

Country *Profile*

A look at the
Pharmaceutical Industry in

THAILAND



Produced in collaboration
with ISPE Thailand

ENGINEERING PHARMACEUTICAL

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ENGINEERING PHARMACEUTICAL INNOVATION



Dear ISPE Members,

It is my pleasure to present the Thailand Country Profile on behalf of the ISPE Thailand Affiliate for this issue of Pharmaceutical Engineering. Thailand is an active participant within the rapidly changing and developing ASEAN region and is ideally placed to take advantage of the exciting and ever increasing opportunities of the region, its neighbors, and the world.

Thailand has both a rich cultural heritage full of proud achievements and an ambitious outlook to further development that will be accomplished using the resourceful and entrepreneurial nature of her people. Thailand has successfully rebounded after the financial crisis of the late '90s and external investment is steadily increasing. Consistent financial growth, social stability, her close relations with surrounding countries, and an experienced and well educated labor pool are all hallmarks of Thailand's potency.

I hope you will be interested enough by this Country Profile to consider Thailand as your base for investment in manufacturing, research, and development.

Yours truly,

Cherporn Tengamnuay

Chairman
ISPE Thailand Affiliate



This feature in *Pharmaceutical Engineering* is designed so that you can tear it out, three hole drill (if desired), and keep it with other Country Profiles as they are published.

Look for the Country Profile on Argentina in the March/April issue of *Pharmaceutical Engineering*.

For more information, please visit the ISPE Thailand Affiliate's Web site at www.ispeth.org or contact:

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A Look at Thailand: History and Financial Profile

Introduction

The land of smiles” as Thailand is often referred, is famous for her variety of beautiful nature and rich culture. It’s also known for its ancient ruins, fine arts and handicrafts, delicious food, and the contagious warmth of the Thai people.

A unified Thai kingdom was established in the mid-14th century. Known as Siam until 1939, Thailand is the only Southeast Asian country never to have been taken over by a European power. A bloodless revolution in 1932 led to a constitutional monarchy and since 1946 King Bhumibol Adulyadej, also known as Rama IX, is the Chief of State.

Thailand has an area of 513,254 sq km. It is situated in the heart of Southeast Asia, and shares borders with Myanmar in the West, Laos in the Northeast, Cambodia in the Southeast, and Malaysia in the South. Bangkok is the capital city and center of political, commercial, industrial, and culture activities. It is the largest city with approximately one sixth of the Thai population of roughly 64.5 million. Thailand is home to various ethnic groups with the largest being Thai and Chinese with 75% and 14% respectively.

Thailand is a participant in international organizations like the Association of Southeast Asian Nations (ASEAN), the United Nations (UN), the United Nations Educational, Scientific, and Cultural Organization (UNESCO), the World Health Organization (WHO), and the World Trade Organization (WTO).

In the past three decades, the overall physical health indicators for Thai people have been improving. For instance, life expectancy at birth has increased from 59 years in 1964 to 71 years in 2004 (Source: National Statistical Of-

fice). Significant improvements in the quality and standard of the Thai healthcare system have contributed immensely to this success. The country’s healthcare system has evolved from a system dependent and built on local wisdom to one that relies heavily on technology and collaborative efforts of healthcare professionals from multiple disciplines.

Thailand ranks as the world’s fourth most attractive nation for foreign investment in a survey by the UN Commission for Trade and Development in 2004. Thailand enjoys a strategic location right at the heart of Asia – home to what is regarded today as the largest growing economic market. It serves as a gateway to Southeast Asia and the Greater Mekong sub-region, where newly emerging markets offer great business potential.

Financial

Thailand has a well developed infrastructure and a free-enterprise

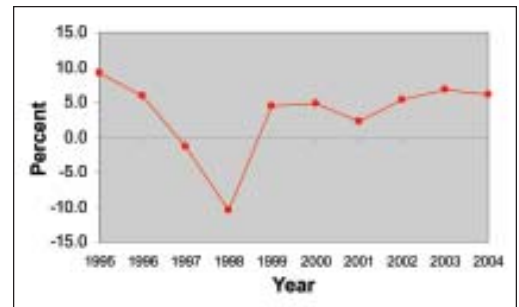


Figure 1. Real GDP Growth %. (Source: National Statistical Office, 2004)

economy. She has fully recovered from the 1997-98 Asian Financial Crisis and was one of East Asia’s best performers in 2002-04. Increased consumption, investment spending, and strong export growth pushed the Gross Domestic Product (GDP) growth up to 6.9% in 2003 and 6.1% in 2004. The growth outlook for 2005 is set to remain impressive, despite a sluggish global economy and the tragic 2004 tsunami that took 8,500 lives in Thailand and caused massive destruction in the southern provinces.

The highly popular government lead by Taksin Chinnawat has pursued preferential trade agree-



Member	Land Area (sq. Km)	Population (thousand)	GDP (million US\$)	GDP/Head in US\$	Population per sq.km	monthly US\$
Thailand	513,254	64,469	163,525	2,536	126	211
Cambodia	181,035	13,589	4,517	332	75	28
Indonesia	1,890,754	216,410	258,266	1,193	114	99
Laos	236,800	5,760	2,439	423	24	35
Malaysia	330,257	25,580	117,776	4,604	77	384
Myanmar	676,577	54,745	10,463	191	81	16
Philippines	300,000	82,664	86,407	1,045	276	87
Singapore	697.0	4,240	106,884	25,208	6,083	2,101
Vietnam	330,363	82,022	45,277	552	248	46
ASEAN	4,465,502	549,852	800,735	1,456	123	

Rank Order - GDP (purchasing power parity):
20th in the world Thailand \$ 524,800,000,000 2004 est.

Rank Order - GDP - real growth rate:
46th in the world Thailand 6.10% 2004 est.

Rank Order - GDP - per capita:
93rd in the world Thailand \$ 8,100 2004 est.

Rank Order - Industrial production growth rate
37th in the world Thailand 8.50% 2004 est.

Figure 2. Thailand fact sheet. (Source: CIA factbook, 2005)

Continued on page 10.

Thailand Pharmaceutical Industry Overview

Market Size and Growth

The Thai pharmaceutical market has a current value of \$1.32 billion. IMS Health has projected that Thailand will soon join China as one of the fastest growing areas for pharmaceuticals. Figures for 2004 show that the market has grown by 6% from 2003.

Key Data	Value	Year	World Ranking
Pharmaceutical Market (US\$ millions)	1,320	2004	33
Pharmaceutical Market per capita (US\$)	21	2004	54
Market Growth (%)	6	2004

Table A. Market overview. (Source: Espicom Business Intelligence, 2004)

The pharmaceutical spend per capita in Asia is forecast to continue its strong growth, and Thailand has one of the highest growth rates which was 19 million US\$ in 2004 and projected to be 36 million US\$ by 2009 (Source: IMS Health, 2005). The largest share of the Thai market for pharmaceuticals is occupied by locally made products according to IMS Health, 2005.

Of the total market share, locally produced products amount to 65% with imported goods back up toward pre-financial crisis levels at 35%. This local growth also has been reflected in the local manufacturers with strong increases at 14% in 2002 compared against 11% for foreign based companies (Source: Diethelm, 2003).

Healthcare

Thailand has a universal healthcare scheme that is in place since 2001 allowing Thai citizen's greater access to medical services. The popular scheme setup by the government is expected to be further funded with taxes on cigarettes and alcohol sales. Currently, more than 95% of the population has health security in Thailand with an increase of 2.85% in 2004 (Source: IMS Health, 2005). However, there have been some negative impacts attributed to the scheme on the finances and number of medical staff leaving state hospitals.

Pharmaceutical Manufacturing in Thailand

In Thailand, there are three categories of drug manufacturers:

1. Multinational corporations: manufacture active ingredients and pharmaceutical formulations in their own manufacturing facilities
2. 171 privately-owned Thai companies: primary focus is on producing pharmaceutical formulations and to a smaller extent, manufacturing active ingredients

3. One Government-owned Thai company: the Government Pharmaceutical Organization (GPO), which primarily prepares pharmaceutical formulations for public medical establishments

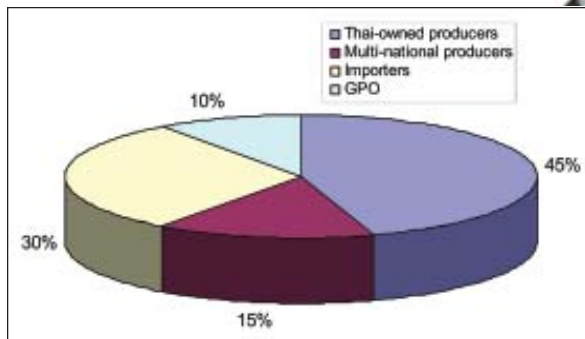
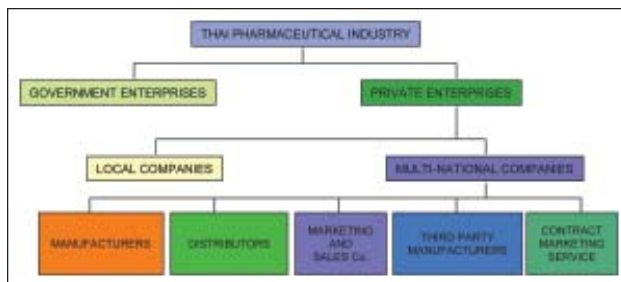


Figure 1. Share of market by manufacturers. (Source: International Trade Centre UNCTAD/WTO, 1999)

Market leaders include: Pfizer Inter. Corp., Siam Bhaesaj Co., GSK, GPO, Biolab, Aventis Pharma, AstraZeneca, Novartis, Berlin Pharma, and Roche (Source: Diethelm 2003).



Industry structure.

Distribution

Access to pharmaceutical products for the consumer is mainly through the general and specialist hospitals in Thailand. The distribution of manufactured drugs is through independent distributors or self distributed by the manufacturers themselves.

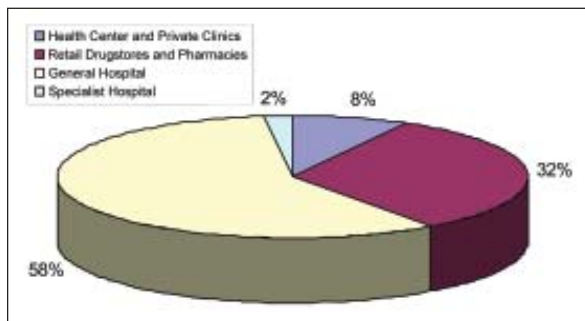


Figure 2. Pharmaceutical distribution at the point of consumption. (Source: Diethelm, 2002)

Thailand: Moving Forward in Biotechnology

by Dr.Thanit (on behalf of Prof. Dr Morakot Tunticharoen, Director, National Center for Genetic Engineering and Biotechnology)

Like other countries in South-east Asia, Thailand's biotechnology has been rapidly developed in the last two decades as a result of government backing. Biotechnology is a priority sector for the country; therefore, it is receiving soaring financial support. Biotechnological activities can be found in many research institutes and universities throughout the country. One of the institutes supporting biotechnology development in Thailand is the National Center for Genetic Engineering and Biotechnology (BIOTEC). BIOTEC provides resources for the country to support Thailand's development of biotechnology. This can be achieved through conducting R&D projects, facilitating the transfer of advanced technologies from overseas, developing human resources at all levels, providing information services, developing collaboration with world class institutes, and promoting public understanding of the benefits of biotechnology.

Strong Political Support for the Promising Future of Biotechnology

Reinforcing biotechnological development, Thailand has formulated the National Biotechnology Policy Framework in line with the government's policy to promote sufficiency of living and enhancement of competitiveness for the country, toward a proper balance and direction. One of the six goals for biotechnological development in Thailand is that Thailand represents a Healthy Community and Healthcare Center of Asia. With this political back-up, the country is anticipated to drive biotechnology forward with a speedy pace. And this also will guarantee any



Figure 1. National Center for Genetic Engineering and Biotechnology.

necessary support for investment in biotechnology.

Key Factors for Pharmaceutical Success: Infrastructure and Skilled Research Personnel

Recognizing that research and development is a driving force for pharmaceutical success, Thailand has developed a variety of scientific infrastructures. The 323,748.5 Sq Metres Thailand Science Park (TSP) is a landmark government initiative. It was built with an initial investment of \$175 million. TSP provides main laboratories, incubator units, pilot plants, greenhouses, and accommodations, as well as financial, management, and legal support for TSP customers. The TSP also offers long term leases of land for construction and ready made wet-lab space for rent.

Skilled research personnel is an

other key workforce of biotechnological development. Most universities in Thailand have educational programs in biotechnology at all levels, ranging from bachelor to doctoral degrees. The development of the qualified human resource system is one goal under the National Biotechnology Policy Framework. This aims that in the year 2011 Thailand will produce no less than 5,000 professional biotechnology researchers, no less than 500 biotechnology managers, and no less than 10,000 students. On average, Thailand can produce 400 Bachelor's degrees, 150 Master's degrees, and 10 Doctoral degrees with the growth of 10% per year. Also, the Thai government has sent Thai students to study biotechnology overseas. The first two phases (1990 -1995) aim to produce approximately 330 biotechnologists, whereas the third phase anticipates to see 370 graduates.

World Class Research and Development Initiatives

Thailand has initiated many world class R&D projects in biotechnology:

1. Thailand SNP Discovery Program

BIOTEC and Centre Nationale de



Figure 2. Thailand Science Park.

Continued on page 6.

Thailand: Moving Forward in Biotechnology

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Genotypage (CNG), in cooperation with the national collaborators, namely Ramatibodi hospital, Rajanukul Institute, and Chulalongkorn University have initiated a collaborative project with an aim to analyze candidate DNA samples from 32 healthy Thai volunteers. The resulting information is curate in Thailand SNP database (ThaiSNP) that could serve as a reference for various SNP spin-off projects. For example, there are several research attempts to study multi-factorial genetic influenced diseases endemic greatly in Thailand, including the investigation of genetic susceptibility to clinical malaria or the search for biomarkers in the development of genetic tests for the prevention of osteoporosis.

To assist these spin-offs, the SNP discovery process covers mainly SNPs inside a certain group of genes believed to be associated with important diseases such as cancer, cardiovascular, SLE, and others. Exonic regions are the main coverage inside these genes. The Thai SNP database also hosts SNP data from public domains such as dbSNP (NCBI) and JSNP (Japan SNP). This allows us to compare SNP properties across different populations. This database also will serve as a basis for Thailand's future research programs in systematic genome screening, pharmaco-genomics, and anthropology. The Thai SNP database also will be used for the Asian SNP consortium as a contribution from Thailand. The preliminary analysis of this data is being conducted by providing bioinformatic Web-based applications for interested researchers. Examples include tools for designing SNP-free primers and tools for inferring a consensus haplotype of SNP from various haplotype inference algorithms. With these current fea-

tures, ThaiSNP database project can host more SNP information from submitters, which will then better ThaiSNP allelotype mapping. In parallel to this database project, an automatic SNP discovery program is being developed. Based on a direct SNP discovery method, this tool can reduce the time researchers spend on correctly identifying SNPs or mutations from input Chromatogram traces. Furthermore, if successful, this SNP discovery tool has good potential in being commercialized.

2. From Biodiversity to Drug Discovery Program

Thais have a long tradition of using nature as a healing tool. Medicinal plants and other remedies from nature have played a vital role and are still important even today. With the advance of scientific methods, Thai scientists started searching for biological active ingredients that confer beneficial activities more than 40 years ago. At that time, the main objective and most activities were confined to identifying new chemical compounds from medicinal plants and reporting the results in scientific publications. Many new compounds were reported, but none have been further developed into modern drugs even though there were many scientists working in this field. The major obstacle was that these 'newly discovered' chemicals did not show beneficial biological activities like those found in medicinal plants or natural remedies. In general, biological assays that should guide every step of the fractionation process have not been used as part of the isolation and identification. Although some scientists have conducted biological assays which offer a better chance of finding potentially useful compounds, most of the assays are low throughput,

and thus greatly reduces the probability of success. In 1997, the National Center for Genetic Engineering and Biotechnology (BIOTEC) established the Bioassay laboratory to systematically screen natural products for different biological activities in a rapid and cost effective manner. The service was first offered to BIOTEC's in-house research group, which focuses on identifying compounds from microorganisms as well as plants using bioassay guided isolation techniques. The number of assays has been subsequently expanded and the service has been offered to scientists within the country and even to foreign researchers. Currently, the discovery of lead compounds from natural resources in Thailand has been conducted more systematically and a number of compounds with relevant biological activities have been discovered which has allowed the private sector or international agencies such as WHO with drug development experience to have access and evaluate them for commercial potential or for the good of humanity. In addition, in the last seven to eight years, the focus of biological resources has shifted from plants to other organisms, such as fungi, bacteria, and marine organisms. This trend has greatly increased opportunities for finding new active compounds beyond those from plants alone. Currently, Thailand is utilizing recent advances in biotechnology that have accelerated the discovery of new drug targets that can be incorporated into biological assays, as well as new techniques to make the existing assays more sensitive, less time consuming, and more cost efficient. With these improvements in the lead discovery process, we aim to be more internationally competitive employing our existing wealth of biological resources. 

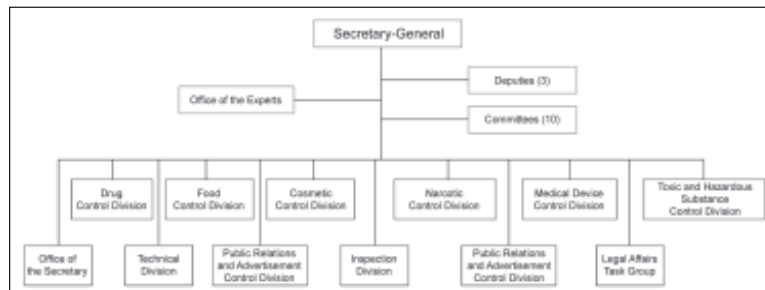


Pharmaceutical Regulations in Thailand

by Dr. Nithima (on behalf of Wilai Bundittanukul, Director of Drug Div., Thai FDA)

Overview

Thailand's Food and Drug Administration (FDA) is one of the departments under the Ministry of Public Health (MOPH). It is a national agency responsible for six health products, i.e., foods, drugs, cosmetics, narcotic/psychotropic substances, toxic and hazardous/volatile substances, and medical devices.



Organizational structure of the Thai FDA.

In relation to pharmaceutical products, the Thai FDA has consulted or cooperated with experts in science, medicine, pharmacy and public health, consumers, manufacturers, importers, distributors and retailers of drugs. It works closely with several other organizations (e.g., universities, industries, hospitals, healthcare professional groups, consumer groups, other relevant agencies, and foreign governments) in the drug development and review processes.

Its mission continues to be protecting the public health by assuring the safety, efficacy, and quality of pharmaceutical and biological products. It also is responsible for advancing the public health by helping technological development and researches to make medicines more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines to improve their health.

Drug Laws and Committees

To achieve the mission in consumer health protection, the FDA functions under the Drug Act BE 2510 (1967). The 1967 Drug Act has been employed for almost two decades and it has quite substantially improved all aspects of drug control. However, four more revisions subsequently emerged in order to cope with the growth of the pharmaceutical industry and the global situation. In the future, a new Drug Act will be promulgated to supersede the 1967 Drug Act. When the new Act becomes effective, many features will be changed accordingly, for example: reclassification of medicines, renewal of product licenses, establishment of product liability, revision process of Good Manufacturing Practice (GMP), and practices of pharmacists and prescribers.

The FDA is not a stand-alone Agency, but works closely with the Drug Committee, which is appointed by the Minister of Public Health every two years to advise him/her on both regulatory and technical aspects concerning the administration of pharmaceutical control. The committee also is authorized to approve or withdraw pharmaceutical registration, standard specifications, criteria and guidelines, including suspending or withdrawal of licenses to manufacture, import, distribute, or sell. There are 14 regular members on the Drug Committee: five of them being ex-officio members who are appointed based on their positions in pharmaceutical-related organizations and the others being appointed from among pharmaceutical and medical experts. The Committee can then

appoint subcommittees to assist them with certain tasks. Presently, 19 subcommittees have been appointed.

Pharmaceutical Control System

The pharmaceutical control system is divided into two phases: **pre-marketing** and **post-marketing**. The pre-marketing phase involves licensing regulations (regarding manufacturing, importing, or selling pharmaceutical products), drug registration, and drug advertising regulation. The post-marketing phase focuses on surveillance activities (e.g., inspection of GMP compliance at manufacturing sites, adverse drug reactions, monitoring the use of marketed drugs for unexpected health risks), responding to consumer complaints, and reevaluation of pharmaceutical products.

Pre-Marketing Phase

Licensing

The Drug Act requires that any person who wishes to sell, manufacture or import drugs into the Kingdom must obtain a licence from the licensing authorities. The Drug Control Division is the licensing and registration authority for manufacturing, import, and sale of drugs within Bangkok metropolis and its territories. Provincial Public Health Offices are the licensing authorities for manufacture and import of traditional drugs and sale of drugs in other provinces.

Applications for licenses must be submitted to the licensing authority. Their buildings and facilities will then be inspected. A license will be issued after the inspection has confirmed that the applicant has adequate capabilities of doing such business, and he/she can secure appropriate facilities and personnel for that purpose. Licences are issued, according to the business

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Pharmaceutical Regulations in Thailand

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of the applicant, in the following nine categories:

- license to manufacture modern medicines
- license to import modern medicines
- license to sell modern medicines
- license as a wholesaler of modern medicines
- license to sell modern medicines in sealed packages which are classified as neither dangerous nor specially-controlled medicines
- license to sell modern veterinary medicines in sealed packages
- license to manufacture traditional medicines
- license to sell traditional medicines
- license to import traditional medicines

Good Manufacturing Practice

The Thai FDA has begun campaigning on GMP compliance since 1984. Projects on development of the local pharmaceutical industry up to internationally acceptable standards were part of the Sixth National Economic and Social Development Plan (1987–1991) and also of the Seventh Plan (1992–1996). The projects aimed to promote and support local drug manufacturers in implementing good manufacturing practices. The first guidelines of Thai Good Manufacturing Practices were published in 1987. Since then, numerous workshops, seminars, and conferences, as well as consultative visits have been held or carried out to promote the guidelines adoption. Currently, the GMP is a mandatory requirement for all manufacturers of modern medicines.

A current GMP standard used in Thailand is the World Health Organization's Good Manufacturing Practices. However, the Pharmaceutical Inspection Cooperation Scheme (PIC/S) is planned to replace this current one to ensure that medicinal products manufactured in Thailand will be in line with international drug market requirements. Additionally, Thailand is speeding up its standard upgrading as ASEAN plans to allow free trading in healthcare products in 2010 and is likely to require all its 10 member countries to adopt the PIC/S standard. Therefore, Thailand is going to apply for PIC/S membership in 2006, expecting to be endorsed in 2008.

Drug Registration

The registration process is necessary to ensure quality, safety, and efficacy of the drugs being marketed in Thailand. Only authorized licensees are qualified to apply for product registration. Manufacturing plants, in which drug products are manufactured, are subject to inspection for GMP compliance. For the purpose of registration, drugs are categorized into three groups:

- **generics** or pharmaceutical products with the same active ingredients and the same dosage forms as those of the original products, but manufactured by

different manufacturers

- **new drugs** include pharmaceutical and biological products of new chemicals, new indications, new combinations, new delivery systems, and new dosage forms
- **new generics** are pharmaceutical and biological products with the same active ingredients as new drugs, which need to prove for their therapeutic equivalent by conducting bioequivalent studies on the same doses, and dosage forms as those of the new compounds registered after 1992

The amended registration procedure for new drug products, adopted in August 1989, involves a two-year period of safety monitoring program. This means that new drug products will be firstly approved for use only in hospitals or clinics for at least two years. Then safety reports must be submitted for consideration as to whether general marketing should be allowed. Meanwhile, new generic products have to pass bioequivalence studies to assure comparatively therapeutic outcomes. The bioequivalence data must be submitted to the authorities as proof of the product bioavailability along with product information and quality dossiers.

Quality assurance of drug safety and efficacy before marketing can undoubtedly be achieved through GMP. Inspection of drug manufacturers and sampling of drug samples from manufacturers, importers, or retail pharmacies for analyses by the regulatory authorities cannot effectively solve the problems encountered. Drug manufacturers, importers, and distributors must establish their quality assurance systems according to the GMP guidelines to ensure that the drug products have and continue to have the quality as claimed.

Drug Advertising

Drug information available to healthcare professionals and consumers is as important as drug quality for the safe use of drugs. Drug advertisements and other promotional materials need to ensure truthfulness, non-misleading, and non-exaggeration.

Advertisements through any means must be approved by the authorities before actually being disseminated. Advertisements of prescription or pharmacy-dispensed medicines are permitted only to professionals, but prohibited to the general public. Drugs in the household remedy category may be advertised directly to the general public.

Post-Marketing Phase

To further ensure quality, safety, and efficacy of the approved drug products, the marketed products are regularly sampled for testing at the drug analysis laboratory of the Medical Sciences Department, Ministry of Public Health. In addition, contracts have been signed with some qualified laboratories of local universities to assist in solving the problems of drug quality.



The surveillance tasks involve the following activities:

- inspection of GMP compliance at manufacturing sites
- monitoring of manufacturing process changes to ensure no adverse effects on the safety or efficacy of the medicines
- monitoring of the use of marketed drugs for unexpected health risks, taking action if risks are detected by informing the public, investigating the cause, and removing the drugs from the market
- lot release system is carried out for biological products to ensure the consistency of the products
- receiving and handling of complaints
- safety monitoring program for new drugs
- re-evaluation of pharmaceutical products

Re-Evaluation of Pharmaceutical Products

Even though drugs have been strictly examined for their quality, efficacy, and safety before being approved for marketing, chronological consumption data in a large population, new findings, and pharmaceutical progress may later reveal very serious side effects that were not previously seen. A balance between efficacy/benefit and potential risks or serious adverse reactions is frequently questioned, especially those in combination. The Drug Committee in 1991 appointed a subcommittee to evaluate the registered products. Some criteria have been set and the evaluation process has been ongoing.

Strategic Directions and Challenges

While continuing with efforts to ensure the availability of safe and effective medicines, the Thai FDA also takes active roles relentlessly in many activities. Among these are, for example, efforts in pharmaceutical harmonization and initiatives to enhance capacity of the domestic pharmaceutical industry.

Toward ASEAN Pharmaceutical Harmonization

Thailand along with other ASEAN member countries moves toward harmonization of pharmaceutical regulations in order to facilitate trade by minimizing technical barriers posted by regulators without compromising drug quality, efficacy, and safety.

To achieve the goal, ASEAN Consultative Committee for Standards and Quality-Pharmaceutical Product Working Group (ACCSQ-PPWG) had agreed to first develop ASEAN Common Technical Requirement (ACTR), ASEAN Common Technical Dossier (ACTD), and Technical Guidelines, followed by training and relevant capacity strengthening. For implementing, the ASEAN had agreed to start from a trial period, then full implementation at the agreed specific timeframe. Along with these implementations, the training, as well as question and answer forum also will be provided to ensure appropriateness, applicability, feasibility, and sustainability of the ASEAN agreement's implemen-

tation. In addition, the ASEAN also will develop some Mutual Recognition Agreements (MRAs) in particular issues, e.g., GMP's Inspection Report, laboratory testing report, and will finally be endorsed.

Prior to and along with the trial period for implementing the ASEAN pharmaceutical harmonized guidelines and requirements, the Thai FDA has arranged seminars and meetings to enhance understanding and know-how to implement the ASEAN pharmaceutical harmonized requirement including methods and procedures to all relevant stakeholders, both in public and private sectors. Brainstorming and workshops about the implementation of harmonization are planned. All comments and suggestions from all stakeholders are welcome to ensure that the implementation of harmonization requirements will pose the minimum obstacle and impact to all.

Enhanced Capacity of Domestic Pharmaceutical Industry

In the face of rising drug expenditures in Thailand, the Ministry of Public Health has realized the necessity to develop initiatives to promote accessibility, availability, and affordability of medicines for Thai people. Currently, the Thai FDA has conducted one important program titled, *Promotion of Domestic Pharmaceutical Industry*. Primarily, the program is designed to assure the public of high quality, safe, and effective generic drug products manufactured by the local drug industry. The ultimate goal of the program is to improve the potential, capacity, and competitiveness of the local industry. To achieve the goal, the Thai FDA has developed strategic plans for the program as follows:

- Provide and improve infrastructures and facilities that are necessary for the manufacturing of generic drug products.
- Create collaborative partnership with related organizations (both public and private sectors) to facilitate generic drug product production.
- Develop mechanisms to assure quality, safety, and efficacy of generic drug products.
- Promote widespread use of locally manufactured generic drug products among prescribers, dispensers, and consumers to substitute imported drug products.
- Promote investments on domestic generic drug industry and increase its competitiveness for the international market.

Currently, one important activity undertaken by the Thai FDA is to upgrade existing bio-equivalence centers to meet the international standards so that we can assure that locally produced generic products are of same quality as that of the innovative drug products. Such an activity is an integral part of our endeavor to increase the competitiveness of our local pharmaceutical industry.

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A Look at Thailand...

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ments with a variety of partners in an effort to boost exports and maintain high growth, and in 2004 began negotiations on a Free Trade Agreement with the US. Thailand's industrial production is orientated toward exports with Japan as the leading country for Thai imports, totalling 23.6% of Thailand's total export (Source: CIA fact book, 2005).

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Questions relating to the article may be directed to: Drug Control Division, Food and Drug Administration, Ministry of Public Health, Web site: <http://www.fda.moph.go.th>.