THAILAND
PHARMA MARKET
&
REGULATORY REPORT

Pharmaceuticals Export Promotion Council of India

(Set up by Ministry of Commerce & Industry, Government of India)

CONTENTS

DEMOGRAPHY

SL. No	Parameter	Description
1	Region	Asean
2	Country	Thailand
3	Capital	Bangkok
4	Population	68,977,400(July2020est)
5	Population growth rate (%)	0.25%(July 2020 est)
6	GDP (purchasing power parity)	1.229 trillion
7	GDP - real growth rate (%)	3.7%
8	GDP - per capita (PPP)	17,800
9	Exchange rates	
10	Population below poverty line	31.5%
11	Age structure (%)	0-14 years: 16.45%
		15-24 years: 13.02%
		25-54 years: 45.69%
		55-64 Years: 13.01%
		65 Years and above 11.82%
Source: CIA World Fact Book updated to on 3rd June 2020		

MARKET REPORT

INTRODUCTION

Thailand's pharmaceutical market will continue on a positive growth trajectory. Efforts are being made to reform regulatory processes for innovative drug registrations helping Thailand to attract greater foreign investment into its domestic pharmaceutical industry. However, comparatively the low levels of affordability and poor access to healthcare, the market will mainly be suited to generic producers.

Market size in 2019 was $ 5.9bn experiencing a growth of 8.17. It is expected to grow at 8.7% in 2020 and reach $ 6.43 bn.

Latest Updates

- In March 2020, Thailand's Ministry of Public Health officially declared Covid-19 (corona virus) a dangerous disease and introduced stricter measures to manage treatment and the spread of the virus.

- In February, Thailand's largest hospital operator Bangkok Dusit Medical Services Pcl (BDMS) made an offer to purchase the remaining shares in Bumrungrad Hospital (BH.BK) it does not already own.

- Also in February 2020, Pfizer Thailand's manager said the company is working with the Thailand Government to find different healthcare related partnerships between the two to help improve Thailand's healthcare access.

- In February 2020, Thai pharmaceutical company Siam Bioscience (SBS) and the Cuban medicine industry agreed a joint venture to begin manufacturing cancer drugs.

Strengths

- Established universal healthcare scheme, resulting in improved access to healthcare.
- Strong hospital sector growth reflecting the ongoing modernization of the healthcare industry.
- Significant pharmaceutical market growth potential, highly reliant on government's interest in developing the pharmaceutical sector.
- Government measures to reduce the cost of pharmaceuticals by promoting a consumption shift towards generic drugs.

Weaknesses

- Low pharmaceutical spending per capita.
- High levels of counterfeit and parallel imported medicines in the country.
- Uncertain pricing regulation and low levels of intellectual property protection.
- Government drug reimbursement policy heavily biased towards local drug producers and excluding many modern medicines.

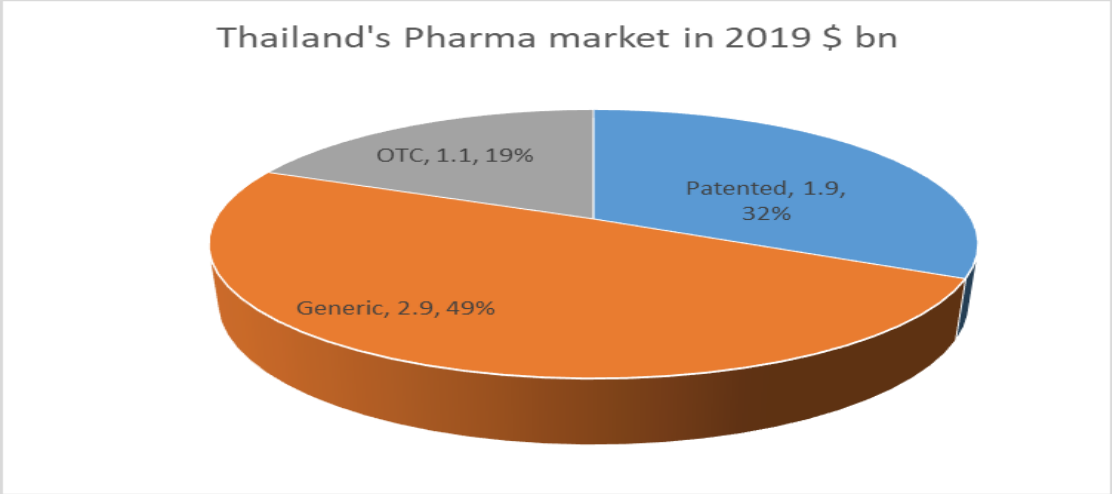
Market Overview

Thailand's pharmaceutical market has grown significantly in the past few years due to impressive developments in the public healthcare system. However, in order for the government to achieve its goals for life expectancy and other key areas, the healthcare sector will need to receive increased and effective investment over the long term. Limited state coverage of medicines and a lack of doctors currently inhibit the market.

In 2019, Thailand's pharmaceutical market was valued at USD5.9bn. In 2020 forecasts show that the market might grow by 4.5%, reaching a value of USD6.4bn. Over the forecast period to 2024, it is expected that the pharmaceutical market will reach a value of USD6.9bn, undergoing a compound annual growth rate (CAGR) of 3.1%. Per capita spending on Pharma was $ 84.9.

Thailand represents a significant growth opportunity for multinational pharmaceutical firms looking to expand their presence into the emerging markets of Asia Pacific. In addition, while still an underdeveloped market with respect to developed APAC countries, itis one of the more developed in the region, providing both potential for growth and a relatively business-friendly environment. The market's growth will be driven predominantly by the imminent transformation of the healthcare system, which will provide a rapid increase in accessibility to medical services. Rapid urbanisation and the low costs of manufacturing and R&D associated with government support are also paving the way to make Thailand a regional hub for innovation. Growing healthcare needs have also prompted the government to make long-term investments. The country has also become a popular destination for drug clinical trials owing to its developing healthcare system and medical infrastructure. Clinical trials in Thailand are cost-efficient, and the government’s Board of Investment actively promotes Thailand as a prime destination to conduct clinical research.

However, with the rapidly rising demand for and consumption of drugs, the country’s government is likely to face sustainability issues in ensuring the populations' access to medicines in a cost-effective manner. The government in particular has a strong incentive to rationalise spending as it contributes substantially to healthcare financing, with the majority of the Thai population covered by one of three government healthcare schemes. Due to greater scrutiny on healthcare spending, increasingly forceful medicine pricing pressures are likely continue over the coming years which will, in turn, squeeze revenue-earning opportunities of innovative drug makers. Critics feel Political instability is also a pertinent risk to the pharmaceutical market’s growth outlook, especially as it could deter foreign investment to the country.



Epidemiology

The rising burden of non-communicable and communicable diseases in Thailand presents a highly attractive epidemiological profile for pharmaceutical companies. This commercial opportunity is further complemented by the government's strong commitment to improve access to medicines through its universal healthcare programme.

Cardiovascular conditions, diabetes and cancer account for a large and growing burden of disease. The growth of non-communicable diseases in Thailand poses a heavy economic burden on the country. Non-communicable diseases exert significant financial pressures on the Thai population.

HIV/AIDS is a prevalent problem in Thailand, with the Department of Disease Control estimating that the cumulative number of cases will exceed 1.25mn by 2020.

Like other countries in the Western Pacific region, Thailand is facing increasing numbers of patients with diabetes due to unhealthy diets, high obesity rates, and an ageing society. Most recent estimates of the International Diabetes Federation, report that there are about 4.2mn people with diabetes as of 2017.

According to Globocan, the number of new cancer cases in Thailand is forecast to rise from 123,801 in 2012 to 168,039 by 2025. In Thailand, five cancer types (breast, cervical, colorectal, liver and lung cancer) contribute to over half of the cancer burden.

Generic Market

The generic medicine market will continue to grow at a faster pace than the overall pharmaceutical market, gaining in market share over the forecast period. This trend will be supported by the government's focus on cost containment, the current pricing and reimbursement policies.

Generic medicines will remain an important segment within Thailand's pharmaceutical market. Forecasts show that generic drug market spending to increase from USD2.9bn in 2019 to, USD3.2bn in 2020 and to USD3.4bn by 2024, equating to a five-year CAGR of 3.1%.

In 2019 generic drugs accounted for 60.7% of prescription drug sales and 49.0% of total sales.

Thailand's poor regulatory environment - defined by its weak patent enforcement and an unpredictable and delayed reimbursement system - will continue to limit the attractiveness of the country to innovative drug makers. Therefore, in addition to the increasing pressures on medicine pricing due to the country's low per capita healthcare expenditure, the demand for cheaper generic medicines will rise at the expense of the innovative market.

Pharmaceutical Trade Forecast

Thailand is highly dependent on pharmaceutical imports and has trade deficit. Imports are likely to continue to increase, further augmented by the rising demand for medicines as the country's disease burden grows. While exports will see a faster growth over the forecast period, but from a low base, with the majority of domestic drug makers remaining focused in low-value generic drugs.

In 2019, pharmaceutical imports were valued at USD 2.5bn. This is forecast to grow to USD2.9bn by 2024 with a five-year compound annual growth (CAGR) of 3.1%. In comparison, Thailand's pharmaceutical export value was USD 0 .48bn in 2019, which is forecast to rise to USD0.5bn by 2024 with a five year compound annual growth (CAGR) of 1.1%.

Growth in export of the pharmaceuticals and medical supplies sector has been slow and, because most exports are of low-value generics, a large share of exports go to neighboring countries, with Vietnam, Myanmar, the Philippines and Cambodia accounting for 57% of the total.

Imports, on the other hand, tend to be of high-value products which the domestic sector is unable to produce. This includes products such as erythropoietin, antibiotics and cholesterol-lowering medications. The main exporters to Thailand are Germany, the US and France. It is worth noting that in the last two to three years, there has been a significant increase in the value of imports from India. However, it is believed that future import growth of high-value medicines will be somewhat restricted by the government's ongoing cost-containment policies and strict pricing controls in order to manage rising medicines demand. These desires to contain costs are likely to be reflected in a change in the source of imports, with a growing role for generics in particular.

Regulatory Review

The main regulatory body of the pharmaceutical sector in Thailand is the Thai Food & Drug Administration (FDA), which operates under the auspices of the Ministry of Public Health.

The Thai FDA has attempted to gain Cabinet endorsement for a new draft Drug Act since 1999, but the legislation continues to be referred back to the Ministry of Public Health. The proposed Drug Act is designed to promote a prescription system in Thailand, which will necessitate drug reclassification to fill in the three lists, namely prescription-only, pharmacy-only and OTC.

The Ministry of Public Health is the principal agency responsible for promoting, controlling and coordinating all health activities.

Thailand Drug Registration

The Thai FDA requires importers and manufacturers in Thailand to obtain approval prior to importing or manufacturing. The Thai FDA categorizes drugs into modern general medicines, traditional medicines and veterinary medicines, each having a separate registration requirement. General medicines are grouped into separate categories of generic medicines, new medicines and new generics. Each category of medicines has a distinct set of requirements. The Thai FDA issues drug licenses for indefinite periods of time.

Biosimilar Registration

In October 2013, the Thai FDA published a notification regarding drug registration dossiers for biosimilars, requiring applicants of biosimilar products to provide the following information:

• Information regarding the biological substance, its manufacturing process and the comparative physicochemical characterization between the biosimilar and the reference biological product.

• Non-clinical and clinical trial data of comparison studies between the biosimilar and reference biological product.

• A risk management plan.

To address ever-increasing healthcare costs, Thailand is promoting the entry of biosimilars. With a focus on quality, efficacy and safety, there is now a distinct registration pathway for biosimilar products. The intellectual property protection available for these innovative products remain uncertain because of the novel and innovative nature of biological products as compared to chemical drugs

Others Registrations

Traditional medicine (TM) is widely used in the country (and known as Traditional Thai Medicine, TTM), although its integration into the mainstream healthcare system is not a standard. Nevertheless, TMs continue to receive attention. For example, the 2017 Traditional Medicine International Development forum, organized by the Naresuan University and the Guangdong-Macau Traditional Medicine Technology Industry Park Development (GMTCM Park) was held in Thailand. The meetings specifically focused on policy-making, academic research and commercial topics related to traditional medicines. A number of prominent local and regional stakeholders took park in the forum, including representatives of the Thai FDA, Thai Traditional Chinese Medicine Doctor Association, Faculty of Public Health and the Department of Thai Traditional and Alternative Medicine. Marketing approval (that is, a drug registration certificate) from the FDA is generally required for traditional medicines. However, the Drug Act exempts traditional herbal medicines from this requirement. Therefore, traditional herbal medicines do not have to be registered with the FDA. Only a manufacturing, sales or import license is required.

Generic Medicines Regulation

In August 2011, the Thai FDA announced plans to amend the requirement regulating bioequivalence studies of new generic drugs. This change is made in an effort to expedite the drug approval process and provide more patients access to generic drugs in Thailand in the near future.

This amendment will allow pharmaceutical companies that want to register new generic drugs to submit bioequivalence study results from foreign institutes or laboratories. Previously, foreign bioequivalence studies were not accepted by the Thai FDA as part of the drug registration process. Drug companies must submit the dossiers within 120 days after the foreign bioequivalence study is completed. The Thai FDA will limit registration applications to no more than one new generic drug at a time per company. The applying pharmaceutical companies need to supply all documents and necessary information for the drug registration in a timely manner.

Local Industry

Multinational pharmaceutical companies account for the majority of research-based firms in Thailand and are largely represented by the Pharmaceutical Research and Manufacturers Association (PReMA), previously known as the Pharmaceutical Producers Association. Established in 1970, PReMA now represents 42 members employing a collective workforce of around 12,000 staff. PReMa is a member of the International Federation of Pharmaceutical Manufacturers' Associations and the World Self-Medication Industry. It is also represented on some government committees concerned with health matters.

The Thai authorities recently selected the healthcare sector as one of the 10 industries to grow and decided to abolish exclusive drug supply privileges previously granted to state-owned companies. The government aims to attract foreign firms and enhance the competitiveness of the local drug sector. The Thailand Board of Investment (BOI) also grants incentives to pharmaceutical investors. Companies engaged in the manufacture of pharmaceutical products or active ingredients are eligible for tax holidays anda range of non-tax benefits, including privileges on imported equipment duties.

Furthermore, with the aim of increasing investor confidence by resolving the patent backlog issue and improving the examination process for the newly filed applications, the Ministry of Commerce and National Council for Peace and Order, along with the Department of Intellectual Property, proposed amendments to the Patents Act in February 2017 to permit faster and more efficient examination of applications. The reforms to improve the regulatory landscape will be a step towards boosting innovation in research and development and allowing new medicines to enter the market quickly. In addition, this will serve to benefit the growing demand of medicines driven by the country's rising disease burden, robust healthcare access under the universal healthcare system and the country's thriving medical tourism sector.

Major international pharmaceutical companies either have manufacturing facilities in Thailand or source products from Thai drug manufacturers. The country has also become a popular destination for drug clinical trials because of its developing healthcare system and medical infrastructure. Clinical trials in Thailand are cost efficient and there is a large patient population. In addition, the government’s Board of Investment actively promotes Thailand as a prime destination to conduct clinical research.

Most of the domestic pharmaceutical companies are engaged in packaging of imported drugs and production of generics and do not have a prominent focus on R&D. Owing to the government's aim to endorse generics to shrink the healthcare burden, domestic pharmaceutical companies shy away from investing in R&D.

The Governmental Pharmaceutical Organization (GPO) is the leading local organisation focusing primarily on manufacturing generic drugs and holds exclusive rights to supply government hospitals with products within the National List of Essential Drugs.

Moreover, the GPO's generic product registration is timely and requires minimal documentation in comparison to standard regulatory procedures. According to the regulations of the office of Prime Minister of Procurement in 1992, Thai government organisations are required to buy pharmaceutical products manufactured by the GPO. Public hospitals are legally obliged to allocate60% of their budget to purchase NLED-listed and GPO-produced medicines, while hospitals attached to the Thai Ministry of Public Health must allocate 80% of their budget towards purchasing drugs from the GPO.

Statistics:

India Pharma exports to Thailand by Category $ Million					
Category	2015-16	2016-17	2017-18	2018-19	Change%
Bulk Drugs & Drug Intermediates	58.63	53.13	62.63	63.56	1.48
Drug Formulations & Biologicals	78.54	76.21	100.35	113.14	12.74
Ayush	0.17	0.29	0.19	0.32	68.65
Herbal Products	1.80	2.41	2.39	1.95	-18.24
Surgical	2.89	2.89	2.84	3.93	38.23
Vaccines	5.51	6.10	4.17	7.15	71.26
Total	147.54	141.03	172.58	190.06	10.12

India's exports of Pharmaceuticals to Thailand $ Mn			
Category	Fy-19	Fy-20	Change%
Bulk Drugs & Drug Intermediates	63.56	59.15	-6.94
Drug formulations & Biologicals	110.59	109.59	-0.90
Ayush	0.32	0.33	0.39
Herbal Products	1.95	2.39	22.43
Surgical	3.94	3.85	-2.34
Vaccines	9.69	7.39	-23.79
Total	190.06	182.69	-3.88

Imports of Thailand

Top Ten Formulations Importing Partners of Thailand $ mn							
Rank	Country	2014	2015	2016	2018	Gr%	Share%
1	USA	312.89	348.68	353.34	431.50	22.12	16.43
2	Germany	207.36	229.81	294.45	382.28	29.83	14.55
3	France	163.1	145.3	167.02	186.25	11.51	7.09
4	India	123.19	136.86	114.26	157.96	38.25	6.01
5	Switzerland	123.68	164.64	129.56	155.96	20.37	5.94
6	Japan	83.96	86.18	89.67	126.55	41.13	4.82
7	Italy	111.17	116.74	110.18	114.41	3.83	4.36

8	China	85.25	87.07	110.93	110.26	-0.60	4.20
9	Belgium	73.36	68.22	73.16	88.58	21.08	3.37
10	United Kingdom	91.66	84.25	86.96	86.90	-0.07	3.31
	World	1932.04	2041.94	2123.44	2,626.70	23.70	100.00

REGULATORY AND REGISTRATION REQUIREMENTS

- Regulatory Authority : Thai Food and Drug Administration (FDA), Thailand
- Website of regulatory Authority : http://www.fda.moph.go.th/
- Fees for Drug Registration : 25000 THB
- Normal time taken for registration : 18 Months
- Registration Requirement [Dossier Format] : ACTD

- Whether plant inspection is mandatory : No
- Validity of Registration : 5 Years

Historical Background

The protection of consumers' health in Thailand can be traced back as far as 1909 — the concerning rise of illegal activities brought about by the influx of products counterfeited and contaminated raised a significant alarm. The agencies which were subsequently established then have been numerously transformed through time, and the scope of their responsibilities has been broadened to keep pace with the dynamic contemporary social changes of public health security.
Here is a summary of some key events which occurred prior the birth of the Thai Food and Drug Administration (Thai FDA):

- In 1922, the Narcotics Act was promulgated. This was the occasion of the establishment of the Narcotics Division, which was then under the Public Health Department, Ministry of the Interior.
- In 1937, the Narcotics Division was restructured and renamed the Food and Drug Division.
- In 1942, the Consumer Support Division, a division of the Department of Public Welfare, was integrated with the Food and Drug Division. There were three sub-divisions in this new structure: Food, Drugs, and Statistics & Registration.
- In 1953, the Food and Drug Division was transferred to the Office of the Permanent Secretary, Ministry of Public Health. The name of the division was changed to the Food and Drug Control Division.
- In 1972, the Food and Drug Control Division was transferred as a division under the Department of Health Promotion and the Regional Inspection Subdivision was established.
- In 1974, a major change took place: the Food and Drug Control Division was promoted to become a department and named the Food and Drug Administration. The new organization was originally divided into eight divisions: Food Control, Drug Control, Cosmetics Control, Narcotics Control, Inspection, Technical, Public Relations and Advertising Control, and the Office of the Secretary.
- In 1985, the Legal Affairs Task Group, which was formerly under the Office of the Secretary, was established directly under the FDA Secretary-General.
- In 1990, two new divisions were set up. They were the Medical Device Control and the Toxic Substance Control.

In 1992, there were 10 divisions: Food Control, Drug Control, Cosmetics Control, Toxic Substances Control, Narcotics Control, Inspection, Technical, Medical Devices Control, Public Relations and Advertising Control, and the Office of the Secretary. There were also three small internal entities: the Legal Affairs Task Group, the Rural Consumer Health Protection Promotion Group and the Office of Experts.

From 2003 to the present, in order to streamline working processes in line with government policies, the FDA has been restructured into six product control units (4 Bureaus and 2 Divisions) and four supportive units as described in the following section.

Mission

1. Regulate and monitor health products to meet quality, safety and efficacy as standards in accordance with international laws.
2. Promote and support the capability of consumers to gain knowledge, understanding and good consumption behaviour of healthy products.
3. Promote and enhance international competitiveness of all stakeholders and non-government parties.

The Roles and Responsibilities of Thai FDA

The main role of Thai FDA is to protect consumers' health thru ensuring safety, quality and efficacy of consumable products within its remit. These include: foods, drugs, psychotropic substances, narcotics, medical devices, volatile substances, cosmetics and hazardous substances available in the country. This has to be implemented in accordance with the national legislation and international agreements as follows:

1. Drug Act, B.E. 2510 (1967) and Amendment No. 2 (1975), No. 3 (1979), No. 4 (1985) and No. 5 (1987),
2. Psychotropic Substance Act B.E. 2518 (1975) and Amendment No. 2 (1985), No. 3 (1992) and No. 4 (2000)
3. Food Act, B.E. 2522 (1979)
4. Narcotic Act, B.E. 2522 (1979) and Amendment No. 2 (1985), No. 3 (1987) and No. 4 (2000)
5. The Emergency Decree on Prevention of Abuse of Volatile Substances, B.E. 2533 (1990) and Amendment No. 2 (2000)
6. Hazardous Substance Act, B.E. 2535 (1992)
7. Medical Device Act, B.E. 2551 (2008)
8. Cosmetic Act, B.E. 2558 (2015)
9. The Single Convention on Narcotic Drugs 1961, commentary on the protocol amended in Geneva on March 25, 1972
10. The International Convention on Psychotropic Substances, 1971
11. The International Code of Marketing of Breast Milk Substitute, 1981
12. The United Nation Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

By law, certain important issues are decided by committees, whose members, all experts in their fields, are appointed by the Minister of Public Health. Currently, there are six committees: Drugs, Foods, Cosmetics, Narcotics, Psychotropic Substances and Medical Devices.
There are two committees whose members are appointed by the other ministries. They are the Committee on the Prevention of Abuse of Volatile Substances appointed by two ministers (Industry and Public Health), and the Hazardous Substance Committee appointed by three ministers (Public Health, Industry and Agriculture).

At the national level, the Cabinet appoints three committees: the National Drug Committee, the National Food Committee and the National Chemical Safety Committee. The national committees mainly assign policies, developmental issues and collaborative activities with other agencies to facilitate the implementation of the food, drug and chemical safety program as well as the control system.

The roles and responsibilities of the FDA may be grouped into five main areas:

1. Pre-marketing Control

This includes control of manufacturing facilities, product quality and advertising before product-launch to the market. In each case, compliance is required with the relevant legislation and regulations.

2. Post-marketing Control
   The aim of this activity is to investigate manufacturing facilities and product quality and to ensure that they maintain compliance with previously-approved standards and with legislation and regulations.
   For example, samples of products are regularly inspected and taken to check for compliance and quality. Previously-approved products are revisited periodically to ascertain the consistency of manufacturing and product standards over time.

3. Surveillance Program for Consumers' Safety
   The aim of this program is to detect any adverse effects or unexpected outcomes from consumer use of products. Research and epidemiological data on adverse effects, including technical information, are collected, summarized, interpreted and reported. There are also operational centres, such as the Adverse Product Reaction Monitoring Centre (APRMC) and the International Program on Chemical Safety (IPCS). Information is exchanged with other agencies at local and international level.

4. Consumer Education
   Consumers are supplied with sufficient, accurate information to enable them to choose products wisely. Access to such information, provided by the FDA, is available from many sources: television, radio, newspaper, leaflets, internet, and other available media. FDA's campaigns on priority topics have been regularly conducted in department stores, schools and villages in many parts of the country. There are many sources for consumers to use so that they can obtain further useful information and be in a better position to protect their selves.

5. Technical Support and Cooperation with other Agencies
   The FDA has conducted many interesting seminars and workshops, with participants from both public and private sectors. On the other hand, officials from the Thai FDA are sent to join seminars and conferences, both local and abroad. As a result, with a widened perspective, they can work more effectively at home. The Good Manufacturing Practice (GMP) program is another example demonstrating successful cooperation with other organizations, in this case, with universities and drug manufacturers.

In relation to cooperation in terms of research and development, the FDA is continually supportive of such endeavour, and some research projects are partly or wholly funded by the agency.

Organization Structure of Thai FDA

Currently, Thai FDA is under the cluster of Public Health Service Support under the Ministry of Public Health. This is a group of departments working on an integrated program in order to achieve greater efficiency and effectiveness. The Cluster of Public Health Service Support comprises of three departments: the FDA, Health Service Support and Medical Sciences as described in Figure 1: Organizational Structure of the Ministry of Public Health.

The infrastructure of the Thai FDA as shown in Figure 2 officially consists of two main units; product control and support. First off to mention, the Product Control Unit, divided into four bureaus and two divisions as follows:

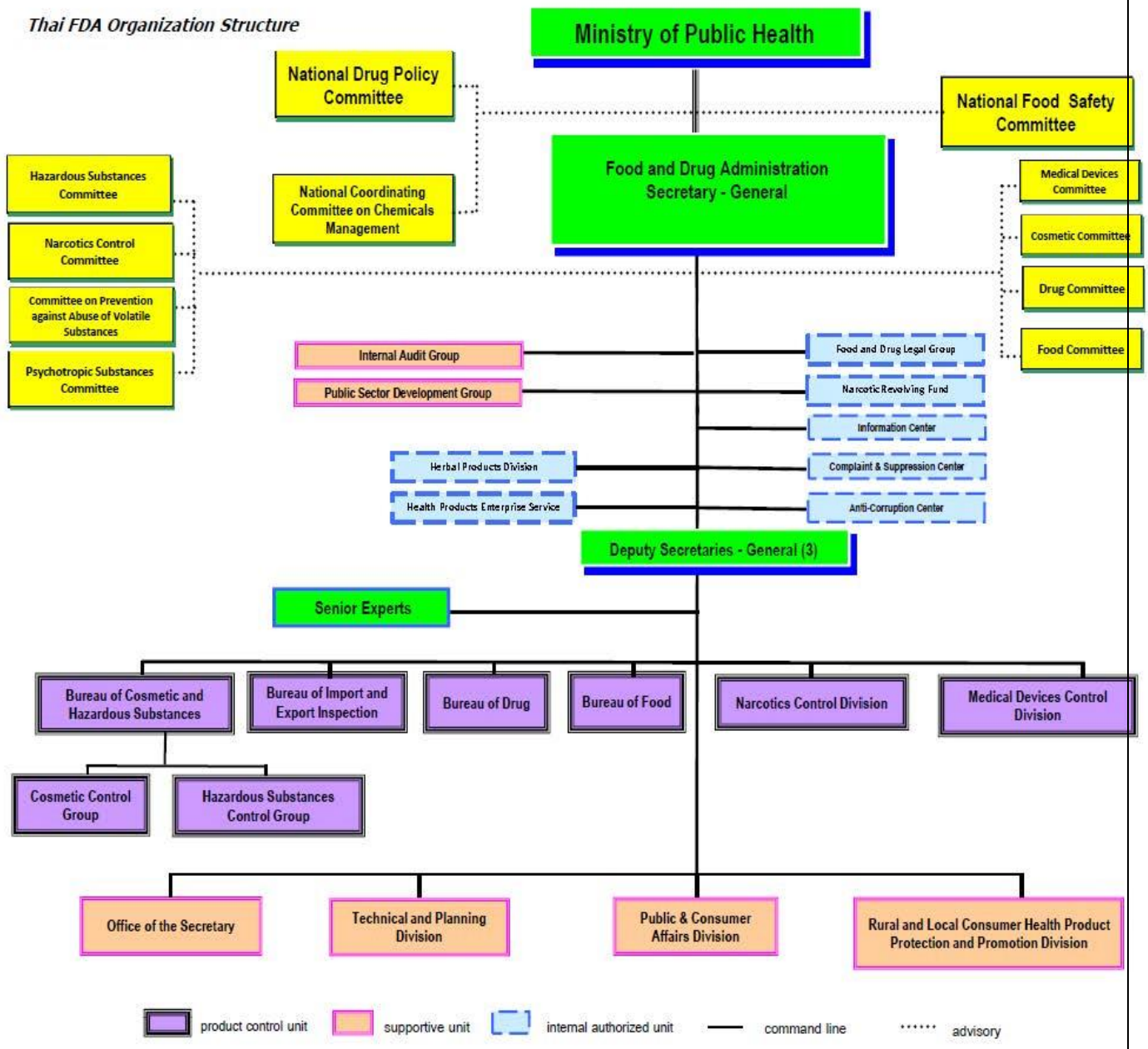
- Bureau of Cosmetics and Hazardous Substances,
- Import and Export Inspection Division
- Drug Control Division
- Food Division
- Narcotics Control Division
- Medical Devices Control Division.

Secondly, the Support Unit consists of six divisions:

- Office of the Secretary,
- Technical and Planning Division
- Public and Consumer Affairs Division
- Rural and Local Consumer Health Product Protection and Promotion Division
- Internal Audit Group
- Public Sector Development Group.

In addition, four internal authorized units have been established to perform particular complementing tasks:

- Food and Drug Legal Group,
- Narcotics Revolving Fund
- One Stop Service Center
- Information Center.



Asean Common Technical Documents (ACTD)

This ASEAN Common Technical Dossier (ACTD) is a guideline of the agreed upon common format for the preparation of a well-structured Common Technical Dossier (CTD) applications that will be submitted to ASEAN regulatory authorities for the registration of pharmaceuticals for human use. This guideline describes a CTD format that will significantly reduce the time and resources needed to compile applications for registration and in the future, will ease the preparation of electronic documental submissions.

Regulatory reviews and communication with the applicant will be facilitated by a standard document of common elements.

This guideline merely demonstrates an appropriate write-up format for acquired data. However, applicants can modify, if needed, to provide the best possible presentation of the

technical information, in order to facilitate the understanding and evaluation of the results upon pharmaceutical registration.

Throughout the ACTD, the display of information should be unambiguous and transparent, in order to facilitate the review of the basic data and to help a reviewer become quickly oriented to the application contents. Text and tables should be prepared using margins that allow the document to be printed on either A4 or 8.5 x 11 papers. The left-hand margin should be sufficiently large that information is not obscured by the method of binding.

Font and size, (Times New Roman, 12-point font), for text and tables should be of a style and size that are large enough to be easily legible, even after photocopying. Every page should be numbered, with the first page of each part designated as page 1. For a paper, Common Technical

Acronyms and abbreviations should be defined the first time they are used in each part. References should be cited in accordance with the 1979 Vancouver Declaration on Uniform requirements for Manuscripts Submitted to Biomedical Journals.

The Common Technical Document is organized into four parts as follows:

Part I. Table of Contents, Administrative Data and Product Information

Part I contains initially the overall Table of Contents of the whole ACTD to provide basically the information that could be looked through respectively. Secondly, the next content is the Administrative Data where required specific documentation in details is put together such as application forms, label and package insert etc. The last section of this part is Product Information where necessary information includes prescribed information, mode of action, side effects etc.

A general introduction to the pharmaceutical, including its pharmacologic class and mode of action should be included.

Part II. Quality Document

Part II should provide the Overall Summary followed by the Study Reports. The quality control document should be described in details as much as possible.

Part III. Nonclinical1 Document

Part III should provide the Nonclinical Overview, followed by the Nonclinical Written Summaries and the Nonclinical Tabulated Summaries. The document of this part is not required for Generic Products, Minor Variation Products and some Major Variation Products. For ASEAN member countries, the Study Reports of this part may not be required for NCE, Biotechnological Products and other Major Variation Products if the Original Products are already registered and approved for market authorization in Reference Countries. Therefore, the authority who requires specific Study Reports should ask for the necessary documents.

Part IV. Clinical Document

Part IV should provide the Clinical Overview and the Clinical Summary. The document of this part is not required for Generic Products, Minor Variation Products and some Major Variation products. For ASEAN member countries, the Study Reports of this part may not be required for NCE, Biotechnological Products and other Major Variation Products if the Original Products are already registered and approved for market authorization in Reference

Countries. Therefore, the authority who requires specific Study Reports should ask for the necessary documents.

The overall organisation of the Common Technical Dossier is presented on the following in Parts:

Part I: Table of Content Administrative Information and Prescribing Information
Section A: Introduction
Section B: Overall ASEAN Common Technical Dossier Table of Contents
Section C: Documents required for registration (for example, application forms, labelling, Product Data Sheet, prescribing information)

Part II: Quality Document
Section A: Table of Contents
Section B: Quality Overall Summary
Section C: Body of Data

Part III: Nonclinical Document
Section A: Table of Contents
Section B: Nonclinical Overview
Section C: Nonclinical Written and Tabulated Summaries
1. Table of Contents
2. Pharmacology
3. Pharmacokinetics
4. Toxicology

Section D: Nonclinical Study Reports
1. Table of Contents
2. Pharmacology
3. Pharmacokinetics
4. Toxicology

Part IV: Clinical Document
Section A: Table of Contents
Section B: Clinical Overview
Section C: Clinical Summary
1. Summary of Biopharmaceutics and Associated Analytical Methods
2. Summary of Clinical Pharmacology Studies
3. Summary of Clinical Efficacy
4. Summary of Clinical Safety
5. Synopses of Individual Studies
Section D: Tabular Listing of All Clinical Studies
Section E: Clinical Study Reports
Section F: List of Key Literature References

Scope of The Guideline

This document is intended to provide guidance on the format of a registration application for drug products regarding ASEAN CTR. This format is appropriate for NCE (New Chemical Entity), Biotech (Biotechnological Products), MaV (Major Variations), MiV (Minor Variations) and G (Generics). To determine the applicability of this format for a particular type of product, applicant should consult with the appropriate National Regulatory Authorities. The "Body of Data" in this guideline merely indicates where the information should be located. Neither the type nor extent of specific supporting data has been addressed in this guideline and both may depend upon national guidance and or accepted leading international references (pharmacopoeias).

For NCE and Biotech requirements please refer to the relevant ICH Guidelines.

Section A: Table of Contents

A table of contents for the filed application should be provided.

Section B: Quality Overall Summary (QOS)

No.	PARAMETERS	COMPONENTS	REQUIREMENTS				
			NCE	BIOTECH	MaV	MiV	G
S	DRUG SUBSTANCE						
S1	General Information						
	1.1. Nomenclature	– Information from the S1	✓	✓	✓*		✓
	1.2. Structure	– Structural formula, including relative and absolute stereochemistry, the molecular formula, and the relative molecular mass.	✓				✓
		– Schematic amino acid sequence indicating glycosylation sites or other post- translational modifications and relative molecular mass as appropriate.		✓			
	1.3. General Properties	– Physico chemical characteristics and other relevant properties including biological activity for biotech.	✓	✓	✓*		✓

No.	PARAMETERS	COMPONENTS	REQUIREMENTS				
			NCE	BIOTECH	MaV	MiV	G
S2	Manufacture						
	2.1. Manufacturer(s)	Name and address of the manufacturer (s).	✓	✓			✓
	2.2. Description of Manufacturing Process and Process Controls	– The description of the drug substance manufacturing process and process control that represents the applicant's commitment for the manufacture of the drug substances.	✓	✓			
		– Information on the manufacturing process, which typically starts with a vial(s) of the cell bank, and includes cell culture, harvest(s), purification and modification reaction, filling, storage and shipping conditions.		✓			
	2.3. Control of Materials	– Starting materials, solvents, reagents, catalysts, and any other materials used in the manufacture of the drugs substance indicating where each material is used in the process. Tests and acceptance criteria of these materials.	✓	✓			
		– Control of source and starting materials of biological origin.		✓			
		– Source, history and generation of the cell substrate.		✓			
		– Cell banking system, characterisation and testing.		✓			
		– Viral safety evaluation.		✓			
	2.4. Controls of Critical Steps and Intermediates	– Critical steps: Tests and acceptance criteria, with justification including experimental data, performed at critical steps of the manufacturing process to ensure that the process is controlled.	✓	✓			
		– Intermediates: Specifications and analytical procedure, if any, for intermediates isolated during the process.	✓	✓			
		– Stability data supporting storage conditions.		✓			
	2.5. Process Validation and/ or Evaluation	Process validation and/or evaluation studies for aseptic processing and sterilization.	✓	✓			
	2.6. Manufacturing Process Development	– Description and discussion of significant changes made to the manufacturing process and/or manufacturing site of the drug substance used in producing non- clinical, clinical, scale-up, pilot and if available, production scale batches.	✓				
		– The development history of the manufacturing process as described in S 2.2		✓			
S3	Characterisation						
	3.1. Elucidation of Structure and other characteristics	– Confirmation of structure based on e.g. synthetic route and spectral analyses.	✓				
		– Compendial requirements or appropriate information from the manufacturer					✓

No.	PARAMETERS	COMPONENTS	REQUIREMENTS				
			NCE	BIOTECH	MaV	MiV	G
		– Details on primary, secondary and higher- order structure and information on biological activity, purity and immunochemical properties (when relevant).		✓			
	3.2. Impurities	– Summary of impurities monitored or tested for during and after manufacture of drug substance	✓	✓			
		– Compendial requirements or appropriate information from the manufacturer					✓
S4	Control of Drug Substance						
	4.1. Specification	– Detailed specification, tests and acceptance criteria.	✓	✓			
		– Compendial specification or appropriate information from the manufacturer					✓
		– Specify source, including as appropriate species of animal, type of microorganism etc.		✓			
	4.2. Analytical Procedures	– The analytical procedures used for testing of drug substance.	✓	✓			
		– Compendial methods or appropriate information from the manufacturer					✓
	4.3. Validation of Analytical Procedures	– Analytical validation information, including experimental data for the analytical procedures used for testing the drug substance	✓	✓			
		– Non-compendial methods					✓
	4.4. Batch Analyses	– Description of batches and results of the analysis to establish the specification.	✓	✓			
	4.5. Justification of Specification	– Justification for drug substance specification.	✓	✓			
S5	Reference Standards or Materials	– Information on the reference standards or reference materials used for testing of the drug substance .	✓	✓			
		– Compendial reference standard.			✓*		✓
S6	Container Closure System	– Descriptions of the container closure systems.	✓	✓			
S7	Stability	– Stability report.	✓	✓			
		– Literature data .			✓*		✓
P	DRUG PRODUCT						
P1	Description and Composition	– Description	✓	✓	✓*	✓*	✓
		– Dosage form and characteristics.					
		– Accompanying reconstitution diluent (s) if any.					
		– Type of container and closure used for the dosage form and reconstitution diluent (s), if applicable.					
		Composition	✓	✓	✓*	✓*	✓
		Name, quantity stated in metric weight or measures, function and quality standard reference.					

No.	PARAMETERS	COMPONENTS	REQUIREMENTS				
			NCE	BIOTECH	MaV	MiV	G
P2	Pharmaceutical Development						
	2.1 Information on Development Studies	– Data on the development studies conducted to establish that the dosage form, formulation, manufacturing process, container closure system, microbiological attributes and usage instruction are appropriate for the purpose specified in the application.	✓	✓			
	2.2. Components of the Drug Product	– Active ingredient					
		• Justification of the compatibility of the active ingredient with excipients listed in P1	✓	✓			
		• In case of combination products, justification of the compatibility of active ingredients with each other.					
		– Literature data.			✓*		✓
		– Excipients	✓	✓			
		Justification of the choice of excipients listed in P1, which may influence the drug product performance.					
	2.3. Finished Product	– Formulation Development	✓	✓			✓
		A brief summary describing the development of the finished product, (taking into consideration the proposed route of administration and usage for NCE and Biotech).					
		– Overages	✓	✓			✓
		Justification of any overage in the formulation(s) described in P1 .					
		– Physicochemical and Biological Properties Parameters relevant to the performance of the finished product e.g pH, dissolution.	✓	✓			✓
	2.4. Manufacturing Process Development	– Selection and optimisation of the manufacturing process	✓	✓			
		– Differences between the manufacturing process (es) used to produce pivotal clinical batches and the process described in P.3.2, if applicable	✓	✓			
	2.5. Container Closure System	Suitability of the container closure system used for the storage, transportation (shipping) and use of the finished product.	✓	✓			✓
	2.6. Microbiological Attributes	Microbiological attributes of the dosage form, where appropriate	✓	✓	✓*		✓
	2.7. Compatibility	Compatibility of the finished product with reconstitution diluent(s) or dosage devices.	✓	✓	✓*		
		Literature data					✓

No.	PARAMETERS	COMPONENTS	REQUIREMENTS				
			NCE	BIOTECH	MaV	MiV	G
P3	Manufacture						
	3.1. Batch Formula	Name and quantities of all ingredients	✓	✓	✓*		✓
	3.2. Manufacturing Process and Process Control	Description of manufacturing process and process control	✓	✓	✓*	✓*	✓
	3.3. Control of Critical Steps and Intermediates	Tests and acceptance criteria	✓	✓			✓
	3.4. Process Validation and/ or Evaluation	Description, documentation, and results of the validation and/or evaluation studies for critical steps or critical assays used in the manufacturing process.	✓	✓			✓
P4	Control of excipients						
	4.1. Specifications	– Specifications for excipients	✓	✓			
		Compendial requirements or appropriate information from the manufacturer			✓*		✓
	4.2. Analytical Procedures	– Analytical procedures used for testing excipients where appropriate.	✓	✓			
		Compendial requirements or appropriate information from the manufacturer			✓*	✓*	✓
	4.3. Excipient of Human or Animal Origin	– Information regarding sources and or adventitious agents.	✓	✓			
		Compendial requirements or appropriate information from the manufacturer			✓*	✓*	✓
	4.4. Novel Excipients	– For excipient(s) used for the first time in a finished product or by a new route of administration, full details of manufacture, charcterization and controls, with cross reference to supporting safety data (non- clinical or clinical)	✓	✓			
P5	Control of Finished Product						
	5.1. Specification	– The specification(s) for the finished product.	✓	✓	✓*	✓*	✓
	5.2. Analytical Procedures	– Analytical procedures used for testing the finished product	✓	✓	✓*	✓*	✓
	5.3. Validation of Analytical Procedures	– Information including experimental data, for the analytical procedure used for testing the finished product	✓	✓			
		Non-compendial method	✓	✓	✓*	✓*	✓
		Verification of compendial method applicability - precision & accuracy			✓*	✓*	✓
	5.4. Batch Analyses	– Description and test results of all relevant batches.	✓	✓			
	5.5. Characterisation of Impurities	– Information on the characterisation of impurities	✓	✓			
		Compendial requirements or appropriate information from the manufacturer			✓*		✓
	5.6. Justification of Specification(s)	– Justification of the proposed finished product specification(s).	✓	✓			
		Compendial requirements or appropriate information from the manufacturer			✓*		✓

No.	PARAMETERS	COMPONENTS	REQUIREMENTS				
			NCE	BIOTECH	MaV	MiV	G
P6	Reference Standards or Materials	– Information on the reference standards or reference materials used for testing of the finished product.	✓	✓			
		Compendial requirements or appropriate information from the manufacturer			✓*		✓
P7	Container Closure System	– Specification and control of primary and secondary packaging material, type of packaging and the package size, details of packaging inclusion (e.g. desiccant, etc)	✓	✓	✓*	✓*	✓
P8	Stability	Stability report: data demonstrating that product is stable through its proposed shelf life.	✓	✓	✓*		✓
		Commitment on post approval stability monitoring					
P9	Product Interchangeability						
	Equivalence evidence	– In Vitro			✓*		✓
		Comparative dissolution study as required					
		– In Vivo			✓*		✓
		Bioequivalence study as required					

remarks : * if required
NCE : New Chemical Entity
Biotech : Biotechnological Products
MaV : Major Variation
MiV : Minor Variation
G : Generics

Nonclinical Document

Section A: Table of Contents
Section B: Nonclinical Overview
Section C: Nonclinical Written and Tabulated Summaries
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1. Table of Contents
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Clinical Document

Section A: Table of Contents
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Section D: Tabular Listing of All Clinical Studies
Section E: Clinical Study Reports
Section F: List of Key Literature References

http://www.fda.moph.go.th/sites/drug/EN/SitePages/DrugsRegistration.aspx
Generic Drug approval application

Procedure of Generic Drugs Registration

The procedure of generic drugs registration is divided into 2 main steps

Step 1: Application for the permission to import or manufacture drug sample intended to be registered.

The following documents are required:

1) Application form to be completely filled by authorized licensee
2) Drug formula [active ingredients(s) only]
3) Drug Literature
4) Drug labelling and packaging

Step 2: Application for the approval of granted credential certificate

The following documents are required:

1) Application form to be completely filled by authorized licensee

2) Permit to manufacture or import drug sample

3) Drug sample

4) Pharmacological and toxicological study (if any)

5) Clinical trials, safety and efficacy study (if any)

6) Complete drug formula

7) Drug literature

8) Labelling and packaging should consist of name of the drug, registration number, quantity of drug per packaging, formula which shows active ingredient (s) and quantity of strength, lot no. batch control number, name of manufacturer and address, manufacturing date, the words " dangerous drug"/ "specially controlled"/ "for external use"/ "for topical use" written in Thai and in red colour if the drug is considered to be of them, the word "household remedy drug" written in Thai if the drug is considered to be, the word "for veterinary use" written in Thai if the drug is considered to be, and the expire date

9) Certificate of Free sale (in case of imported drug)

10) Manufacturing method

11) In-process control with the relevant acceptable limits

12) Raw material specifications of active(s) and inert ingredients with the corresponding control methods in details

13) Finished product specification with the corresponding control methods in details

14) Certificate of analysis of active ingredient (s) (raw material) [To be required in case of that active substance dose not conform to official pharmacopoeias (USP, NF, BP,……etc)

15) Drug analytical control method

16) Packaging

17) Storage condition

18) Stability studies of finished product

19) Certificate of GMP (in case of imported drug)

Note: Certificate of Free Sale should be issued/legalized by the competent authorized officer and endorsed by Thai Embassy / Thai consular Office residing in correlation to the country where the documents being issued.

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Details of Indian Embassy abroad: https://embassyofindiabangkok.gov.in/

Details of importing country Embassy in India: http://newdelhi.thaiembassy.org/en/home/

List of local pharma organization abroad:

The government pharmaceutical organization	• https://www.gpo.or.th/ • Address: 75, 1 Thanon Rama VI, Thung Phaya Thai, Ratchathewi, Bangkok 10400, Thailand • Phone: +66 2 203 8000