examples of these indicators are Life Expectancy, GNP per Capita, Infant Mortality Rate, Total Health Expenditures, and Total Number of Registered Drugs.

- Structural indicators provide qualitative information on the basic structures necessary for implementing a drug policy. Each structural indicator is phrased as a Yes/No question; the response to which basically indicates the existence or non-existence of a particular drug policy structure. There are 50 structural indicators in the WHO list, which are further divided into 7 groups for capturing the various key components of drug policy: 1) legislation and regulation,

2) essential drug selection and drug registration, 3) drug allocation in the health budget and public sector financing policy, 4) public sector procurement procedures, 5) public sector distribution and logistics, 6) pricing policy, and 7) information and continuing education on drug use.

- Process indicators assess the degree of functioning of the process for carrying out drug policy. The process indicators monitor the main aspects under the same seven key components of drug policy mentioned in the structural indicator category. The 38 process indicators in the WHO list are measured by a percentage, so that each policy activity is calculated against a total upon which that particular activity is based.

- Outcome indicators provide quantitative information on the achievement of national drug policy objectives. WHO identified four common objectives shared by the majority of NDPs as the basis for outcome indicators: availability of essential drugs, affordability of essential drugs, quality of drugs, and rational use of drugs. There are 10 outcome indicators in the WHO list, which are measured by a percentage or a figure.

The Thai research team selected 81 indicators from the WHO list that were deemed appropriate to the policy situation in Thailand. Indicators that are not applicable to the Thai context or that require extensive survey were excluded. For instance, since Thailand does not employ a national central drug procurement system, indicators that are intended to measure the performance of a national central procurement system were not included in this study. Moreover, the team developed 2 additional outcome indicators considered highly relevant to drug use practice in Thailand for the country study. Data were obtained from records and statistics from government and other sources, results of recent surveys of drugstores and hospitals, and interviews with relevant officers. Main data sources and data collection methods for the indicator study are listed in Table 1.

Table 1: Data Sources and Data Collection Methods Used for NDP Indicator Study

	Data Sources	Data Collection Methods
Background Information	NESDB MOI, BOT MOPH	Document.
Structural Indicator	MOPH	Document, Interview.
Process Indicators	FDA Rural Hosp Dv. Hospitals Drugstores	Document, Interview, Survey.*
Outcome Indicators	Hospitals Drugstores Med. Science Dept.	Survey,* Document.

Note: NESDB = National Economic & Social Development Board,
 MOI = Ministry of Interior, MOPH = Ministry of Public Health,
 BOT = Bank of Thailand, FDA = Food & Drug Administration
 * = Analysis of primary survey data collected for other studies

List of Specific Data Sources:

- ◆ National Drug Committee (1993). *National Drug Policy 1993*. Thailand: Food & Drug Administration.
- ◆ Ministry of Public Health. *Public Health Statistics 1993*.
- ◆ United Nation Development Programme, (1994). *Human Development Report 1994*.
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RESULTS AND DISCUSSION

Although Thai government adopted a comprehensive National Drug Policy (NDP) in 1981, regulation of the pharmaceutical sector can be traced back long before that time. Drug Act of 1967 is a major piece of legislation upon which the current drug regulatory system is based. The Act sets basic mandates for drug product quality, labeling, advertising, as well as requirements related to licensing of drug manufacturers, importers, and sales. The NDP document, by contrast, does not limit itself to regulatory requirements, nor does it establish new legal structure; instead it puts forth directives to guide government actions in a broader scope.

Public policy can be broadly defined as a purposive course of action developed by governmental bodies and is directed toward the accomplishment of some purpose or goal; or simply as "whatever governments choose to do or not to do"(5,6). Following these definitions, this study considers national drug policy to include not only the NDP document, but also the Drug Act, Pharmaceutical Patent Act, and administrative orders issued to implement these legislations.

The Thai NDP covers five areas: 1) pharmaceutical supply and distribution systems, 2) rational drug utilization

and essential drug list, 3) drug quality control, 4) production of pharmaceutical raw materials, and 5) research and development of herbal medicines (7,8). Because the WHO's NDP indicators were designed for examining NDPs based on the four common policy goals--availability, affordability, quality, and rational use--shared by most countries, these indicators therefore do not capture areas of the Thai NDP that involve development of domestic pharmaceutical raw material production capability and promotion of herbal medicines.

In this study, the majority of the indicators reflect data from 1993 and 1994. Where data from this period were not available, the most recent data were used.

Results of selected indicators are presented in the Tables that follow. Findings of all other indicators can be found in Ratanawijitrasin, et al (1996) (9). Analysis of the indicator data is based on the structure-process-outcome framework, and, hence, cuts across the indicator categories. The discussion addresses five areas: 1) Legislation, Regulation, Selection, and Registration; 2) Procurement and Distribution; 3) Price; 4) Use; and 5) Public Health and Pharmaceutical System Information.

Table 2: Results of Selected Background Indicators

ID	INDICATOR	VALUE	NOTE
BG1	Total population	59,095,419	As of 31 Dec. 1994
BG2	Average annual growth of the population	1.98%	1980-1990
BG3	Rate of urbanization	23	Urban population as % of total
BG4	Life expectancy at birth	69.58	● M 67.35, F 71.80
BG5	GNP per capita	52,961 Baht	(1650 USD)
BG25	Total number of drug manufacturing units in the country	177	● Manufacturers of modern drugs ● Private pharm factories only ● Excludes Government Pharm. Organization, hospitals and others
BG26	Total number of wholesalers in the country		● Not Applicable # of drug importers = 496
BG27	Total number of pharmacies and drug outlets in the public sector (including health facilities and hospitals that dispense drugs)	9,648	● 5 GPO + 842 hospitals + 8,202 hlth centers + 540 cmnty hlth centers + 59 metro hlth centers ● Excl 36,189 Drug Funds
BG28	Total number of pharmacies and drug outlets in the private sector	23,842	● 12,184 drugstores + 263 hospitals + 11,395 clinics
BG30	Total number of registered drugs (in dosage forms and strengths)	29,461	● Includes 28,800 drugs, 462 psychotropic substance, and 199 narcotic drug preparations.
BG31	Total number of drugs on the national essential drugs list (in dosage forms and strengths)	389 drugs	● 467 items in dosage forms and strengths ● 29 categories

Table 3: Results of Selected Structural Indicators

ID	INDICATOR	VALUE	NOTE
ST1	Is there an official national drug policy document updated in the past 10 years?	Y	NDP 1993
ST2	Is there drug legislation updated in the past 10 years?	Y	Drug Act
ST3	Have regulations based on the drug legislation been issued?	Y	
ST4	Is there a drug regulatory authority whose mandate includes registration and inspection?	Y	FDA and Provincial Health Offices
ST5	Is there a licensing system to regulate the sale of drugs (wholesalers, pharmacists, retailers)?	Y	
ST6	Are pharmacists legally entitled to substitute generic drugs for brand name products?	N	<ul style="list-style-type: none"> ● Not legally specified ● Practices vary
ST7	Are there legal provisions for penal sanctions?	Y	
ST8	Is there a check-list for carrying out inspections in different types of pharmaceutical establishments?	Y	For - Routine inspection - GMP - First-time factory inspection
ST9	Are there any institutions within or outside the country where quality control is carried out?	Y	Dept of Med. Sc., MOPH
ST10	Is the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce used systematically?	N	<ul style="list-style-type: none"> ● Certificate of free sale is required for registration of import drugs ● Thai FDA issues WHO certification of drugs for export.
ST11	Are there controls on drug promotion based on regulations and consistent with the WHO ethical criteria for medicinal drug promotion?	Y	<ul style="list-style-type: none"> ● Regulation on drug Promotion: Yes ● Consistent with WHO: Partially
ST12	Is there a national essential drugs list (EDL)/formulary using INN officially adopted and distributed countrywide?	Y	<ul style="list-style-type: none"> ● EDL: Yes ● INN: Yes ● Distributed: Public sector

Table 4: Results of Selected Outcome Indicators

ID	INDICATOR	VALUE	NOTE
OT5	Number of drugs/batches that failed quality control testing, out of the total number of drugs/batches surveyed.	21.8%	N = 669 D = 3214 FY 1993
OT8	Number of prescriptions with at least one injection, out of the total number of prescriptions surveyed.	2.6%	N = 49 D = 1896 Data from a survey of 2 provincial hospitals.
OT9	Number of children under five with diarrhoea receiving antidiarrhoeal drugs, out of the total number of children under five with diarrhoea surveyed.	95.5%	N = 86 D = 90 Data from a survey of drugstores in Bangkok. Preparations with antidiarrhoeals and/or antibiotics are counted for N.
OT11	Percentage of drugs dispensed with drug name shown on label.	1.1%	N = 1 D = 89 Data from a survey of drugstores in Bangkok.
OT12	Percentage of drugs dispensed with instruction for use shown on label.	41.6%	N = 37 D = 89 Data from a survey of drugstores in Bangkok.

Note : N = Numerator, D = Denominator

1. Legislation, Regulation, Selection, and Registration

The structures for pharmaceutical legislation, regulation, drug registration, and essential drug selection are considerably well established. The Drug Act defines the functions of Drug Committee and the FDA. Drug Act, and the various ministerial orders that have been issued to implement it, also spell out the requirements for drug registration, for licensing of drug manufacturing and sale facilities and personnel, as well as the penal sanctions.

The main concern of the Drug Act is ensuring efficacy and safety of drug products and use. Consequently, no limit is placed on the number of drug preparations allowed to be registered. This has resulted in the number of registered products as high as 29,461 (as indicated by BG30). To what extent the availability of such a wide variety of products under different brands in the market leads to irrational drug use was not established by this study. Nonetheless, within the current context where drug use review of prescriber is rare and where

self-prescribing by consumer is widespread, the large number of brands available may be a cause of confusion that results in irrational use.

Although findings from structural indicators show relatively well-established policy structures, results from process and outcome indicators suggests some aspects of implementation lag.

One area of implementation lag is the discrepancies found in law enforcement between Bangkok and surrounding provinces under the FDA direct supervision and other provinces which are under the jurisdiction of provincial health offices. Implementation of the legal requirements on pharmaceuticals rests mainly with the FDA. In practice, the FDA has a high degree of discretion to determine how the implementation is to be carried out. In an attempt to decentralize its function, the FDA has recently apportioned some of its authorities to the Provincial Health Offices. A repercussion of this decentralization policy has appeared in enforcement

Table 5: Process Indicator Data Related to Inspection and Sanctions

	PR1			PR2			PR3		
	Bkk	Prvn	Total	Bkk	Prvn	Total	Bkk	Prvn	Total
N	405	6453	6858	24	499	523	27	95	122
D	3414	8048	11462	405	6453	6858	24	499	523
Ratio	0.119	0.802	0.598	0.059	0.077	0.076	1.125	0.190	0.233

	PR6			PR7		
	Bkk	Prvn	Total	Bkk	Prvn	Total
N	14	46	60	10	4	14
D		1863	1863	14	46	60
Ratio		0.025		0.714	0.087	0.233

- Note:**
- PR1, Number of drug outlets inspected, out of total number of drug outlets in the country.
 - PR2, Number of drug outlets in violation, out of total number of drug outlets inspected.
 - PR3, Number of sanctions and administrative measures implemented, out of total number of violations identified.
 - PR5, Number of samples tested, out of total number of samples collected.
 - PR6, Number of advertisements in violation of regulations on the ethical promotion of drugs, out of total number of advertisements monitored.
 - PR7, number of sanctions implemented for advertisements in violation of regulations, out of total number of violations identified.
 - PR7 for Bangkok contains 1995 data. All other entries contain 1994 data
 - Bangkok figure for PR3 which has a ratio of greater than 1 may indicate rollover cases from previous year. 1993 Data for this indicator for Bangkok show 100% enforcement rate (which again may include past year's cases).

of drug laws. Table 5 presents disaggregate data for indicators PR1-3 and PR6-7 which reveal such a discrepancy.

Process indicators 1-7 address how NDP is carried out by looking at inspection of drug outlets and advertisements, violations found, and sanctions applied. Although the indicators require aggregate national data, information collected in this study allows for more detailed disaggregate data analysis. During 1994, the FDA inspected 12% of drug facilities while the provincial health offices inspected an impressively large percentage (80%) of these facilities (PR1). However, as shown in PR3, there is a stark contrast between sanctions imposed on the violations found. While the FDA imposed sanction on 112% of the violations identified (with some rollover cases from the previous year), in the provinces legal actions were taken on only 19% of the violations identified. The large discrepancy indicates that enforcement of law in the provinces significantly lag behind. Similar trend was also found in the 1993 data. Enforcement of advertisement viola-

tions (PR7) reflects the same phenomenon. The information available to this study does not permit analysis on factors leading to this phenomenon, however. This findings, nevertheless, implies that delegation of authority alone is not sufficient for effective implementation. Supports from central authority may be required to carry out the delegated functions.

This analysis strongly suggests that 1) Policy implementation, addressed as process in the present analytic framework, is complex and multi-faceted. Distinction should be made between policy monitoring and enforcement, i.e., inspection and sanction for this particular aspect of the pharmaceutical system. 2) When policy is carried out by multiple implementing organizations, disaggregate data pertaining to individual organizations may provide valuable insights into the policy process.

Another aspect of the policy that indicates incongruity between policy structures, process, and results is the licens-

ing of drugstores. Although licensing system to regulate the sale of drugs is in place and the inspections of drug outlets are being carried out on a regular basis, in practice most drugstores do violate the law regarding personnel. In addition, a significant number of drug outlets violate the prescription requirements of certain drugs. The result is a severely problematic drug use situation in the drugstore sector that has become a policy predicament. Statistics on drug use problems will be discussed in the drug use section below.

On the aspect of drug selection, Thailand has multiple systems of drug selection for different levels/ sectors of the health system. Besides drug registration which is a selection system for drugs to be allowed in the Thai market, National Essential Drugs List (NEDL) and hospital formularies serve as additional selection systems. The NEDL was envisioned as a tool that would guide drug procurement, prescribing, and dispensing nationally. It was initially implemented only within the Ministry of Public Health as a policy instrument for drug procurement. The list was expanded to cover the entire public sector in 1986. Steps have not been taken to broaden the scope of coverage to include private sector, however. The list, therefore, still remains today as a sector list rather than a national list. At the hospital level, all public (government) hospitals have a Pharmacy and Therapeutic Committee (PTC) with the function of determining which drugs to be included in the hospital list. Experience from hospital pharmacists and physicians indicates that the effectiveness of the PTCs vary vastly from hospital to hospital.

2. Procurement and Distribution

Pharmaceutical procurement in Thailand is a pluralistic system. Hospitals, both public and private, purchase a large proportion of their drug supply directly from pharmaceutical firms. Public hospitals in some provinces organize their own provincial level central procurement units to gain purchasing power from bulk purchase. These units have their own distribution systems. According to the government rules, competitive tender is required only when a purchase values more than 50,000 Baht (2,000 USD). Prices vary greatly depending on the negotiation of individual purchase order.

3. Price

The NDP statement explicitly spells out providing drugs at "reasonable price" as one of the policy goals. The goal of affordability is thus implicit in the policy. However, Thai-

land has no concrete policy measure to ensure affordable price for pharmaceuticals. Public hospitals have traditionally acquired pharmaceutical products to be sold to their patients at low price by building their own production capabilities to manufacture some products and by purchasing drugs from the Government Pharmaceutical Organization (GPO), or employing the power of group procurement.

According to the way the NDP was originally designed, affordable or "reasonable" drug price relied on mechanisms for price competition rather than price control. Central procurement system was instituted by the 1981 NDP. Drug purchases through the central procurement unit (the GPO) then were carried out by price negotiation or tender. After the central procurement system was abandoned in 1986, procurement as a mechanism to contain drug price in the public sector has become weakened. Substituting the public sector central procurement system is a national level Standard Price Committee, established to determine price ceiling for ED as a standard for public sector procurement.

At present, some degree of price competition is still in effect because the many pharmaceutical firms--multinational subsidiaries and domestic companies--can import and manufacture products containing the same active ingredients. At the same time, some small scale provincial central procurement systems exist. These systems rely on price competition as the main mechanism for pushing prices down. With the adoption of the pharmaceutical product patent system in the early 1990s, price competition of new products is abolished because of the legal provision of monopolistic supply. The 1993 NDP suggests that the government will collaborate with the private sector to monitor and to set prices of new drugs. How this mechanism is to be put in place and how effective it can be is still unclear, however.

4. Use

Although precise statistics for the process indicators on information and continuing education on drug use are not available, various academic and professional institutions and government agencies in the country do provide training and drug information services and publish drug bulletins, either on a regular or occasional basis. The users of these services are largely health personnel in the public sector. Some kind of mechanisms or incentives need to be instituted to encourage more attention and greater efforts on improving drug use.

Making available curricular, continuing education, drug bulletins, and drug information as interventions to promote rational use of drugs presumes qualified health personnel as the users of such information. In a sector where drugs are prescribed and dispensed by unqualified people who lack adequate knowledge base to comprehend the information provided in any form listed above, all the measures will be rendered ineffective. Although the law requires pharmacist in all Class I drugstores, most drugstores do not make pharmacist service available, but are staffed with unqualified personnel. The results of several outcome indicators on drug use in the drugstore sector, which remains the first contact to the health care system for the majority of Thai people, reveal that serious drug use problems exist. Study found 95.5% of child diarrhoea cases given antidiarrhoeal drugs or antibiotic preparations when the case was presented verbally to the drugstore keepers. Furthermore, the same study also shows that 58.4% of drugs dispensed for cases of arthritis pain did not have instruction for use on label. As elucidated to in the previous section, the legal structures of drug sale licensing has long been instituted. Such a problem is hence a consequence of ineffective policy implementation.

5. Public Health and Pharmaceutical System Information

In the process of gathering data for background indicators, the research team had difficulty finding reliable information on some important public health and pharmaceutical system statistics. In particular, data on infant mortality rate (IMR) and maternal mortality rate (MMR), which are used as standard statistics for health status assessment, fall within this group. The official publication of Public Health Statistics underestimates both. Adjusted values are given for IMR between 1977-1984, but has not been provided for the subsequent years. Another publication of the Ministry of Public Health—Health in Thailand 1994 (10)—presents three different IMR estimates in different sections of the book. Moreover, statistics on health manpower, such as the number of physicians and pharmacists, are likely to be underestimated. For pharmaceutical system information, data on such basic statistics as Total Drug Expenditure (BG19) and Total Public Drug Expenditure (BG17) are either controversial or incomplete. The public health and pharmaceutical information system needs to be strengthened in order to better serve health policy and planning.

CONCLUSION AND RECOMMENDATIONS

The findings suggest that Thailand has a considerably well established policy structure as regard to drug legislation, regulation, registration, and selection. Some lags and discrepancies exist in policy implementation of drug regulation. Pharmaceutical procurement and distribution rely on multiple, and basically decentralized, systems. Pharmaceutical prices are not controlled. Problems of drug use, especially in drugstore sector, call for serious policy intervention.

The NDP indicator study suggests the need to address the following areas in order to strengthen the Thai national drug policy:

1. Policy Information

A key factor to rational policy decision-making is relevant, accurate, and up-to-date information. Because of the current lack of certain critical policy information, serious efforts should be made to create an information system that can provide adequate, timely, and quality information to be used as input for drug and health policy making and monitoring.

2. Policy Implementation

How a policy is implemented significantly determines the extent of success the policy will achieve. Mechanisms should be established to regularly monitor how the many aspects of the NDP are being carried out and to evaluate policy outcomes. Emphasis should be made on continuously assessing how policy activities relate to policy objectives. For example, findings from this study point to the need for process monitoring to examine what results are actually produced by putting resources to carry out inspection of drug outlets; or in other words, whether enforcement measures are taken on violations found by such inspection and what policy outcomes are achieved.

3. Decentralization

For an effective decentralization policy, provincial health offices should be provided, along with the delegation of authority from the FDA, clear and specific policy mandates, capacity building programs, and other forms of support from the central agency.

4. Drug Use

Problems of inappropriate drug use involve multiple factors, from quality of products and product information, to

qualification of providers, to prescribing and dispensing behavior. Concerted efforts by all parties involved are required to ensure effective implementation of drug regulation, to institute incentive arrangements that promote rational professional practice, to provide adequate education and training, as well as to make available unbiased drug information.

5. Prospective Policy

Public policy operates in a dynamic environment. A policy, therefore, should be forward looking. That is it should not be designed to solve only current problems, but also to address problems that are likely to arise in the future. With the emphasis in the international platform on protection of intellectual properties and the introduction of pharmaceutical product patent in Thailand, NDP should take a prospective approach in preparing the country for possible price and affordability related problems that may become policy impediments in the future.

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