The Study Programme
for the Pharmaceutical Affairs Experts

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Country Reports

Ministry of Health, Labour and Welfare (MHLW)
Japan International Cooperation Agency (JICA)
Japan International Corporation of Welfare Services (JICWELS)

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for the Pharmaceutical Affairs Experts

Botswana


Botswana
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0 50 100 Kilometers
0 50 100 Miles
Lambert Conformal Conic Projection, SP 6S/30S
The town councils of Francistown, Gaborone, Lobatse, and Selebi-Phikwe have status equal to that of districts.
ZAMBIA
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Sishen
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Bethlehem
Ladysmith
Upington
Aroab
Bokspits
Base 802422 (A04503) 12-95

1. Geographical and political features

Formerly the British protectorate of Bechuanaland, Botswana adopted its new name after independence in 1996. The country which is located in Southern Africa is landlocked and forms borders with South Africa, Zimbabwe, Namibia, Angola and Zambia. It has a total area of 600, 370 square kilometers (585, 370sq km land and 15,000 sq km water) with a population of 1, 640, 115 people. Most of the population is concentrated on the eastern side of the country as the west is desert. Though most of the country is desert, it has a lot of areas of tourist interest and these include the national parks with a vast array of wildlife, the Okavango delta and Makgadikgadi salt pans. The country is democratically ruled.

After four decades of independence, Botswana is one of the most dymanic economies in Africa. Economic activities include mineral extraction, tourism and agriculture. Therefore Botswana is one of the largest exporter of diamonds and beef in the world.

Over the years Botswana has seen an increases in the number of human immunodeficiency virus which leads to acquired immunodeficiency syndrome (HIV/AIDS) infections (with about 350 000 people living with the disease in 2003) and hence became one of the countries of the highest rates of infections in the world. This called for progressive and comprehensive programs for dealing with the disease.

English is the official language and Setswana is the national language. Because of the migration of people into the country and from internal movements the Setswana language has many different dialects. There are also several other languages spoken in different parts of the country. The term “Batswana” is used to refer to all people who speak the Setswana language and all citizens of the country regardless of their ethic background. There are about eleven tribes in the country.

The arrival of missionaries from Europe and America in the 19th century saw the introduction of Christianity as a religion which continued to the present time. Prior to the missionaries, most Batswana believed in “Badimo” (ancestors) and a few still believe in them up to today. The migration of other people into the country saw the introduction of other religions such as Islam, Muslim and Hinduism.

The school system is 12 years (7 years of primary and 5 years of secondary) from which one can go to a tertiary. The literacy rate is 81.2% as of 2004 statistics with an enrolment rate of 49.5% for females and 49.3 for males as of 2004 statistics.

2. Statistical data

2.1 Population

a. Population density per 1 km
   Data: The population is unevenly distributed with more than 80% along the eastern and north of the country
   Year: 2005

b. Number of population

	Total	Male	Female
Data:	1, 640,115	802,013	838,102
Year:	2005		

c. Percentage distribution by three broad age groups [%]

	0-14	15-64	65 years and over
Data:	38.8%	57.5%	3.8 %
Year:	2005		

d. Rate of natural increase of population [% per annum]
Data: Total 1.7 %
Year: 2008

2.2 Vital Statistics

a. Rate of vital statistics [per 1000 population]

	Live births rate	Death rate	Infant death rate
Data:	23.33	29.36	54.58
Year:	2005		

b. Five main diseases causing morbidity

2001 **Causes and numbers**	**2003** **Causes and numbers**	**2004** **Causes and numbers**
1. Ill-defined intestinal infections [IDII] **7,230**	AIDS **7,854**	Diarrhoea and gastroenteritis **6,196**
2. Pneumonia **6,998**	Ill-defined intestinal infections [IDII] **6,768**	Pneumonia **4,332**
3. Other direct obstetric causes **6,315**	Other direct obstetric causes **6,129**	Retrovirus infections **4,321**
4.Pulmonary tuberculosis [PTB] **6,117**	Pneumonia **6,068**	Pulmonary tuberculosis [PTB] **3,361**
5. Abortions **4,870**	Pulmonary tuberculosis [PTB] **4,859**	Ill-defined conditions **1,985**
Total all diseases: 96,796	**Total all diseases:** 98,452	**Total all diseases:** 102,980

c. Five leading causes of mortality

2001 **Causes and numbers**	**2003** **Causes and numbers**	**2004** **Causes and numbers**
1. Pneumonia **1,378**	AIDS **2,688**	Pneumonia **925**
2. Pulmonary tuberculosis [PTB] **1,274**	Pneumonia **1,064**	AIDS **923**
3. Ill-defined intestinal infections [IDII] **938**	Ill-defined intestinal infections [IDII] **901**	Retrovirus infections **905**
4. AIDS **920**	Pulmonary tuberculosis [PTB] **895**	Diarrhoea and gastroenteritis **892**
5. Ill-defined conditions **446**	Ill-defined conditions **462**	Pulmonary tuberculosis [PTB] **630**
Total all diseases: 9,387	**Total all diseases:** 10,062	**Total all diseases:** 11,041

d. Life expectancy

	Male	Female	Total
Data:	52.3	57.4	55.6

Year: June 2008

2.3 Medical care

a. Number of hospitals by establishing organ

	Government Referral Hospitals	Primary Hospitals	Private Hospital	Clinics
Data:	3	34	3	277

Year: 2008

b. Number of health manpower

	Physicians	Dentists	Nurses
Data:	478	42	4,468
Year:	2007	2004	2007

c. Number of pharmacists

Data: 260

Year: 2008

d. Number of drug manufacturers

Data: 0

Year: 2007

e. Number of traditional medicines manufacturers
   Data: 0
   Year: 2007

f. Number of cosmetic products manufacturers
   Data: 0
   Year: 2007

g. Number of drug importers
   Data: 105
   Year: 2009

h. Number of drug wholesalers
   Data: 15
   Year: 2009

i. Number of pharmacies
   Data: 96
   Year: 2008

j. Number of registered drugs
   Data: around 1550
   Year: August 2009

k. Registered drugs according to therapeutic classification
   - Antiretrovirals = 109
   - Antifectives = 301
   - Antihypertensives = 117
   - Antidiabetics = 38
   - Antimalarials = 13
   - Anti- TB = 16
   - Others = 938

2.4 Educational information for pharmacists

a. System of education

Primary school	:	seven [7] years
Age of enrollment	:	six [6] years old
Secondary school	:	five [5] years

b. System of university or college education
   Currently there are no pharmacy schools in Botswana. All pharmacists in the country were trained at different universities around the world (e.g. USA, UK, Australia, Canada, India, Nigeria, Lesotho, South Africa, Ireland etc) and the length of training at these universities varies between five and seven years post secondary/high school.

After completion of the Pharmacy degree, all pharmacists are expected to do one year of internship (practice) which can be done in the country of training or they can be done in Botswana covering different areas of pharmacy (about six months hospital pharmacy). The internship's objective is to familiarize the pharmacy graduates on the conditions of service (pharmacy) in Botswana.

c. National examinations for pharmacists
There is the Botswana Health Professions Council whose mandate is to ensure that all health professionals, including pharmacists, practicing in Botswana are dully registered. Therefore the examinations are carried out by the Council in the form of a written and oral exam over a two days period. The exams are for both the nationals and the expatriates, with the nationals taking them before commencing with internships and the expatriate before commencing with work with their different employers. Upon successful completion of the exams one is registered as a pharmacist and can therefore practice in Botswana.

d. Requirements to obtain pharmacy license
X be a university graduate
X passes the national exams
X concludes practical training as described above.

3. Historical Development of Pharmaceutical Services

a. History of Traditional (Herbal) Medicines in Botswana
Traditional medicines were the only medicines known to Batswana centuries ago. These medicines however still form an important number of peoples' lives. There is little documentation/ literature references of these medicines because the practice was kind of hereditary in the past, it was always handed down family lines and for the most part this is done verbally and on hands type of training. Today, because of the HIV/AIDS scourge a lot of researches are in the pipeline to see if the traditional medicines used with modern medicine can't be helpful in managing the disease, or even cure it.
Furthermore, the pharmaceutical services is planning to establish a technical committee for traditional medicines, compile a national database of indigenous medicinal plants as well as promote preservation and protection of medicinal plants.

b. Introduction of Modern Drugs
Modern medicine came in with the occupation of the continent by missionaries from Europe and America in the 19th century.

Traditional medicines and modern drugs are still practiced side by side though very little communication exists between the different practitioners. Progress is being made in collaboration of the two practices through the Traditional Doctors Association and the Botswana Medical Association.

c. History of the national plan and legislation on Pharmaceutical Services

As a result of collective efforts from government institutions, international organizations, non-government organizations, professional bodies, academic institutions and individual professionals, the Botswana National Drug Policy (BNDP) was born as part of the National Development Plan 8 (NDP 8) and the document was thus published in 2002. The need for the policy was due to an increase in the health services and as such an increase in the need for pharmaceutical services. The aim of the BNDP was to make drugs of acceptable safety, efficacy and quality available and affordable to Batswana (nation of Botswana) who need them and to promote their rational use thorough the establishment of Botswana Essential Drug Action Programme (BEDAP), a semi-autonomous Drugs Regulatory Authority (DRA) which will implement the Drugs and Related Substances Act (DRSA), National Drugs and Information Center (NDIC) and National Drug Quality Control Laboratory (NDQCL).

To date, BEDAP has been established and has published the Botswana Essential Drugs List in 2005 and the Botswana Treatment Guidelines which was updated in 2007. The Drugs and Related Substances Act 18 of 1992 is still under review so that the semi-autonomous DRA can be established and also merged with NDQCL. Currently there is the Drugs Regulatory Unit (DRU) and the NDQCL and both work separately. The NDIC is still to be established.

d. Pharmaceutical Administration Systems and Services.

The Pharmaceutical Services has evolved over the years as follows:

1970s:

- The pharmaceutical services gained prominence in the early seventies with the help of the Norwegian government. A training institution for pharmacy technicians was established in the country in 1976 with the first graduates of 1979.
- Central Medical Stores (CMS) was established, by then it was called Botswana Central Pharmacy and core business was as bulk storage and distribution.

1980 -2000

- Pharmacist started joining the pharmacy technicians in the early 1980s and provided clinical pharmacy activities in hospitals.
- There was an expansion of pharmacy roles with the formulation of the BNDP and as such there was establishment of a Quality Assurance unit at CMS, DRU, BEDAP and NDQCL. Pharmacists have been trained in and outside the country through government sponsorships and currently there are 260 pharmacists in the country deployed in hospitals, medicines regulation, drug selection, medical aids schemes, pharmaceutical wholesaling, and community pharmacy. The services have developed with improved

skills from cooperation with international organizations, though the services are still hampered by the relatively few numbers.

2000 to date

- The Drug Management Unit was set up
- Pharmaceutical Care concepts introduced by clinical pharmacists
- Training in Provision of comprehensive pharmacy services care to HIV/AIDS patients (Drug adherence counseling, drug availability, drug side effects ADR Monitoring, involvement in drug selection)
- Set up of Pharmacy and Therapeutics Committees at hospitals to provide guidance on drug issues

4. Pharmaceutical affairs administration

a. The Pharmaceutical Services are housed in the Ministry of Health within the Clinical Services Department. Clinical Services Department is one of the seven departments and is comprised of medical, nursing, pharmaceutical, diagnostic, dietetic, rehabilitative and biomedical engineering services.
The head of the pharmaceutical services is the Chief Pharmacist who is responsible for the different units which are:

- Drugs Regulatory Unit – responsible for medicine regulation and control, drug registration and inspectorate functions.
- Central Medical Stores – responsible for procurement and distribution of drugs to government health facilities.
- Botswana Essential Drugs Action Programme – responsible for drug selection and essential drugs list and rational drug use.
- National Drug Quality Control Laboratory – responsible for testing of drugs to ensure conformity to the standards of quality recognized internationally.
- Hospital Pharmacies – responsible for providing clinical pharmacy services.
- Drug Management Unit – responsible for supply logistics.

b. List of laws/ regulations covering pharmaceutical affairs

- Drugs and Related Substances Act18 of 1992 (DRSA) and Regulations of 1993
- Botswana Health Professions Act 17 of 2001
- Pharmacy Practice Standards
- Botswana National Drugs Policy
- Botswana Labour Act
- Trade Act

c. Medicines regulation encompasses the registration of medicines and inspection of facilities where medicines are stored, distributed from and dispensed for compliance with good distribution and dispensing practices. This is done under the mandate of the Drugs and Related Substances Act of 1992. All drugs with medicinal indications have to be registered including biologicals. There is currently no manufacturer in the country so all medicines are imported. The Ministry, through DRU, has conducted some GMP inspections, not all manufacturing facilities whose products are applied for registration

are inspected as we sometimes are dependant on other regulatory authorities for these kind of information.
Herbal medicines have to be evaluated for exemption from registration. An average of 190 applications are received each year by the unit and it takes about three days to process each application. Traditional medicines are also exempted from registration because as of now they are in crude form and not in dosage formulations.

d. The DRU is still in the process of developing guidelines for Pharmacovigilance as well as sensitization of the health professionals. Therefore there is not much that is currently done on post marketing surveillance. There is a need for this office to be set up as it will be responsible for processing of all information about the medicines on the market, coordinating the analysis of the samples collected by the inspectorate and processing reports, this office alos will be responsible for ADR monitoring.

e. The National Quality Control Laboratory [NDQCL] was established in 2005 with the aim of testing pharmaceuticals for quality. The laboratory is currently able to do some simple tests on most pharmaceuticals including antibiotics and antiretrovirals. There are still challenges to be faced with biologicals.

5. National Drug Policy

The Botswana National Drugs Policy was published in August 2002 after it was approved by Parliament. It is aimed at improving the management of drug supplies including ensuring safety, quality and efficacy. The Policy recommended the establishment of the above mentioned offices so as to meet its objectives.

6. Drug supply system and drug price mechanism

Supply of medicine is from both the private and public sectors. All drugs are imported as there is no manufacturer in the country. The public sectors accounts for more than seventy percent [70%] of the consumptions and the services from the public sector are funded by government for the most part. Procurement is done through an open tender system and there very little price control. There is a growing private sector which was relatively small several years back and an increase in the number of medical aids schemes which funds about 30% of the health services.

7. Management of hospital pharmacies in Botswana

Hospital pharmacies are managed by pharmacists who report to the Chief pharmacist in the Ministry. They provide pharmaceutical care by taking responsibility for the therapeutic outcome of therapy and by being actively involved in the design, implementation and monitoring of clinical of pharmacy services.

8. Research and Development of drugs
Research and development of drugs is not done in the country.

9. Pharmacopoeia

The country does not have its own pharmacopoeia, however, international pharmacopoeias such as the British, United States and European pharmacopoeias are the main references used in Botswana.

10. Donor Coordination

There have been a number of donor agencies in Botswana. Most coordination is through the Department of Public Health which sources technical assistance from the different departments in the ministry depending on the type of donations. Funding activities are coordinated from Ministry of Finance and Development Planning. The efforts are usually in line with the requirements of the donors with memoranda of understating signed between government and the donor agencies. However all drugs donated must meet the following criteria:

- They must be based on Botswana's expressed need and must be relevant to the disease pattern in the country.
- They must be of good quality and have a shelve life of more than 12 months at the time of handing over to the recipient.
- They must be authorized for use in Botswana and must meet the labeling requirements as stipulated in the DRSA.
- They must all be tested by the NDQCL for conformity to specifications.

11. References

1. Health Statistics Report 2001: Published by Central Statistics Office
2. Health Statistics Report 2003: Published by Central Statistics Office
3. Health Statistics Report 2004: Published by Central Statistics Office
4. 2001 Population and Housing Census, National Statistical Tables report
5. 2001 Population and Housing Census, Dissemination Seminar, September 2003
6. Statistics Update, June 2008, Central Statistics Office
7. List of drugs allowed into Botswana 2007
8. Botswana National Drug Policy 2002
9. Pharmacy Practice Standards 2002
10. Botswana Health Professions Act 17, 2001
11. 2003 Adult Literacy Survey Report

The Study Programme

for the Pharmaceutical Affairs Experts

Indonesia

COUNTRY REPORT

THE STUDY PROGRAMME FOR PHARMACEUTICAL AFFAIRS EXPERTS

(#J0900794)

JAPAN, November 8, 2009 ~ December 9, 2009

WARTA BR GINTING
NATIONAL AGENCY FOR DRUG AND FOOD CONTROL
INDONESIA

1. COUNTRY PROFILE

Indonesia is the largest archipelago in the world, stretching for more than 5,000 kms across the equator. It lies on crossroads between two oceans, the Pacific and the Indian, and bridges of two continents, Asia and Australia.

It is an appropriate description of the archipelago as there are estimated to be a total of 17,508 islands, of which only about 6,000 are inhabited.

Five main islands and about 30 smaller archipelagoes are home to the majority of the population. The five main islands are: Sumatra (473,606 sq. km); Java/Madura (132,187 sq. km); Kalimantan, which comprises two-thirds of the island of Borneo (539,460 sq. km); Sulawesi (189,216 sq. km); and Papua (421,981 sq. km) which is part of the world's second largest island, New Guinea. The capital city of Indonesia, Jakarta is located in Java Islands.

Indonesia has tropical climate with two seasons, namely the dry season and the rainy season. Indonesia's populations are almost 220 millions which consist of hundreds of ethnic groups, languages and cultures. It is about 300 ethnic groups and cultures, each with its own language (speaking in 583 languages), but possessing one national language i.e. Bahasa Indonesia. A part of people are follower of Moslem, beside other religions like Christianity, Catholic, Hinduism, and Buddhism.

2. STATISTICAL DATA

1) Population

a) Population density per 1 sq km

Data : 42,174,719

Year : 2007

b) Number of population

Data : 230.873.595 ....

Year : 2007 2008

c) Precentage distribution by three broader age groups (%)

	0-14	15-64	65 years and over
Data :	36,3 %	38,3%	6,1%
Year :	2007	2007	2007

d) Rate of natural increase of population (% per annum)

Data : 1,3%

Year : 2007

2) Vital statistics

a) Rate of vital statistics (per 1,000 [population)

(per 1,000 live births*)

	Live birth rate *
Data :	61,5
Year :	2007

b) Five main diseases causing morbidity

	causes	number	year
1	Periodental	60	2006
2.	Upper respiratory canal infection	30	2006
3.	Refraction disorder	25	2006
4.	Anemia	20	2006
5.	Gastro Intestinal Tract Infection	15	2006

c) Five leading causes of death

	causes	number	year
1.	Lower Respiration disease	15,5%	2006
2.	Obstetric & abortion complication	11,8%	2006
3.	Intestine infection disorder	10%	2006
4	Injury and poisoning disease	7,1%	2006
5	Stomach, intestine and peritonea	4,1%	2006

3) Medical care

a) Number of hospitals

	Government Hospital	Public hospital	Private hospital	Clinics
Data :	578	273	812	575
Year :	2007	2007	2007	2007

b) Number of health manpower

	Physicians	Dentists	Nurses
Data :	16,115	8750	227,560
Year :	2007	2007	2007

d) Number of Pharmacists

Data : 7,495

Year : 2007

c) Number of drug manufacturers/plants

Data : 204

Year : 2009

d) Number of traditional medicine manufacturers/plans

Data : 1597

Year : 2007

e) Number of cosmetic products manufacturers/plants

Data : 6775

Year : 2007

f) Number of drug importers

Data : 89

Year : 2007

g) Number of drug wholesaler

Data : 2740

Year : 2007

h) Number of pharmacies

Data : 4955

Year : 2007

i) Number of drug stores

Data : 9412

Year : 2007

j) Number of registered drug (please specify number of traditional medicine if possible)

Data : 2050

Year : 2007

k) number of registered drugs

Data : 14196

Year : 2009

4. Educational Information for Pharmacist

a) System of Education

Primary School	:	6 years system
Age at enrolment	:	6 years old
Secondary school	:	3 years system
High school	:	3 years system

b) System of university or college education

University or college years	:	4 years
Professional education	:	1 years
Practical training	:	18 – 20 weeks
Duration of training each facility	:	1 – 7 weeks
Hospital Pharmacy	:	8 weeks
Pharmacy	:	8 weeks
Pharmaceutical company	:	8 weeks
Other (government office)	:	8 weeks

c) National examination system for pharmacist

Academic exams	:	6 days
Clinical exams	:	5 days

None

d) Requirement to obtain pharmacist's license

e)-1 Be a university or college graduate

e)-2 Pass the national examination

e)-3 Conclude practical training after graduating in drug factory, pharmacy, hospital, and government office

e) Graduates number of pharmaceutical university or college. people per year (as of 600-800)

3. Historical Development of Pharmaceutical Services

A. History of the Traditional (Herbal) Medicine

Traditional medicine is still widely used by many people. Most of the traditional medicine raw material can be obtained locally and only a small amount of the raw material is imported. In the period of the Dutch rule, the traditional medical plants were collected and written. In the period Japanese rule, to anticipate the lack of the medicine, the Japanese Government complied the formulas of The Indonesia Traditional Medicine.

In 1974, The Directorate of Traditional Drug Control was established. Since 1976, The Traditional Medicine has been registered gradually. Control has been taken by sampling from the market and checked by the National and Regional Quality Control Laboratory of The Ministry of Health. The Traditional Medicines that have curative effects have to pass the pre-clinic/clinic test. The uses of the traditional medicines has increased. However, the real efficacy of most traditional medicine has not yet been scientifically proved. The effort is focused mostly on the improvement of the safety and quality of the traditional medicines. The improvement of the production should be accompanied by the preservation of medical plants and animals.

B Describe how the pharmaceutical administration system and services in your country have been transformed, improved, strengthened through the various training programmes for human resources provided by international partners such as WHO<JICA<JICWELS,ect.

To add knowledge administration system and services and support our daily tasks administration system and services are more effective and efficient

4 . Pharmaceutical Affairs Administration

1) Organization Chart

a. Details of the National Agency of Drug and Food Control (see Figure 1.)

b. Details of the Provincial Office of Drug and Food Control (see Figure 2.)

2) The role of national/state and local pharmaceutical administrative organizations.

The Main Functions of NADFC are:

a. Legislation, regulation and standardization;

b. Licensing and certification of pharmaceutical industries based on Good Manufacturing Practices;

c. Pre-market evaluation of products;

d. Post-marketing vigilance including product sampling and laboratory testing, inspection of production and distribution facilities, investigation and law enforcement;

f. Research on drug and food policies implementations;

g. Public communication, information and education including public warning.

A Technical implementation unit of the National Agency of Drug and Food Control is Regional Office of Drug and Food Control.

3) List of regulation covering pharmaceutical affairs

Classification of Regulation

3)-1 Product Regulation

- Drug, Foog, Cosmetic, D
  - Head of National Agency of Drug and Food Control Decree on Criteria and Procedure of Drug Registration No. HK.00.05.3.1950 year 2003

- The Ministry of Health Regulation for imported drug registration No. 920 year 1993
- Head of National Agency Drug and Food Control for Good Manufacturing Practise No HK 00.05.3.02152 year 2002
- Head of National Agency Drug and Food Control for Good Distribution Practise No HK 00.05.3.2522 year 2003
- The Ministry of Health Regulation for Wholesaler No 938/Menkes/per/X year 1993
- The Ministry of Health Regulation for Food Registration No. 382 year 1989
- The Ministry of Health Regulation for cosmetic and medical device production and distribution no. 220 year 1976
- The Ministry of Health Regulation for traditional medicine license and registration no. 246 year 1991
- The Ministry of Health Regulation for medical device, cosmetic, and domestic medical device registration no. 140 year 1991

- Counterfeit Drugs

  The Ministry of Health Regulation No 1010 year 2008 has regulated the counterfeit drug is a medicinal product with is manufacturer by illegal manufacturer or deliberately mislabled with respect to identity

- Genetics

  The Government of Indonesia has not made the regulation of genetic/genetic modification of drug, genetic/genetic modification of food has regulated by The Law of Food, No. 7, 1996

3)-2 Profession Regulation

Pharmacist

The Ministry of Health Regulation for Replacing The Ministry of Health Regulation no. 184 year 1995 for Implementation of serve period and license of pharmacist no. 149 year 1998.

The pharmacist before getting the license of pharmacist, they must work in non government sectors, except in government sector.

There is a standard competency for pharmacist certificated by professional organism

3)-3 Health Promotion and Regulations

- Health Establishment Regulation

  The Government of Indonesia has two regulations that support regulation of health; they are he Law of Health No 23, 1992 and the Law of Food, No. 7, 1996

- Traditional Medicine

  Traditional Medicine are regulated by The Law of Health No. 23, 1992 because traditional medicine is one of pharmaceutical preparation. Production of traditional medicine from the small industry until the large industry, the people of Indonesia like the traditional medicine for therapy or to keep health.

- Health Economics

  In Indonesia the cost of therapy are paid by the people themselves. In Indonesia there is insurance of health that is managed by the government that gives medical guarantee to the government official by paying premi.

  The people who don't pay the premi, they go to the health center get diagnosis services and been given generic medicine they pay cheap cost or consult to private doctor with more expensive checking cost.

4) Licensing system of factory and registration system of drug

A license of manufacture drugs is given after confirming that the applicant has an adequate ability or condition to do such business, and whether he can secure appropriate facilities and personnel for that purpose. Requirements for approval license applications for drugs are needed.

The license is granted on examination of material conditions such as buildings and facilities for safe and hygienic manufacture, and of the conditions of personnel such as the manufacturing control managers, quality control manager accordance to GMP.

Criteria to get approve of marketing authorizator :

- NADFC carries out pre-market evaluation on efficacy, safety and quality of drugs, biological products in Indonesia as well as operates a clinical trial.
- The Quality of product should complythe specification according to GMP Implementation specification and testing method
- Tabel which consist of complete and objective information to assure the used of drug property rationaly and safetly.

5) Pharmaceutical inspection including quality control check system

The period of drug inspection is conducted after pharmaceutical manufacture has it license for drug production and license for distribution and registration number. The inspector of drug will examine whether the GMP concept is applied on production infrastructure. The inspection covers all the production aspect.

List of GMP Inspection and Guidance**:**

- o General Provision
- o Personnel
- o Premises
- o Equipment
- o Sanitation and Hygiene
- o Production
- o Quality Control
- o Self Inspection
- o Handling of product recall; Product Complaint & Return drug product
- o Documentation

6) **Good Manufacturing Practice (GMP)**

The Activities of GMP in Indonesia have been stated since 1986, by implementation the WHO GMP. By April 1994, all drug manufacturers should implement GMP. The fisrt edition GMP quideline was establisted on 1988 and second edition was revised in 2001 and the Third edition was revised in 2006. The GMP quideline are complited with operational manual for GMP implementation on each edition.

Manufacturer should conform GMP requirement, GMP certificate will be given if the requirement is confirmed and GMP certificate issued for each dosage form

The implementation of GMP in Pharmaceutical Industries is under control of National Agency of Drug and Food Control.

7) Post marketing surveillance system (PMS)

One of main functions of NADFC is post marketing vigilance including Pharmacovigilance(Adverse drug reaction monitoring), product sampling and laboratory testing, inspection of production and distribution facilities, labeling ing and promotion control. NADFC undergoes a multi face dimension and a complex aspect of consequences. Therefore, a comprehensive control system is needed from the use in community.

There are three layers of control sub-system:

- Producer Control Sub-system

  Producer should have an internal control system for complying with the requirements of the Code of Good Manufacturing Practices to enable early detection of every product deviation of quality standards.

- Consumer Control Sub-system

  The control system by consumers is through increased awareness and improved knowledge on product quality and safety for the intended purpose.

- Government Control Sub-system

The control system conducted by the government includes legislation and regulation, standardization, evaluation of safety, efficacy and quality of products before marketing, inspection and investigation, product sampling in the market and laboratory testing, public warning together with law enforcement.

Recognising that in Indonesia we rely on voluntary spontaneous reporting, by health professionals, to increase the reporting by health professionals, to increase reporting rate we have to create a culture of ADR Reporting.

To do that, we have to make health professionals aware of and understand the pharmacovigilance programme in Indonesia. NADFC, as National Centre has responsibilility to communicate with health professionals by conducted workshops for health professionals especially in some large hospitals.

Alongside workshops or seminars in hospitals, we encourage health bulletin consists of new information on drug safety, regulatory actions, labeling updates (if any) and also a sample of reported ADRs cases.

8) Sale and distribution of drug

Drug, food, traditional medicine professionals to report by sending them the *Indonesian ADR Bulletin* twice a year with blank yellow ADR reporting forms in it. For every report submitted, feedback or an acknowledgement will be sent back to the reporter. Theand cosmetic product have to be registed NADFC before distributed. Drug distribution should implementation Good Distribution Practise (GDP) to assure the quality of the product consisten since release GMP manufacturing until end user and also to keep the product in the legal distribution

Flowchart of drug distribution system on figure 3.

9) Additional requirements for biological (vaccines) and antibiotics such as National test system

Stable Supply of Vaccines

Manufacturing of vaccine production should comply to the recent GMP in Indonesia. Bio Farma in Bandung West Java has manufactured vaccine productions.Additional requirements for biological (vaccines) and antibiotics is

clinical test, and there is only the National laboratory of drug and food control can do the test.

5. Present situation and future plan (ex National plan, introduction of GMP concept etc) in the National drug policy

Drug control system are comprehensive control system.. There are three layers of control sub-system :

- Producer Control Sub-system : Producer should have an internal control system for complying with the requirements Good Manufacturing Practices
- Consumer Control Sub-system, consumers is through increased awareness and improved knowledge on product quality and safety for the intended purpose.
- Government Control Sub-system The control system conducted by the government includes legislation and regulation, standardization, inspection and investigation, product sampling in the market and laboratory testing, public warning together with law enforcement.

To achieve public health protection from substandard product, counterfeit drug and product that not meet safety, quality and eficacy spesification

6. Drug supply system and drug price mechanism including local product, imported and exported drugs

- Drug Supply

Imported, exported and local produce drug should be registered according to drug registration regulation with the same criteria in safety, efficacy and quality. Registration of imported drug products should be carried out by local pharmaceutical industries, pharmaceutical wholesaler that have written agreements from the pharmaceutical industry abroad. This pharmaceutical industry must fulfill criteria of

GMP which are proved by relevant document. If necessary, Inspection to the sites will be carried out by competent inspectors from NADFC.

Drug Price Mechanism

The expensive drug price is one of the problems for people to get the medication. The contribution of higher distribution and promotion cost increase the price of drugs. One of the Government efforts on the expensive drug problem is to introduce the generic drug. The government (The Ministry of Health) controls the generic drug price. Drug price control is only prevailed for generic product (copy product using International Non-proprietary Names). For branded product, there is no control on price setting; the producers set the price based on the market mechanism. To protect public health interest, NADFC implement some strategies on drug pricing policy. Namely initial price control, price comparison information on drug price in pharmacy, as well as active and passive price monitoring.

7. Information on the management of hospital pharmacies

Pharmacy departement is one of Departement under the hospital organization structure. A pharmacist is responsible as a head of hospital pharmacies. Hospital also has “therapeutical comitte” consist of doctor, pharmacies etc. One of its task is to built a drug list as aquide to prescription by the doctor. This drug list are composed by consider type of diseases, drug price etc.

Hospital pharmacies also give information services, that can be acessed by website

The other service is give conselling to certain patient about drug usege

8. Activities of research and development of drug

8.1 Research Development

The drug of health research development is conducted by The Health Department (NIDH), The National Agency of Food and Drug Control, The University, Drug Research directs to clinic examination. Dug Research has not directed yet to a new discovery drug (New chemical structure)

8.2 Industrial development

Industrial development of drug and medical devices continue the old policy and there is the addition of some new manufacturer. New industrial invest walks slowly after “Reformation Era”

8.3 Educational Development

- Pharmacy Education

Pharmacy Education Development in Indonesia walks fast enough, some Universities conduct post graduate program. There are Government university and private university, with length of study are 4 year for bachelor degree and 1 year for pharmacist.

8.4 Other

The traditional medicines are developing in Indonesia namely Curcuma xanthorriza (temulawak), Morinda citrifolia fruit (Mengkudu), it’s an extract or fermentation which is made in capsule or syrup, it’s useful for some diseases. Food supplements or health foods have the same development in Indonesia, either traditional medicines or food supplements have to be registered at NAFDC before distributed.

9. Pharmacopoeia

Pharmacopoeia Indonesia is the official standard for drugs, which is published by Ministry of Health. The standard has objectives on guidance of quality control for raw

material and drugs. The latest edition of pharmacopoeia was fourth edition that was published on 1995.

Figure 1.

ORGANIZATION STRUCTURE OF NATIONAL AGENCY OF DRUG AND FOOD CONTROL

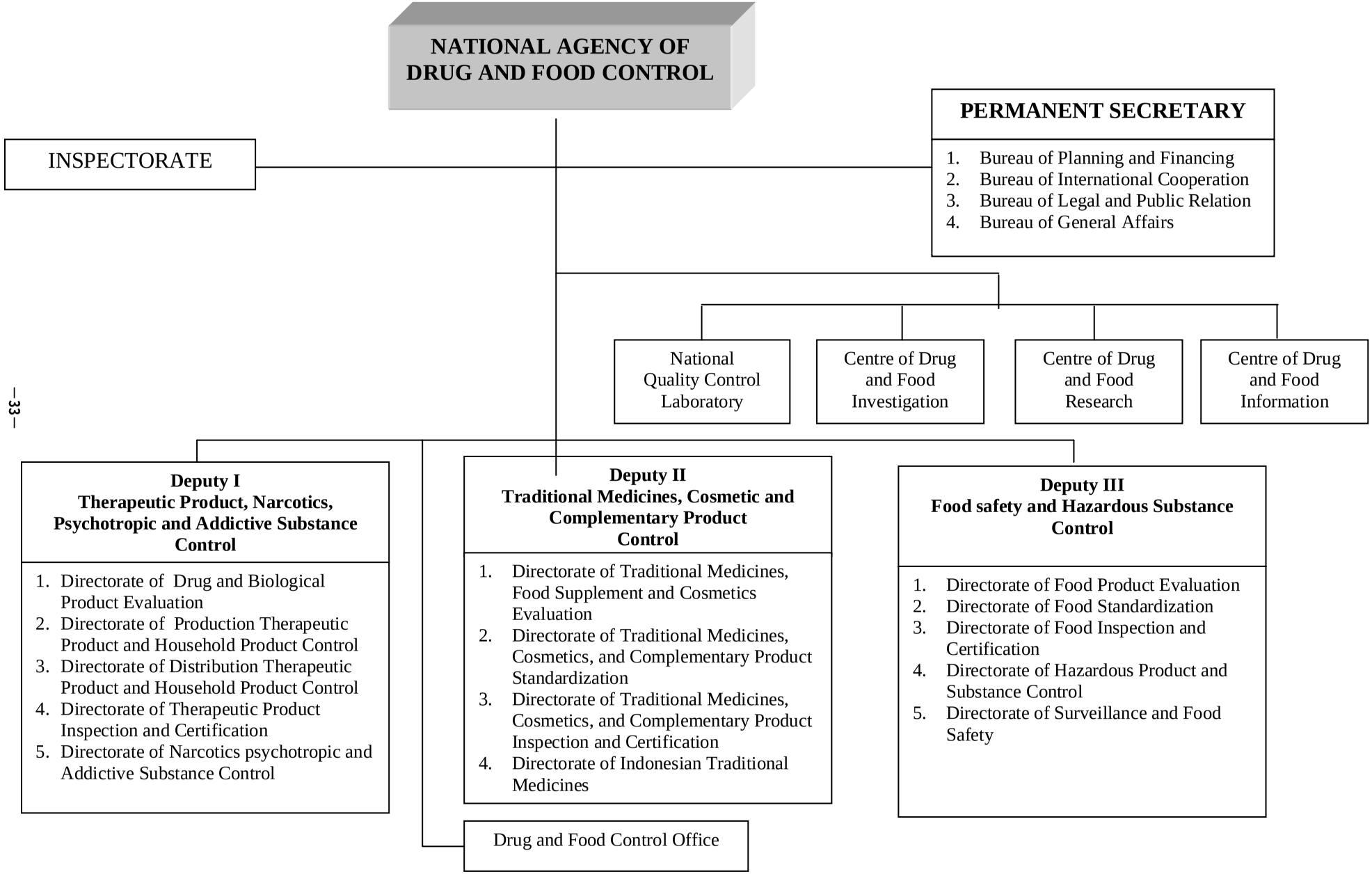


Figure 2.

ORGANIZATION STRUCTURE OF REGIONAL DRUG AND FOOD CONTROL OFFICE

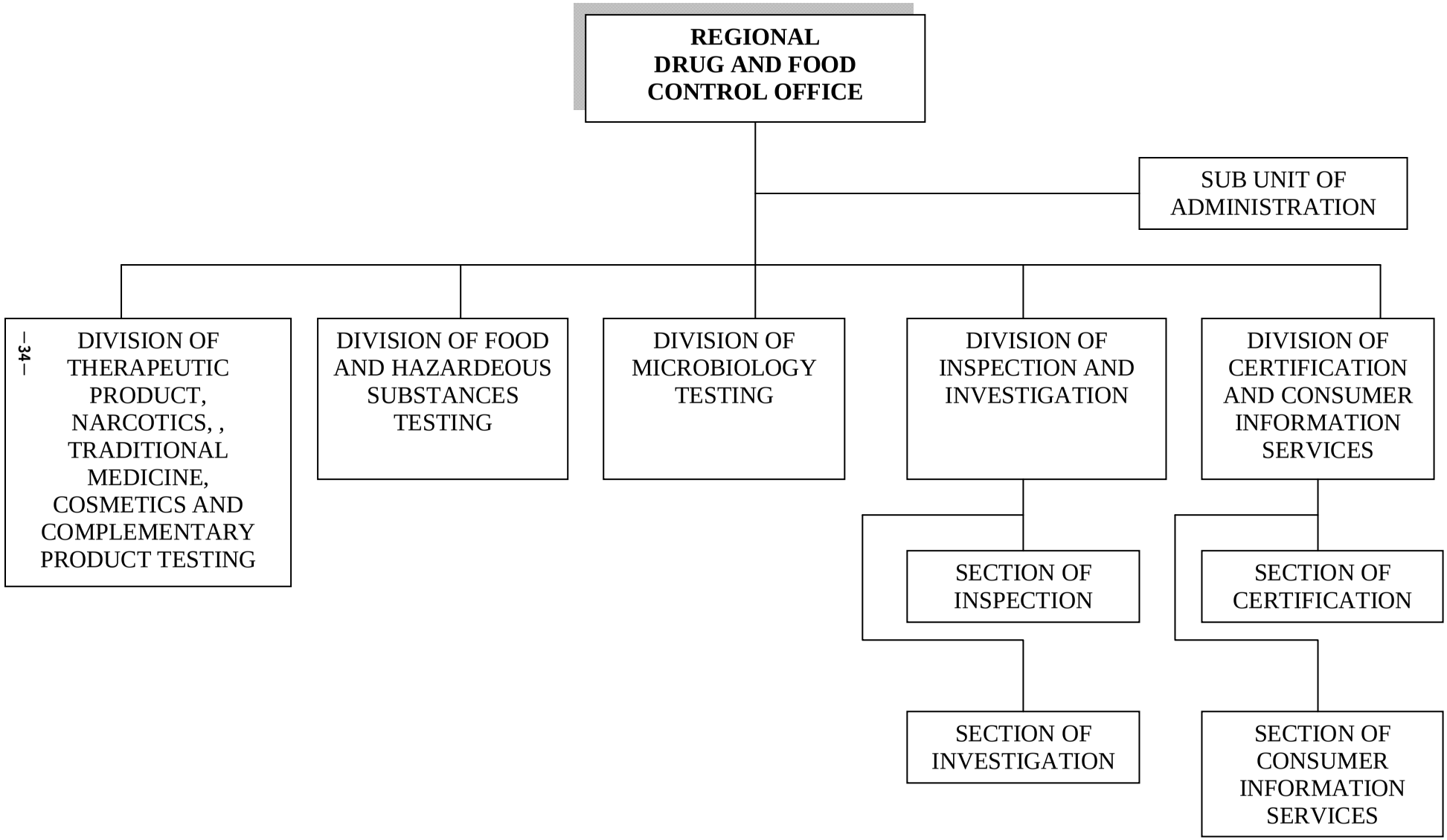
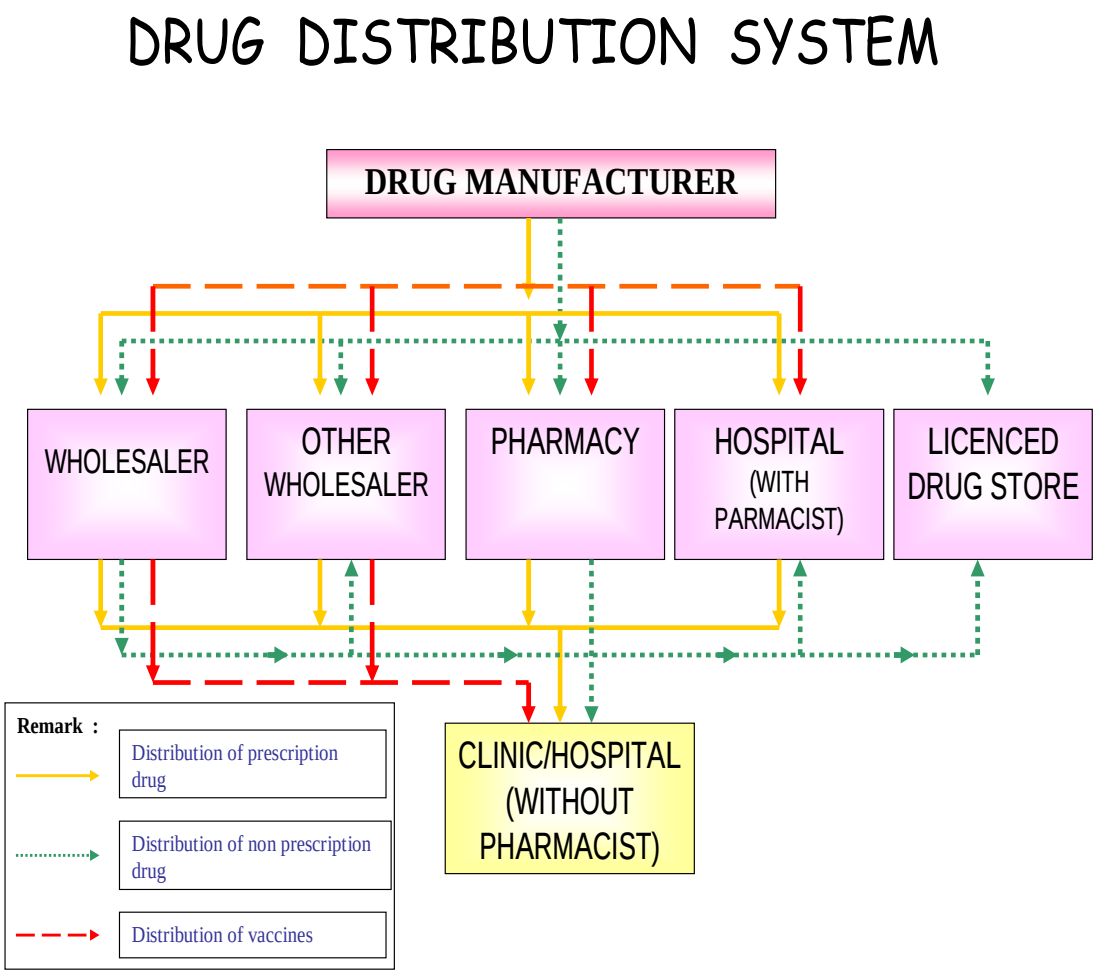


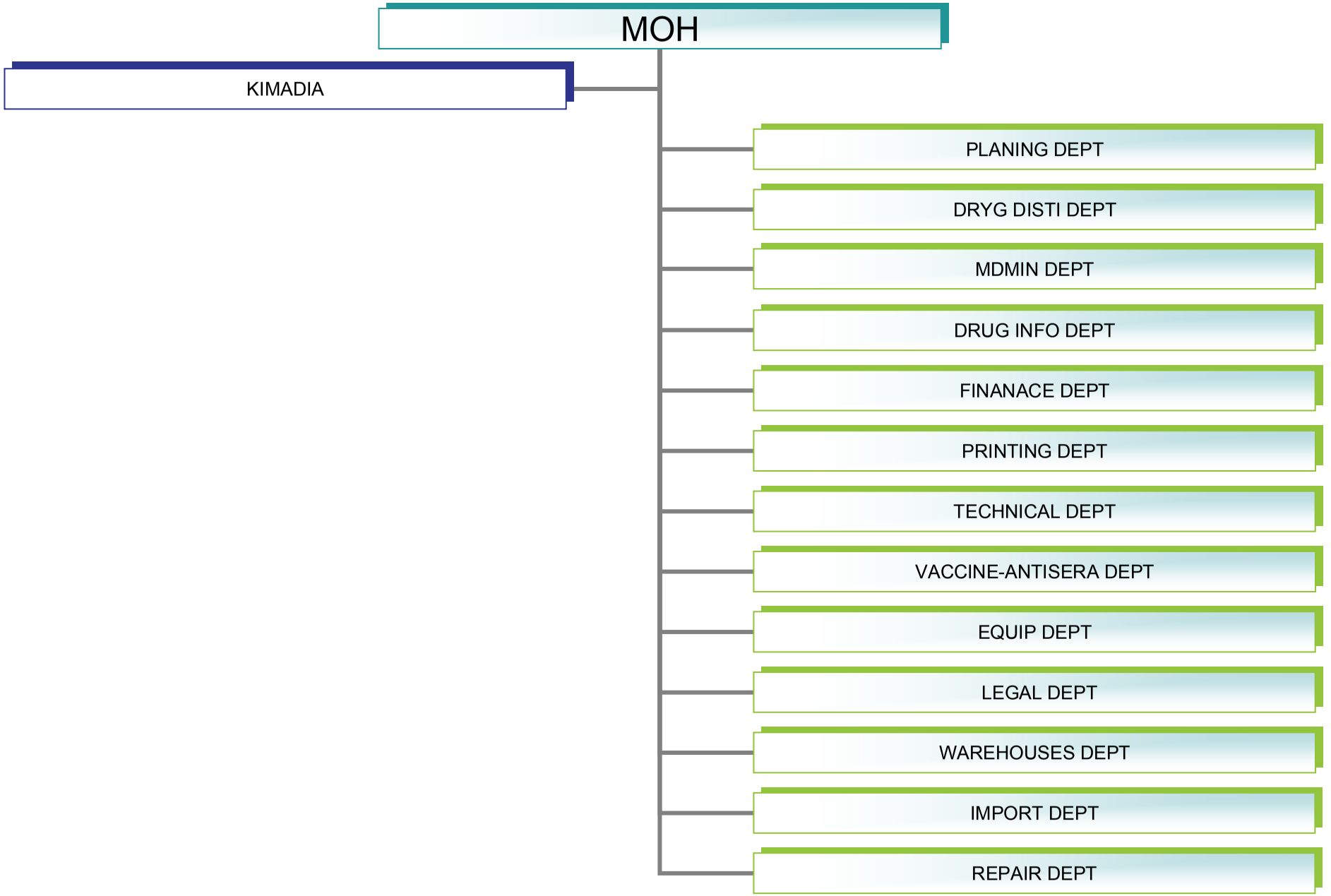
Figure 3.


DRUG DISTRIBUTION SYSTEM
DRUG MANUFACTURER
WHOLESALER
OTHER WHOLESALER
PHARMACY
HOSPITAL (WITH PARMACIST)
LICENCED DRUG STORE
CLINIC/HOSPITAL (WITHOUT PHARMACIST)
Remark :
Distribution of prescription drug
Distribution of non prescription drug
Distribution of vaccines

The Study Programme

for the Pharmaceutical Affairs Experts

Iraq

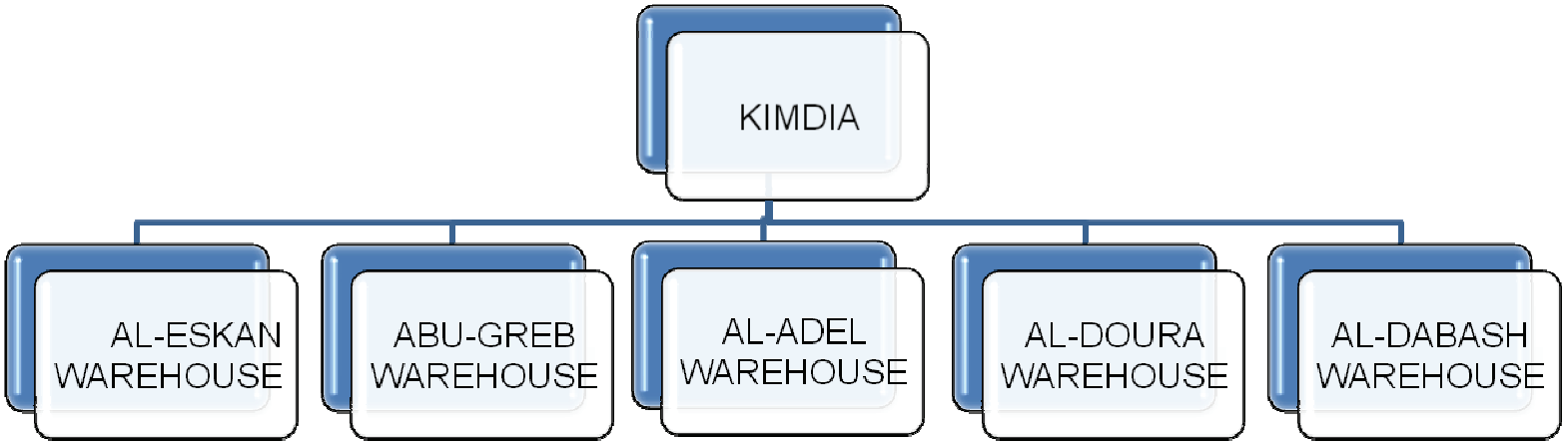

MOH
KIMADIA
PLANING DEPT
DRYG DISTI DEPT
MDMIN DEPT
DRUG INFO DEPT
FINANACE DEPT
PRINTING DEPT
TECHNICAL DEPT
VACCINE-ANTISERA DEPT
EQUIP DEPT
LEGAL DEPT
WAREHOUSES DEPT
IMPORT DEPT
REPAIR DEPT

2-CHARACTERISTICS OF PAA IN IRAQ

PHARMACY DEPT IS A PART OF TECHNICAL AFFAIRS DIRECTORATE IN MOH AND IS CONCERNED WITH THE MANAGEMEN OF TECHNICAL ASPECTS OF THE PHARMACEUTICAL AFFIARS

WHILE KIMADIA WORK INVOLVES IMPORT/STORAGE AND DISTRIBUTION OF DRUG AND MEDICAL SUPPLIES

THE KIMADIA SYSTEM IS LOCATED IN FIVE LOCATIONS



3-PROBLEMS TO BE SOLVED IN THE CURRENT SYSTEM

- NO TREATMENT GUIDELINES
- IRRATIONAL DRUG USE
- NON QUALIFIED PHARMACISTS IN THE WAREHOUSES
- BAD COMUTERIZED SYSTEM
- WEAK QCL
- AVAILABILITY OF ILLEGAL AND UNREGISTERD DRUG FROM UNKNOWN SOURCES
- POOR PRIVATE LOCAL MANUFACTURING PLANTS
- ABSENCE OF HEALTH INFORMATION SYSTEM BOTH IN KIMADIA AND PHARMACY DEPT IN MOH

4-CONTENTS OF THE REFORM TO SOLVE THE PROBLEMS

- NEED FOR NEW AND UPDATED RULES AND REGULATIONS FOR PHARMACY DEPT
- CONTINEOUS TRAINING PROGRAMMS FOR PHARMACISTS AND PHYSICIANS
- STRENGTHENING THE QCL CAPACITY
- AVAILABILITY OF INSURANCE COMPANIES
- AVAILABILITY OF GOOD COMPUTARIZED SYSTEM FOR CARRYING OUT WAREHOSES WORK
- NEED FOR HEALTH INFORMATION SYSTEM IN MOH
- EXPANDING AND ENCOURIGING PRIVATE LOCAL DRUG MANUFACTURING PLANTS

5-PROBLEMS FOR CARRYING OUT THIS REFORM

THEABSENCE OF SECURITY AND PEACE IN IRAQ EFFECTS CARRYIG OUT ANY POSSIBLE

SOLUTION

THE ABSENCE OF IDEAL OR PERFECT HEALTH SYSTEM

UNQUILIFIED ADMINSITRATION

6-MAJOR ACHIEVEMENTS IN RECENT YEARS IN PAA DEVELOPMENT IN IRAQ

THERE IS NO MENTIONABLE ACHIEVEMENTS HAS BEEN TAKEN PLACE IN THE RECENT YEARS

The Study Programme

for the Pharmaceutical Affairs Experts

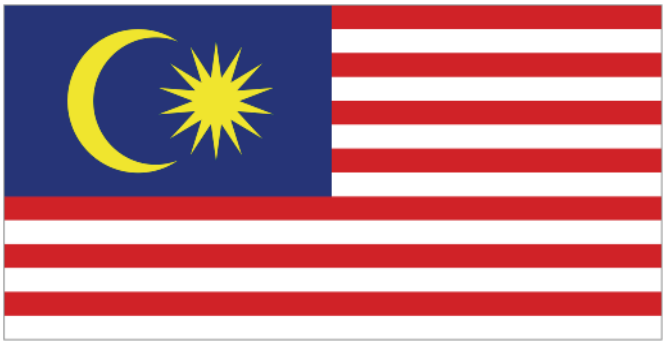
Malaysia

STUDY PROGRAMME FOR PHARMACEUTICAL AFFAIRS EXPERTS

08 November 2009 – 09 December 2009

Tokyo, Japan

COUNTRY REPORT



MINISTRY OF HEALTH, MALAYSIA

1. GEOGRAPHICAL AND POLITICAL FEATURES

Introduction

In 1948, the British-ruled territories on the Malay Peninsula formed the Federation of Malaya, which became independent in 1957. Malaysia was formed in 1963 when the former British colonies of Singapore and the East Malaysian states of Sabah and Sarawak on the northern coast of Borneo joined the Federation. The Federation of Malaya Agreement was signed in August 1957. At the end of the month, Independence was finally achieved with Tunku Abdul Rahman as the first Prime Minister.

Geographical Background

Malaysia is a country with two distinct parts. Peninsula Malaysia constitutes the long fringe of land, extending down from Asia, which borders Thailand and Singapore. The South China Sea separates the mainland from the East Malaysian provinces of Sabah and Sarawak. The dense jungles of Sabah and Sarawak support abundant plant and wildlife. It is the Peninsula that seems to attract the most visitors, probably because of the diversity it offers in the way of people, activities and climates.

The capital city is Kuala Lumpur, while Putrajaya is the seat of the federal government. The population stands at over 28 million inhabitants. Malaysia consists of thirteen states and three Federal Territories (Kuala Lumpur, Putrajaya and Labuan). The 13 states are Johor, Pahang, Negeri Sembilan, Melaka, Selangor, Perak, Terengganu, Kelantan, Kedah, Pulau Pinang, Perlis, Sabah and Sarawak.

Climate

Malaysia lies near the Equator between latitudes 1^{o} and 7^{o} North and longitudes 100^{o} and 119^{o} East. The year is generally divided into the South-East and the North-East Monsoon seasons. The average daily temperature throughout Malaysia varies from 21^{o}C to 32^{o}C. Humidity is high that is 80%.

Society and Culture

Malays, Chinese, Indians and many other ethnic groups have lived together in Malaysia for generations. The largest ethnic groups in Malaysia are the Malays, Chinese and Indians. In Sabah and Sarawak, there are a myriad of indigenous ethnic groups with their own unique culture and heritage. The Malays, Malaysia's largest ethnic group, make up more than 50% of the population in Malaysia.

The base of the national culture is Malay culture, which is native to this region. Islamic values are embedded in Malay Culture. The Malay culture emphasises values on courtesy, moderation, tolerance, harmony and cordial relations among family members, neighbours and community.

As Malaysian respect each other's beliefs and faiths, cultural and religious festivals such as Hari Raya, Chinese New Year, Deepavali, Christmas, Gawai Day and other auspicious occasions are given due importance. One of the unique features of Malaysia is its multi-racial population which practices various religions

such as Islam, Buddhism, Taoism, Hinduism and Christianity. Each ethnic group has its own beliefs. Under the Federal Constitution, Islam is the official religion of Malaysia but there is freedom of worship. The Malay Language (Bahasa Melayu) is the national language of the country. However, the people are free to use their mother tongue and other languages. English as the second language is also widely used especially in business.

Constitution and Separation of Power

Malaysia is a federal constitutional elective monarchy. The federal head of state of Malaysia is the *Yang di-Pertuan Agong*, commonly referred to as the King of Malaysia. The Yang di-Pertuan Agong is elected to a five-year term among the nine hereditary Sultans of the Malay states. The states are Perlis, Kedah, Perak, Selangor, Negeri Sembilan, Johor, Pahang, Terengganu and Kelantan. In the other states, namely Melaka, Pulau Pinang, Sabah and Sarawak, the Head of State is the Yang di-Pertua Negeri of Governor of the State. The Yang di-Pertua Negeri is appointed by the Yang di-Pertuan Agong for a four-year term. The

Federal Constitution of Malaysia clearly divides the authority of the Federation into its Legislative Authority, Judicial Authority and Executive Authority. The separation of power occurs both at federal and state levels, as in keeping with the concept of federalism, which form the basis of the government administration.

Executive Authority

Executive power is vested in the cabinet led by the prime minister; the Malaysian constitution stipulates that the prime minister must be a member of the lower house of parliament who, in the opinion of the Yang di-Pertuan Agong, commands a majority in parliament.http://en.wikipedia.org/wiki/Malaysia - cite_note-46 The cabinet is chosen from among members of both houses of Parliament and is responsible to that body.

State governments are led by Chief Ministers (*Menteri Besar* in Malay states or *Ketua Menteri* in states without hereditary rulers), who is a state assembly member from the majority party in the Dewan Undangan Negeri. In each of the states with a hereditary ruler, the Chief Minister is required to be a Malay Muslim, although this rule is subject to the rulers' discretions.

Education System

Education in Malaysia is monitored by the federal government Ministry of Education. Most Malaysian children start schooling between the ages of three to six, in kindergarten. Most kindergartens are run privately, but there are a few government-run kindergartens. Education in Malaysia may be obtained from government-sponsored schools, private schools, or through homeschooling. The education system is highly centralised, particularly for primary and secondary schools. Education in Malaysia broadly consists of a set of stages which are:

- Pre-school
- Primary Education (6 years)
- Secondary Education (5 years, excluding pre-university education for 2 years)
- Tertiary Education
- Postgraduate

Primary and secondary education in government schools is handled by the Ministry of Education, but policies regarding tertiary education are handled by the Ministry of Higher Education, created in 2004. In addition to the Malaysian National Curriculum, Malaysia has many international schools. International schools offer students the opportunity to study the curriculum of another country. These schools mainly cater to the growing expatriate population in the country.

Literacy Rate

The literacy rate among Malaysian citizens aged 10 - 64 years improved from 88.6% in 1991 to 93.5% in 2000, thus representing an increase of about 5 percentage points over the 1991-2000 periods. The percentage of Malaysian citizens aged 20 years and over with post secondary, college or university education increased from 8.9% in 1991 to 16.0% in 2000. This pattern was also observed for all the major ethnic groups.

School Attendance

At Malaysia level, it was observed that 92.7% of the male population aged 6 years and over had ever been to school compared to 87.6% for females in Census 2000. This represented a narrowing in the gap between the sexes when compared to Census 1991 where these percentages stood at 88.4% for males and 79.8% for females.

2. STATISTICAL DATA

1) Population

According to the 2008 statistic, Malaysia has a population of 27.73 million consisting of approximately 61% Malays, 30% Chinese, 8% Indians and 1% of other ethnic groups. Other significant groups are the indigenous races of Sarawak and Sabah, that is, the Dayaks, Kadazans (Dusuns), Bajaus, Melanaus and Muruts; and the aborigines of Peninsular Malaysia. There are also Europeans and Eurasians.

2) Vital Statistics

a) Rate of vital statistics (per 1,000 population) (per 1,000 live births*)

Year : 2008

Live Birth Rate	17.5
Death Rate	4.5
Infant Death Rate	6.3

b) Five main diseases causing morbidity

	2002	2004	2006	2008
1	Normal Deliveries (17.70%)	Normal Deliveries (15.65%)	Normal Deliveries (14.91%)	Normal Deliveries (13.99%)
2	Complications of Pregnancy, Childbirth and the Puerpeirum (11.49%)	Complications of Pregnancy, Childbirth and the Puerpeirum (11.75%)	Complications of Pregnancy, Childbirth and the Puerpeirum (12.39%)	Complications of Pregnancy, Childbirth and the Puerpeirum (12.77%)
3	Accident (8.79%)	Accident (8.74%)	Accident (9.11%)	Accident (8.40%)
4	Diseases of the Circulatory System (6.96%)	Diseases of the Circulatory System (7.11%)	Diseases of the Respiratory System (7.30%)	Diseases of the Respiratory System (8.05%)
5	Diseases of the Respiratory System (6.35%)	Diseases of the Respiratory System (6.83%)	Diseases of the Circulatory System (7.26%)	Diseases of the Circulatory System (6.99%)

c) Five leading causes of death

	2002	2004	2006	2008
1	Septicaemia (15.44%)	Septicaemia (15.10%)	Septicaemia (14.87%)	Heart Diseases & Diseases of Pulmonary Circulation (16.54%)
2	Heart Diseases & Diseases of Pulmonary Circulation (14.51%)	Heart Diseases & Diseases of Pulmonary Circulation (14.52%)	Heart Diseases & Diseases of Pulmonary Circulation (15.70%)	Septicaemia (13.18%)
3	Malignant Neoplasma (9.23%)	Malignant Neoplasma (9.54%)	Malignant Neoplasma (10.59%)	Malignant Neoplasma (11.21%)

4	Cerebrovascular Diseases (8.18%)	Cerebrovascular Diseases (8.40%)	Cerebrovascular Diseases (8.49%)	Pneumonia (9.28%)
5	Accident (6.32%)	Accident (6.07%)	Pneumonia (5.81%)	Cerebrovascular Diseases (8.65%)

d) Life expectancy

Year : 2008

Male	71.70
Female	76.46
Total	74.08

3. MEDICAL CARE POLICY

Year : 2008

a)

b) Number of hospitals by establishing organ

Government Hospitals	130
Government Clinics	802
Private Hospitals	209
Private Clinics	6,371

c) Number of health manpower

Physicians	25,102
Dentists	3,640
Auxiliary medical personnel*	100,582

d) Number of pharmacists : 6,397

e) Number of drug manufacturer / plants : 73 (until Sept 2009)

f) Number of traditional medicine manufacturers / plants : 175

g) Number of drug importers : 373 (until Sept 2009)

h) Number of drug wholesalers : (until Sept 2009)

Drug : 460

Non Poison/Trad./Cos : 453

4-1. PHARMACEUTICAL AFFAIRS ADMINISTRATION

A) National Pharmaceutical Control Bureau, Ministry of Health

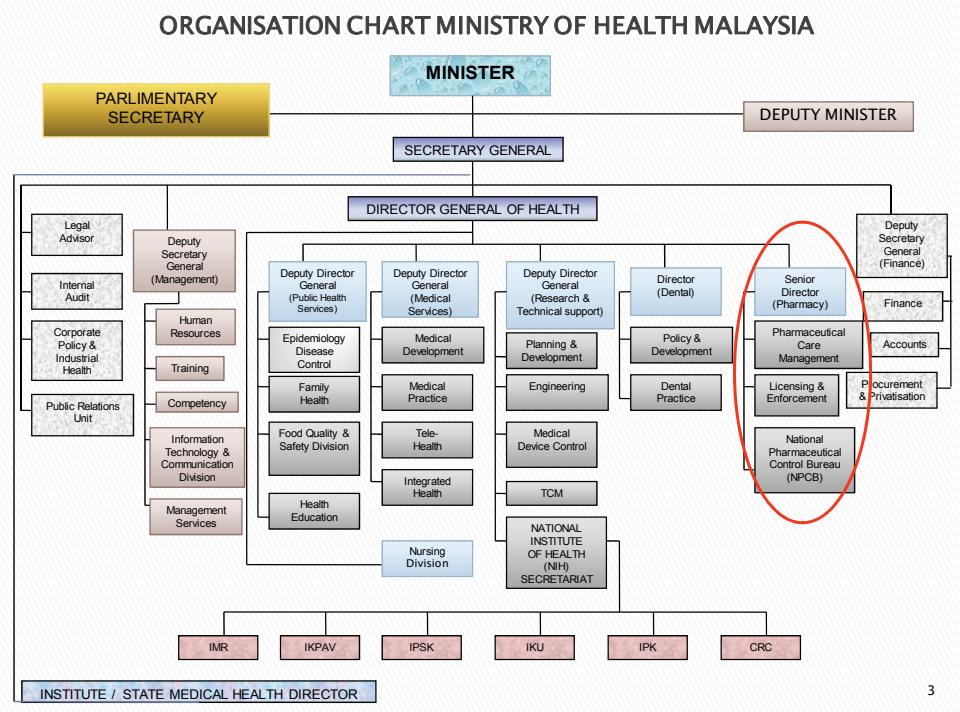
1-1) Administrative Organization

The National Pharmaceutical Control Bureau (NPCB) under the Ministry of Health Malaysia is an institution that carries out pharmaceutical regulatory control in Malaysia and ensures the quality, efficacy and safety of pharmaceutical products as well as the quality and safety of natural products and cosmetics marketed in the country (Refer organization charts below).

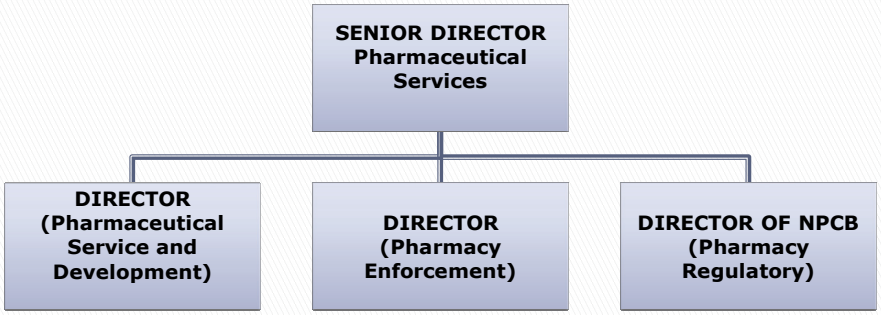
The NPCB was recognized by the World Health Organisation (WHO) as a Collaborating Centre in the Regulatory Control of Pharmaceuticals and has been providing training in pharmaceutical quality assurance and regulatory affairs to fellows from other countries.

The NPCB gained accession as the 26th member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) from 1st January 2002.

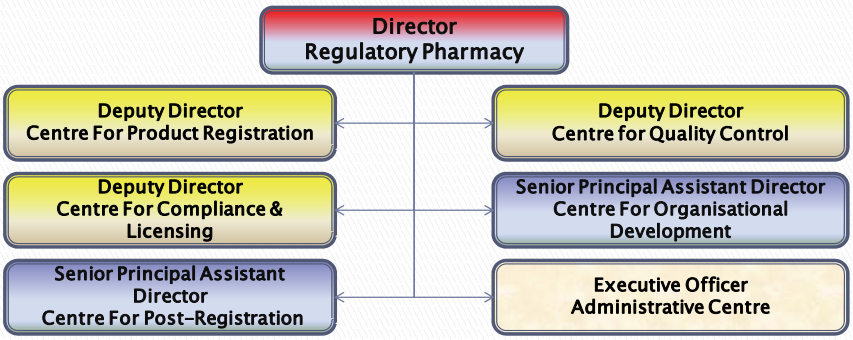
The NPCB has implemented the ISO 9001:2000 Quality Management System and acquired certification from SIRIM for the regulatory control of pharmaceuticals, natural products and cosmetics.



Pharmaceutical Services

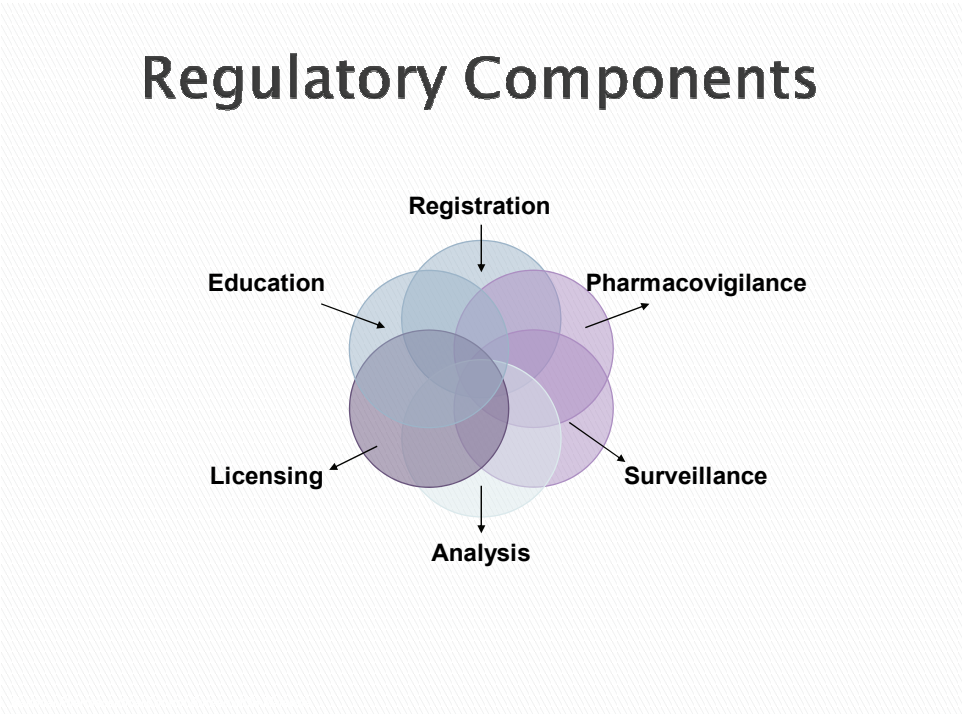


Organisation Chart
National Pharmaceutical Control Bureau



Total number of staff: 321

- Pharmacists: 188
- Pharmacy Assistants: 68
- Scientific Officers: 15
- Support Staff: 50



FUNCTIONS OF NPCB

- Evaluation and Registration of Products, Issuance of CPP, CFS
- Sample analysis
- Inspection and Licensing of premises (Manufacturers, Importers, & Wholesalers)
- Issuance of Licenses for Clinical Trial
- Post-registration market surveillance
- Adverse drug reaction (ADR) monitoring
- Dissemination of product information
- Training
- International & Regional collaboration

The Drug Control Authority (DCA) - established for the purpose of making policies as well as the authority in registration of products.

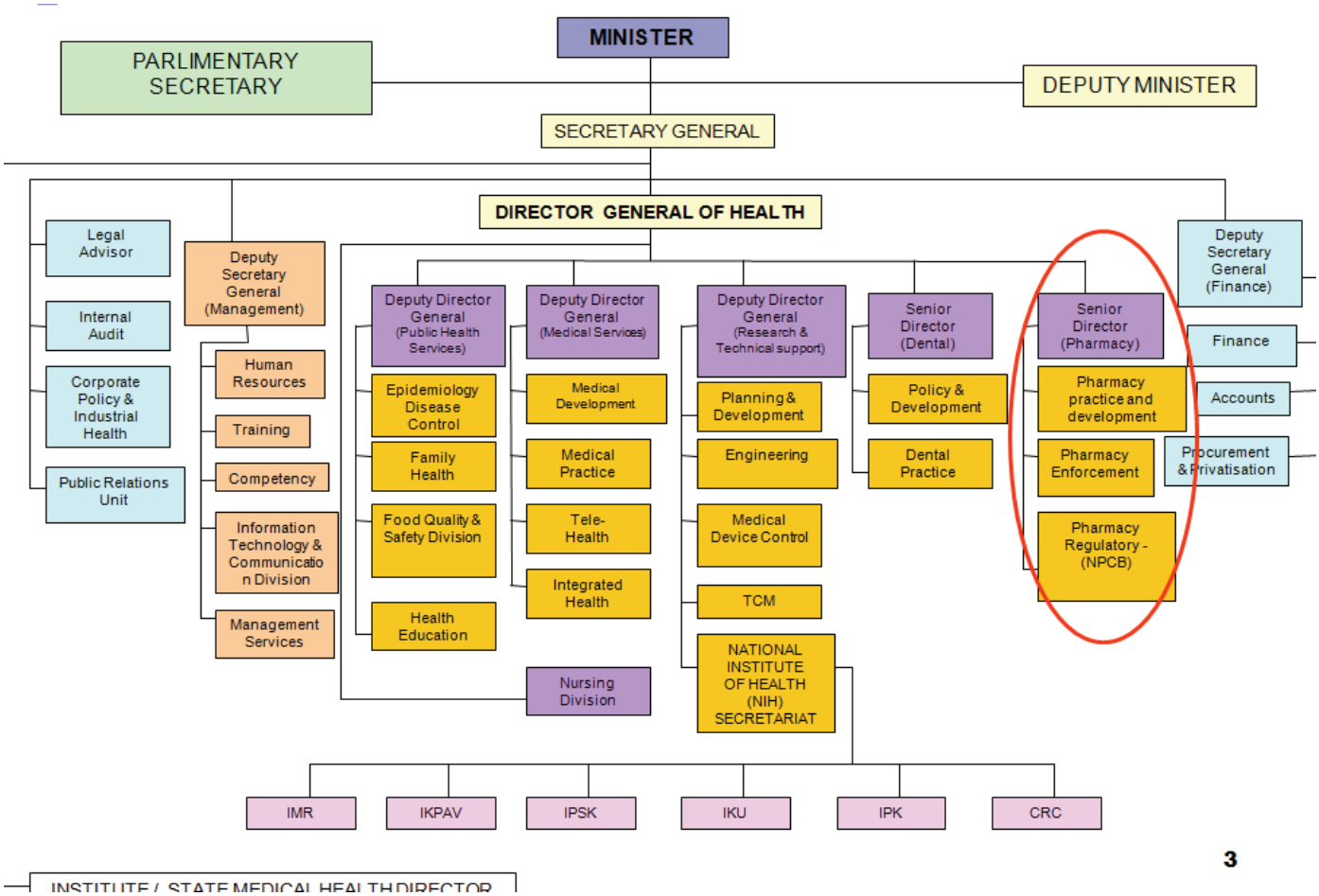
MEMBERS:

- Director-General of Health (chairman);
- Director of Pharmaceutical Services (alternate chair);
- Director of the NPCB; and
- 7 other members appointed by the Minister of Health

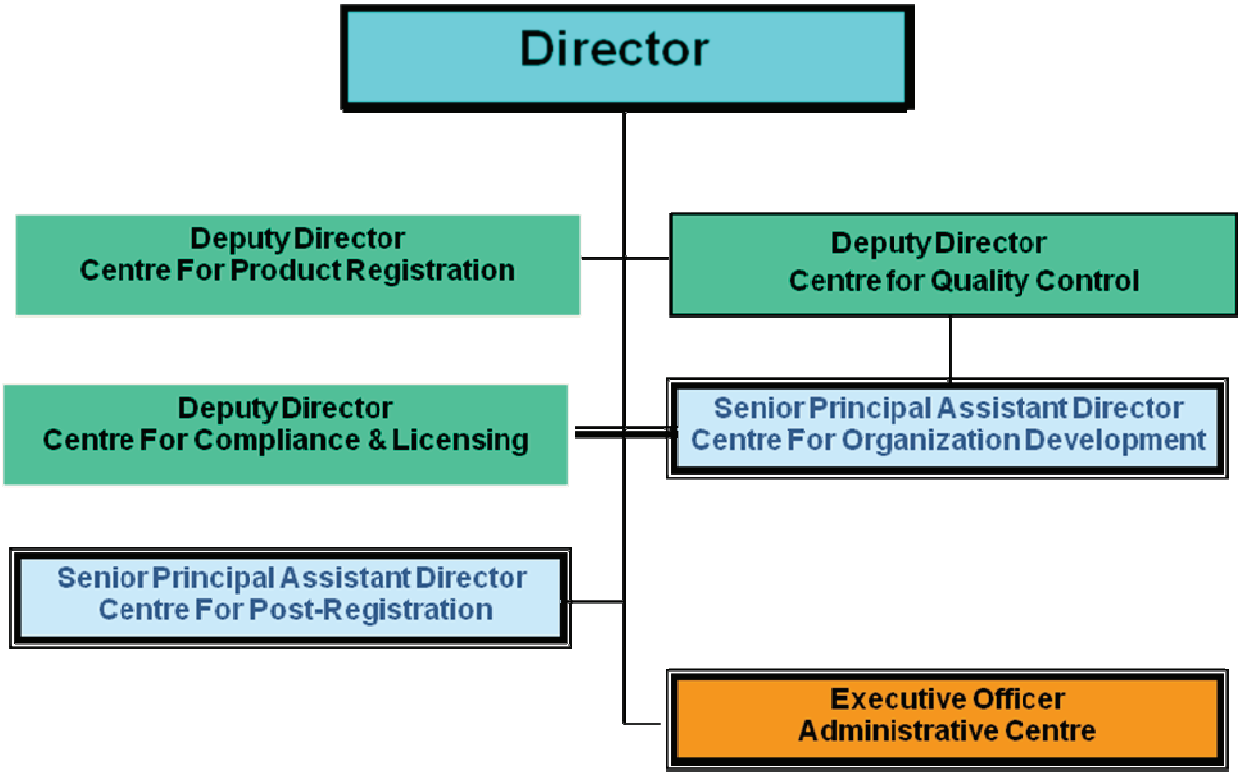
- NPCB functions as the secretariat of the DCA in which NPCB ensure that therapeutic products are approved for the local market are safe, efficacious and of quality, and also to ensure that traditional medicines and cosmetics approved are safe and of quality.

B) Pharmaceutical Service Division, Ministry of Health

1-1) Administrative Organization



1-2) Pharmaceutical Affairs Administration

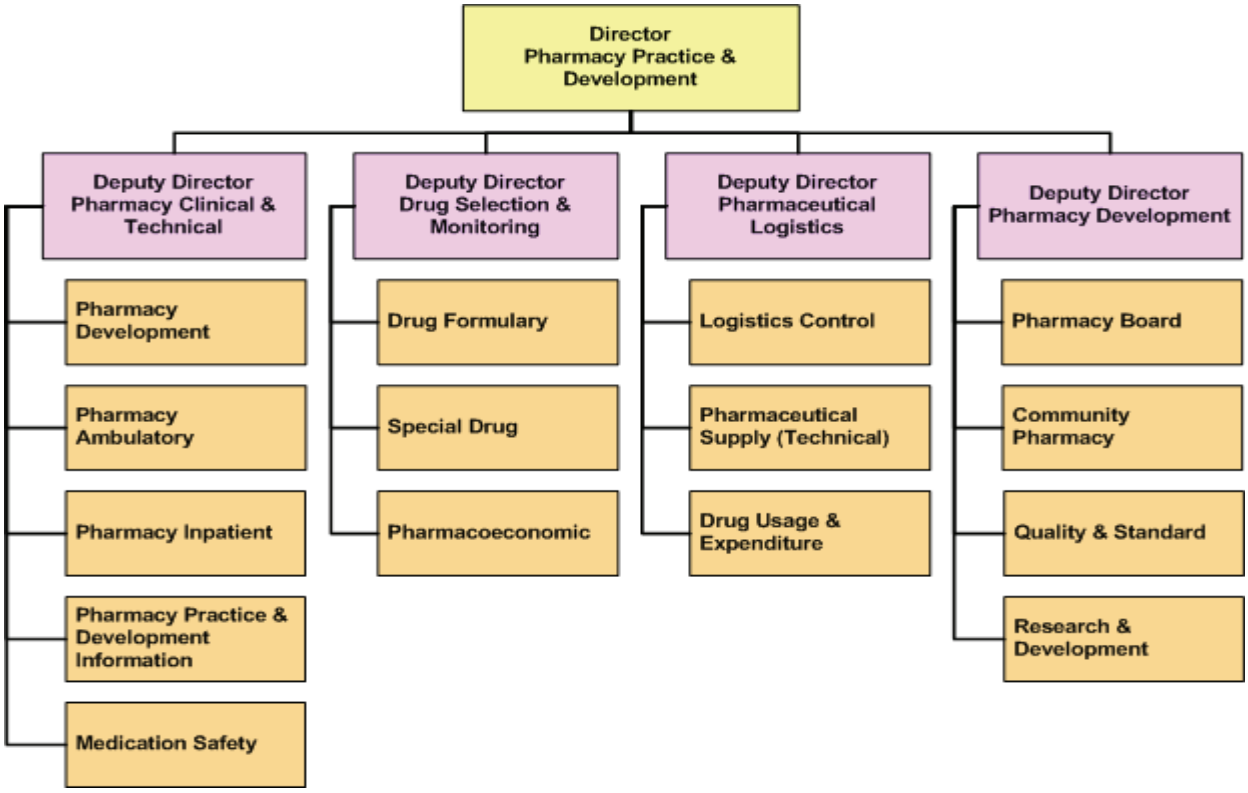


The Pharmaceutical Services Division in the Ministry of Health ensures that the Malaysian public is accessible to quality, safe, efficacious and affordable **pharmaceutical and healthcare products** including advice in using them rationally. In this context, the division plays the following 3 major roles :-

- Contributing directly towards public health through quality assurance whereby the Pharmaceutical Services Division, through the National Pharmaceutical Control Bureau, is responsible for regulating the pharmaceutical industry. This is to ensure that pharmaceutical products

conform to acceptable standards of quality, safety and efficacy before they are registered; and that all premises and practices employed to manufacture, store and distribute these products comply with the required standards till they are delivered to the end users.

- Enforcement of related acts and regulations.
- Provision of pharmaceuticals for hospitals and health clinics under the Ministry of Health. Ensuring a patient-focused service through the concept of Pharmaceutical Care. The ultimate aim is to ensure provision of optimum drug therapy, both by contributing to the preparation/manufacture, supply and control of medicines and associated products, and by providing information and advice to those who prescribe or use pharmaceutical products.



Regulatory Pharmacy – National Pharmaceutical Control Bureau

2) List of Laws / Regulation Covering Pharmaceutical Affairs

Pharmacy Legislation in Malaysia

The establishment of the Pharmaceutical Services Division in January 1974, under the Ministry of Health Malaysia, has remarkably led to the expansion in the role and functions of the overall pharmacy services, which contributed towards development of the healthcare sector. The Pharmaceutical Services Division currently undertakes 3 component activities namely **Quality Assurance of Pharmaceutical Products, Pharmacy Enforcement and Licensing, and Pharmaceutical Care**. The enabling powers that allow the

division to control and regulate the pharmaceutical sector are embodied in the following legislations :

- ***Registration of Pharmacist Act 1951 (revised 1989)*** which provides the establishment of the Pharmacy Board and Registration of Pharmacists
- ***Poisons Act 1952 (revised 1989)*** which regulates the importation, possession, manufacture, compounding, storage, transport, sale and use of scheduled poisons. Basically this Act determines whether a pharmaceutical product is a prescription item, a pharmacy-only item or an OTC.
- ***Sale of Drugs Act 1952 (revised 1989)***
- ***Control of Drugs and Cosmetics Regulations 1984*** which regulates the sale of pharmaceuticals through a system of product registration and licensing of manufacturers, importers and wholesalers.
- ***Dangerous Drug Act 1952 (revised 1980)*** which regulates the importation, exportation, manufacture, sale and use of narcotics.
- ***Medicines (Advertisement and Sale) Act (revised 1983)*** which regulates advertisement of over-the-counter (OTC) medicines in the lay media.

- Others related – ***Patent Act 1983, Trade Description Act 1972, Pesticides Act 1974***

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optimum drug therapy, both by contributing to the preparation/manufacture, supply and control of medicines and associated products, and by providing information and advice to those who prescribe or use pharmaceutical products.

Drugs and Cosmetics Regulations

The promulgation of the Control of Drugs and Cosmetics Regulations in June 1984 marked the dawn of the regulatory era in Malaysia. This laid the groundwork necessary towards moulding a systematic pharmaceutical regulatory system in Malaysia. In January 1985, the Drug Control Authority (DCA) was established under the chairmanship of the Director General of Health Malaysia, with a mission of ensuring the safety, efficacy and quality of pharmaceuticals as well as safety and quality of traditional medicines and cosmetics marketed locally. To accomplish this goal, the DCA through its Secretariat based at the National Pharmaceutical Control Bureau (NPCB) undertakes several functions which include evaluation and registration of products; analysis of samples; inspection and licensing of manufacturers, importers and wholesalers premises; post-marketing surveillance; adverse drug reaction (ADR) monitoring and dissemination of information.

Counterfeit Drugs

Sales of counterfeit pharmaceuticals are a growing problem in Malaysia. Counterfeit medicines include "drugs" with the wrong ingredients, insufficient active ingredients, and those with fake packaging. The counterfeit medicines siphon off profits of legitimate manufacturers, and leave companies vulnerable to lawsuits from patients who may have adverse reactions to the counterfeit products. Due to that, activities in monitoring of drugs, precursors, essential chemicals with potential abuse of being diverted and counterfeit medicines remain the top priority of the Pharmaceutical Enforcement Branch in Pharmaceutical Services Division, Ministry of Health.

As of 1st May 2005, the Ministry of Health has implemented Phase 1 of the compulsory ruling requiring manufacturers and importers of pharmaceutical products to fix security hologram labels onto their products or packaging. When affixed, the hologram labels raise the expectation that these products have been duly registered with the Drug Control Authority (DCA). This latest move by the Ministry was motivated by the need to curb counterfeit problems with pharmaceutical products and augment enforcement efforts against

imitation of such products. The hologram label will have a unique serial number that can be traced to the licensed manufacturer or importer of the product, which makes it easier for monitoring purposes.

Food Regulations

Food safety responsibilities throughout Malaysia are executed through a system of administration including the central, state, district and local authority levels. Within the Ministry of Health, the Food Safety and Quality Division, which was established in 1974, is responsible for the overall technical supervision of food safety activities; formulation of legislation, codes of practice and guidelines; determination of food safety policies; adoption of food sampling and food premises inspection strategies; and coordination of activities at the state and district levels. The Food Act 1983 (Act 281 of the Laws of Malaysia) and its regulations are the primary legislative documents for food safety activities in Malaysia. The regulations deal with such subjects as food hygiene, labelling, import and export, advertising and laboratories, and also contain numerous and detailed food standards.

Medical Device Regulations

In February 2005, a decision was made by the Malaysian Government to regulate medical devices in Malaysia. The Ministry of Health Malaysia is responsible for developing and implementing a regulatory framework to control medical devices in Malaysia. The aims of the medical devices regulation are to protect public health and safety; to allow patients for earlier access to new technology for early detection, diagnosis and treatment; and to facilitate trade and invigorate the medical devices industry.

3) Licensing System of Factory and Registration System of Drug

The issuance of Manufacturer's License, Import License and Wholesaler's License are under the purview of the NPCB. In the year 2008, there was a decrease in the number of licenses issued due to the fact that the DCA does not issue those licenses for cosmetic products, in line with the execution of the cosmetic products notification system effective 1st January 2008. The NPCB is also responsible for the issuance of Clinical Trial Import Licenses (CTIL), issuance of Registered Product Additional List, issuance of Good

Manufacturing Practice (GMP) Certificate, and revocation of manufacturing license. The NPCB also carries out pre-certification inspections of veterinary manufacturers for the purpose of issuing GMP Certificates. GMP Certificates issued would then confirm compliance to GMP whereby it is required for the registration of veterinary products overseas.

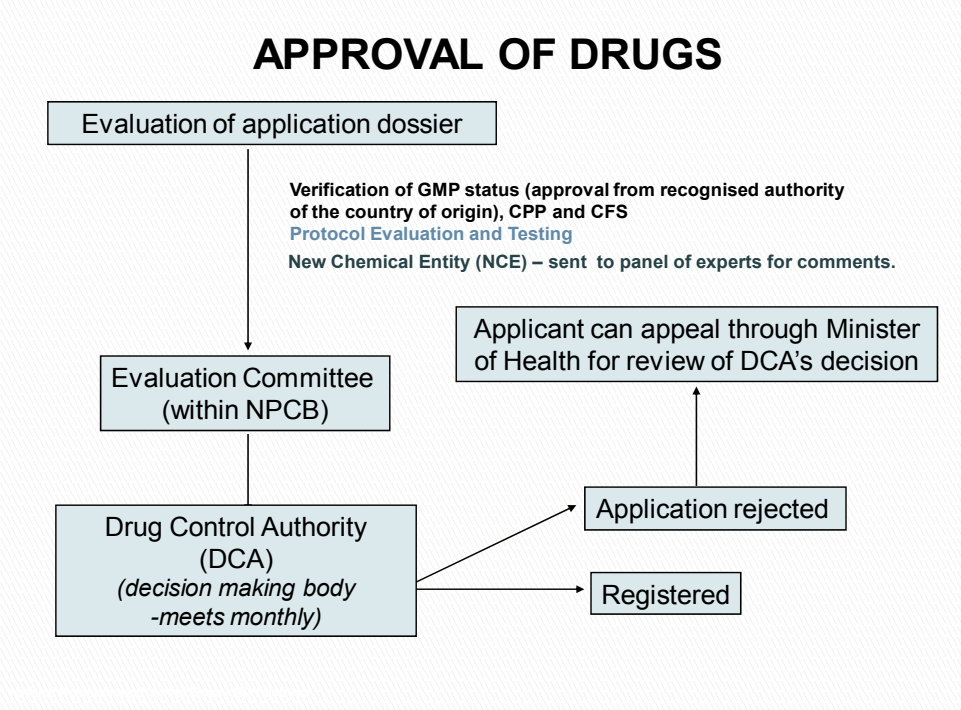
The Drug Control Authority (DCA) plays an important role in ensuring the quality, safety and efficacy of pharmaceutical products as well as the quality and safety of natural products in the market. The NPCB in line with its role as secretariat to the DCA is responsible for the registration of new chemical entities (NCES), biotechnology, prescription, non-prescription, veterinary, health supplements and natural products (refer chart below). Following the application for the registration of a product, the DCA is the body that makes decisions on approving or rejecting such applications. The aim of the DCA is to review policies and to deliberate upon applications for product registration and licensing. As for cosmetic products, the registration process is through notification process since 1st January 2008. Hence, cosmetic products are no longer required to be registered by the DCA. The existing registration numbers for cosmetic products has been changed to notification numbers

which begin with NOT instead of MAL. As for new cosmetic products, companies are only required to submit notification to market their products and the NPCB will issue notification notes, which are valid for two years.

Registrations of products are conducted via the online system (QUEST2) which was introduced since the year 2002. The QUEST2 system enables the registration of products through a readily accessible system and thus reduces the need of submitting documents manually. This results in faster registration of products and reduces the bureaucracy involved. The current system of QUEST2 will be upgraded to QUEST3 and the system is expected to be up and running by the year end 2009. The new and upgraded system of QUEST3 will introduce new online modules namely NCE, biotechnology, veterinary and For-Export-Only products.

The NPCB ensures the quality of pharmaceutical, natural and cosmetic products through two important procedures of protocol evaluation and data validation as well as analytical laboratory testing. This allows pre-registration and post registration sample testing as well as quality testing for complaint cases and adulterated samples from enforcement sources to be carried out.

Currently, analytical method protocols and validation data replaces the testing of pre-registration samples for pharmaceuticals.



Online Product Registration System (QUEST2)

- On-line web based registration system implemented since 2002
- Allows for submission of data 24 hrs a day, 365 days a year from any part of the world
- For all categories of products except for the submission of applications for New Chemical Entities and Biotech products

4) Pharmaceutical Inspection including Quality Control Check System

The NPCB conducts inspections on manufacturers of pharmaceutical, natural and cosmetic to ensure compliance with GMP. To ensure compliance with Good Storage Practice (GSP) among the importers and wholesalers, the NPCB collaborates with the State Pharmacy Enforcement Branch in conducting GSP inspections. Inspections are also carried out to ensure that clinical research conducted in Malaysia is in accordance to the Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) guidelines as well as applicable legislations. As of 1st January 2008, all cosmetic products are not required to undergo the registration and licensing processes but GMP requirements are still required for all cosmetic product manufacturers. Thus, the NPCB still continues to carry out GMP inspections for cosmetic manufacturers according to a pre-determined schedule. The NPCB also carries out inspections of facilities for the preparation of pharmaceuticals

(including public and private hospitals) in an effort to ensure that all products prepared by hospitals and research institutes are safe for patient use, staff are

safe from dangerous emissions and the environment is protected from medicine contamination.

The Centre for Quality Control has constantly given support and technical input to the Centre for Compliance and Licensing in auditing cosmetic and therapeutic product manufacturers.

The Centre for Quality Control is responsible for ensuring that the quality of all registered products marketed in Malaysia are compliant to the specifications claimed by the manufacturer, and to ensure that products are of quality, safe and effective. The quality control on the pharmaceutical, traditional and cosmetic products registration process are based on protocol evaluation and data validation and analytical testing. The tests conducted follows in-house or manufacturer's approved protocol and specification as well as the international pharmacopoeias as reference. The centre is actively involve in collaborative research and proficiency testing scheme organised by ASEAN, WHO and EDQM to ensure continual competency in testing. The centre also establishes a unit called the Reference Standard Unit which prepares and

provides reference standards to all laboratories in the NPCB as well as to pharmaceutical companies and other government agencies.

5) Good Manufacturing Practice (GMP)

The promulgation of the Control of Drugs and Cosmetics Regulation in 1984 provided the foundation for development of a systematic pharmaceutical regulatory system. To maintain standards and safeguard public well-being, measures were undertaken by the National Pharmaceutical Control Bureau (NPCB) to implement a drug and cosmetic registration and licensing scheme which covered pharmaceutical manufacturers, importers and wholesalers as well as clinical trials. NPCB also provided technical assistance to local pharmaceutical manufacturers to upgrade manufacturing standards to levels equivalent to the requirements of Good Manufacturing Practice (GMP) as recommended by the World Health Organisation (WHO) and other relevant organisations.

With globalisation and trade liberalisation, efforts were made to ensure the competitiveness of the pharmaceutical industry through continuous improvement in standards and quality assurance requirements. Effective from 1st January 2002, Malaysia became the 26th member of the Pharmaceutical Inspection Cooperation Scheme (PICS), a cooperative arrangement between international pharmaceutical inspection authorities in the field of GMP. The acceptance of Malaysia into the PICS paved the way for the local pharmaceutical products to be recognised internationally. The GMP guidelines that are currently applied are PIC/S Guidelines on GMP for Pharmaceuticals, Malaysian Guidelines on GMP for Traditional Medicines and ASEAN Guidelines on GMP for Cosmetics. Being a member of PIC/S, the Quality Management System of manufacturers and the quality of pharmaceutical products produced must be at par with other member countries. Manufacturers having a tough time to comply with the high standards, need to spend much to upgrade their facilities and also need to train the personals involved.

In order for the products to be registered, all manufacturers must comply with Good Manufacturing Practice (GMP). Poor understanding of GMP and

registration procedures, communication breakdown, used of undeclared ingredients i.e. premixes in production and increasing number of adulteration cases were some of the major problems encountered. Nevertheless, several initiatives have been taken by the Ministry to assist the local industries. Regular dialogues, guidance and advice, training programmes and dissemination of information have led to fruitful outcomes. Ministry is also proactively making wide surveillance on the products in the market and would continue to monitor the situation. Should any product found to contain harmful substances, there would be an immediate recall of these products from the shelves.

6)Post Marketing Surveillance System (PMS)

The NPCB is responsible on regulatory matters pertaining to registered medicinal products and notified cosmetics that have been placed on the Malaysian market. It is conducted through a range of activities such as surveillance and investigation of product complaints to ensure the maintenance of the appropriate established product standards and compliance to requirements as set by the DCA. Post-Marketing Surveillance

(PMS) programme was initiated in 1990. The NPCB is also involved in assessment of product variations and change of manufacturing sites. Thus, once the products are registered, the quality of the products in the market is continuously monitored by NPCB through its PMS programme.

7)Sale and Distribution of Drugs

Drug Advertisement

The Medicine (Advertisement and Sale) Act 1956 provides the basis for the control of advertisements of medicines, appliances, remedies, skill and services that relate to medical and health claims. The Pharmaceutical Services Division, Ministry of Health as the custodian of this Act has put into place an enforcement mechanism that is committed to eradicating illegal advertisements. A total of 81 cases were investigated under Medicine (Advertisement and Sale) Act 1956 and 160 warning letters were issued in 2005.

8)Additional requirements for biological (vaccines) and antibiotics such as National Test System (if any)

Vaccines used for public sectors are supplied by Pharmaniaga Berhad with stringent control on cold chain requirements.

5. PRESENT SITUATION AND FUTURE PLAN

The registration online system, QUEST2, which was introduced since the year 2002 is currently in the process of upgrading to QUEST3. The new online system, QUEST3, is scheduled to be ready for implementation in year end of 2009.

A Technical Working Group (TWG) for biotechnology products has been established to prepare relevant guidelines for biosimilar products. Representatives from various agencies such as Ministry of Science, Technology and Innovation (MOSTI), Malaysian Bio-Industry Organisation, Malaysian Biotechnology Corporation Sdn Bhd, Pharmaceutical Association of Malaysia (PhAMA), Malaysian Organisation of Pharmaceutical Industries (MOPI) attended the meeting at the NPCB. In line with the government's mission to further develop areas related to

biotechnology products in Malaysia, the skills of officers or evaluators of the products need to be enhanced. Officers in this area need to undergo a comprehensive training within Malaysia and overseas to develop and improve their skills in this area.

The NPCB continues to play an active role in the harmonisation efforts through ASEAN Consultative Committee for Standards and Quality (ACCSQ), Pharmaceutical Product Working Group (PPWG), Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) as well as ASEAN Cosmetic Committee (ACC). Other international involvements include Pharmaceutical Inspection Cooperation Scheme (PIC/S) activities.

The NPCB continue to improve GMP and Good Storage Practice (GSP) standards of manufacturers, importers as well as wholesalers, to strive towards implementing GMP requirements on veterinary product manufacturers and to regulate GMP requirements on the manufacture of biologic/blood products.

Several training programmes have been conducted since the implementation of cosmetic notification procedure as of 1st January 2008. The aim of these programmes was to improve the skills and competency of regulators and the industry to ensure smooth implementation of the notification procedure as well as compliance to the ASEAN Cosmetic Directive requirements.

The Cabinet has approved the use of the Good Laboratory Practice (GLP) of the Organisation for Economic Cooperation and Development (OECD) in Malaysia and the NPCB was appointed as the GLP Compliance Monitoring Authority (CMA) for the conduct of clinical trial tests for pharmaceutical products.

As for the future plans, NPCB continues to strive towards excellence in the regulatory area by maintaining a high standard in the regulatory practice. In tandem with the rapid growth of the pharmaceutical industry, NPCB needs to keep abreast in terms of capacity and capability building so as to stay relevant. Strategies have been identified to further improve services in NPCB. Among the strategies identified are developing human resource

and maintaining staff and expertise, emphasizing on Information Technology (IT) culture within the organisation, additional emphasis on training programme, overall development plan for Quality Management System (QMS) and reinforcing cooperation with other regulatory agencies. The current system of QUEST2 will be upgraded to QUEST3 in which it will be in operation by year end 2009. The QUEST3 system is to facilitate the implementation of online registration for New Chemical Entities (NCE) and Biotechnology products. In addition, the QUEST3 system will facilitate the integration of different online modules involving product registration, licensing of premises, analytical testing, surveillance, Adverse Drug Reaction (ADR) monitoring and dissemination of information.

Efforts are also taken to enhance the Quality Management System (QMS) of the NPCB and to reinforce compliance to the Pharmaceutical Inspection Cooperation Scheme (PIC/S). In terms of compliance of products to Good Manufacturing Practice (GMP), the NPCB will improve the processing of Registered Product Additional Lists and GMP certificate, introduce the Good Distribution Practice (GDP) guideline to replace the Good Storage Practice (GSP) guideline, provide training regarding the system of

documentation and records to natural product manufacturers, inspect stem cell based product processing facilities, ensure compliance of clinical research centres to Good Clinical Practice (GCP) as well as ensure laboratories comply to Good Laboratory Practice (GLP).

The NPCB, after attaining the MS ISO 9001:2000 certification, will continue its efforts towards obtaining MS ISO/IEC 17025:2005 accreditation for heavy metal tests and microbial contamination for natural products. Efforts are also intensified in Research & Development (R & D) of i) Lovastatin in herbal medicines, ii) Development of reference materials for the adulterants and to iii) Perform complete validation on the analytical methods of cadmium testing in natural products which are determined by graphite furnace atomic absorption spectrophotometry technique.

National Medicines Policy

The Malaysian National Medicines Policy (MNMP) presents the framework of strategies and commitments of the government and all stakeholders in both public and private sectors to a common medium and long term goals for the national pharmaceutical sector. It comprises of four main components namely,

Quality. Safety and Efficacy of Medicines, Availability of Medicine, Affordability of Medicines and Quality Use of Medicines. Four other supporting components are Human Resource Development, Research and Development, Technical Co-operation and Management of the National Medicines Policy.

In 2008, the monitoring of MNMP indicators was implemented on 29 backgrounds, 39 structural and 18 process indicators. Background indicators are intended to provide data on demography, economy, health and pharmaceutical status while structural indicators provide qualitative information assess the pharmaceutical system's capacity to achieve the policy objectives. Process indicators impart quantitative information on the processes by which the policy is implemented, and outcome indicators measure the result achieved and the change that can be attributed to the implementation of the National Medicines Policy.

6. DRUG SUPPLY SYSTEM AND DRUG PRICE MECHANISM INCLUDING LOCAL PRODUCTS, IMPORTED AND EXPORTED DRUGS

Drug Distribution System

Pharmaniaga Berhad, a private company, is currently responsible in distributing the medicines to hospitals and health centres.

Drug Supply System

Private company, Pharmaniaga Berhad currently responsible in distributing the medicines to hospitals and health centres.

Drug Advertisement

The Medicine (Advertisement and Sale) Act 1956 provides the basis for the control of advertisements of medicines, appliances, remedies, skill and services that relate to medical and health claims. The Pharmaceutical Services Division, Ministry of Health as the custodian of this Act has put into place an enforcement mechanism that is committed to eradicating illegal advertisements. A total of 81 cases were investigated under Medicine

(Advertisement and Sale) Act 1956 and 160 warning letters were issued in 2005.

Drug Price Mechanism

The expensive drug price is one of the problems faced by people to get their medication but drug price regulation does not exist in Malaysia. The Government of Malaysia has no control over the prices of medicines. Under the present practice, market forces are expected to stabilize drug prices. In Malaysia, medicines are available from many outlets such as private clinics, hospitals, retail pharmacies and supermarkets (for OTC products only) but however patient treated in government hospitals will get the medicines almost free of charge. Ministry of Health Malaysia has set-up a Price Monitoring Unit (PMU) under the Pharmaceutical Services Division to carry out continuous price monitoring activity for trending purposes guided by the WHO Consultant.

National Essential Drug List

The National Essential Drugs List was formulated by using the Ministry of Health's (MOH) Drugs List as a basis. The MOH Drugs List which was introduced in 1983 serves as the essential drugs list for the public healthcare

sector. Every drug in this list is classified according to the category of medical officer or healthcare provider allowed to prescribe it. This list is dynamic and is reviewed every 4 months by a panel consisting of specialists from the main disciplines and pharmacists.

The Committee for Creating the National Essential Drugs List has decided that the List shall consist of two parts. The first part called the Essential Drugs List contains all preparations needed for primary and secondary healthcare treatment commonly used by Medical Officers and paramedics in primary healthcare facilities. Several preparations used in tertiary care are included in order to be consistent with WHO's Model Essential Drugs List. This part contains 358 chemical entities and 605 preparations. The second part called the Supplementary List consists of drugs used by specialists for tertiary level treatment. This part contains 257 chemical entities and 391 preparations.

7. PHARMACOPOEIA

Quality control activity is an important element in the evaluation of pharmaceutical, traditional and cosmetic products. The products tested include products for registration, post-marketing surveillance of registered products, complaints on registered products and products from enforcement activities. The tests conducted are based on pharmacopoeias mainly British Pharmacopoeia (BP) and United States Pharmacopoeia (USP), in-house or manufacturers' approved protocols of analysis and specifications.

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The Study Programme

for the Pharmaceutical Affairs Experts

Papua New Guinea

PAPUA NEW GUINEA (PNG) - COUNTRY REPORT

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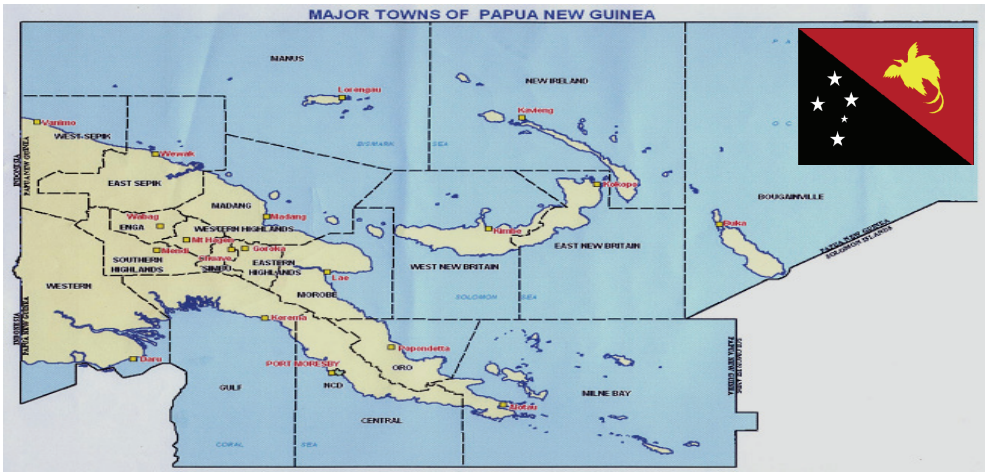
Suggested Guidelines for Country Report

The Study Programme for Pharmaceutical Affairs Experts -2009.

1. **Country Profile/ Introduction of Papua New Guinea.**

   (Includes geographical and political features, and general information such as language, system of school education, GNP and political system).



With a total landmass of approximately 465,000 km2, Papua New Guinea (PNG) is by far the largest and most populated of all the Pacific Island Countries (PIC). Topographically,

it is one of the most rugged and diverse countries in the world, with an extraordinary range of ecosystems.

PNG has vast natural resources, especially mineral, forest and marine resources and it is home to many rare and endangered species of animals and plants.

PNG's governance system is a parliamentary democracy based on the Westminster model. As a member of the Commonwealth, the head of the Independent State of PNG is the Queen of England, represented by the Governor General who is elected by the National Parliament for a five-year term.

The current single chamber parliament has 109 members comprising of one representative from each of the nineteen provinces and the National Capital District, and one representative from each of the 89 open constituencies. Every five years the political leaders are elected at the two tiers of government: national and local level government (LLG). Presently, there is only one women representative in the National Parliament.

PNG has a decentralized system of government. At the sub-national level, there are three levels of administration viz. at the province, district and LLG level.

PNG is a country with an extremely diverse sociocultural profile. More than 800 distinct languages are spoken, which is a serious impediment for development. In recent times,

development pressures and globalization have had an impact on the social life and traditional culture of Papua New Guineans.

The current system of education in PNG is a top up system whereby children are enrolled into elementary schools at the age of 5years and enter primary school at the age of 8.At the primary level, the children do grades one to eight (1-8) and than move on to the secondary school to do grades nine to twelve (9-12). After grade 12, the students than move on to the tertiary institutions (colleges and universities) after which they are graduated once excelled than employed.

Ninety Six percent (96 %) of PNG's population are Christians. The other 4 % are from the other religions or religious groups.

2. Statistical Data (Please fill in with the latest data).

1. Population.

The national census usually takes place every 10 years in Papua New Guinea. According to the country's National Statistics Office, the last census was taken in the year 2000 and the next one will be next year (2010). The figures below are therefore current until next year when a new count on the population is taken.

Indicator	Year	Data
Area (in 1000sq.km)	2005 estimated	462.84 (in 1000sq.km)
Estimated population	2005 estimated	5,950.69 million (5,950,690)
Annual population growth	2000	2.7%
Percentage of population - Less than 15 years old - Over 65 years old	 2004 estimated 2004 estimated	 41.68% (248.25 million) 2.54 % (151.15 million)
Urban population	2003	13.20 % (785.5 million)
Rate of natural increase of population	2000	2.3%

2) Vital Statistics

Indicator	Year	Data
a) Rate of vital statistics: Live birth rate (per 1000 population) Death rate (per 1000 population) Infant death rate (per 1000 live births)	 2000 2000 2000	 35 % 12.00 % 64.00 %
b) Five main disease causing morbidity The data below is only for the year 2004. Currently, no data is available for the years 2002, 2006 and 2008.		No. of cases per 100,000 (all ages, male and female)

i) Malaria	2004	27, 376
ii) Pneumonia	2004	27, 369
iii) Other Intestinal Infectious disease	2004	6, 829
iv) Disease of other parts of the digestive system	2004	6, 085
v) Tuberculosis	2004	6, 008
c) Five leading causes of death		
i) Normal deliveries (incl. BBA)	2004	49,461
ii) Pneumonia	2004	27,369
iii) Other types of Malaria	2004	14,799
iv) Cerebral malaria	2004	12,577
v) Certain conditions originating in the perinatal period	2004	8,282
d) Life expectancy (from birth; years)		
i) Male	2000	53.70 years
ii) Female	2000	54.80 years
iii) Total	2000	54.2 years

3. Medical care policy

Indicator	Data	Year
a) Estimated number of patients who received medical treatment on specific date (not yearly total) i) Government Hospital ii) Public Hospital iii) Private Hospital iv) Others Currently, no data is available in relation to the number of patients who receive medical treatments at different hospital settings as above.		
b) Number of hospitals by establishing organization	Year	Data
i) Government hospital	2008	23 (includes 20 provincial hospitals and 3 district hospitals)
ii) Public hospital	2008	26 (includes 23 government hospitals, 2 mission hospitals and 1other hospital.

iii) Private hospital iv) Others – Health centers - Health sub centres v) Clinics	2008 2008 2008 2008	4 (all located in Port Moresby) 196 (Govt = 142, Mission = 47. Joint G+M = 5, Others = 2) 436 (Govt = 153, Mission = 276, others = 7) 72 (Govt = 43, Mission = 14, Others 15
c) Number of health manpower The figures below for number of health manpower are current estimated figures for year 2009. i) Physicians ii) Dentists iii) Auxiliary medical personnel - Medical technologists - X-ray technician - Registered Nurses (RN) - Community Health Nurses (CN)	 2009 2009 2009 2009 2009 2009	 3182 (registered) 311 (registered) 331 (registered) 124 (registered) 9, 856 (registered) 19

- Primary Health Nurses (PHN)	2009	-
d) Number of pharmacist	2009	145 (registered, nationals = 53 whiles expatriates = 92)
e) Number of drug manufacturers/plants	2009	0
f) Number of traditional medicine manufacturers/plants	2009	0
g) Number of drug importers	2009	37 (registered)
h) Number of drug wholesalers	2009	30 (registered)

Note:

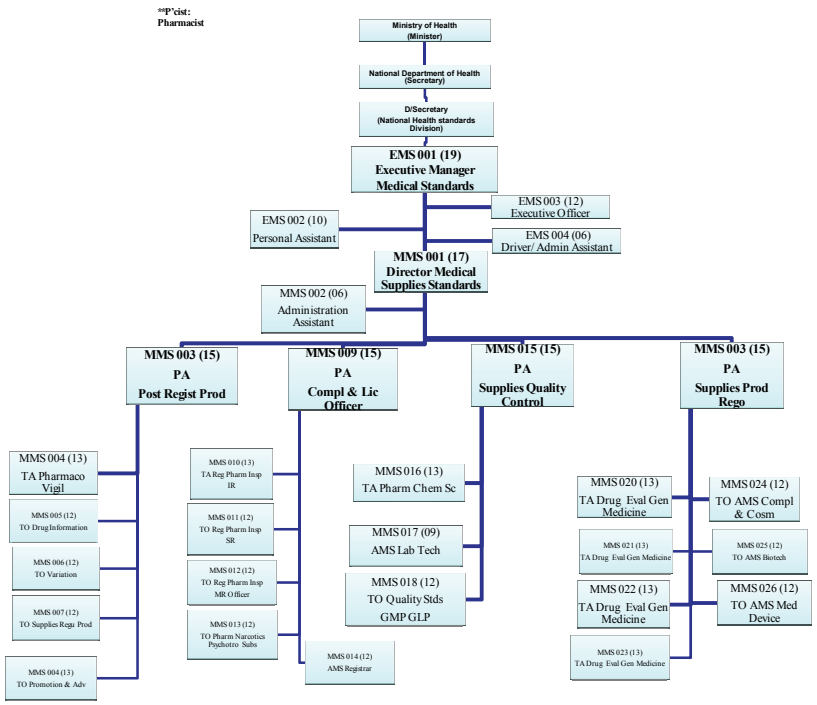
a) The total number of Pharmacists registered in 2009 is 145. Of these, only 33 are nationals while the rest (92) are Foreign Pharmacist.

b) Papua New Guinea does not produce/ manufacture drugs and other medicinal products because there are no manufacturing plants in the country. There are also no traditional medicine manufacturing plants in the country.

4. Pharmaceutical affairs administration in PNG

1) Administrative organizational chart showing PNG's pharmaceutical administration at national and local level (covering licensing, registration, quality control, production sale, import/export of drugs; and same for biologies and antibiotics)

* The Current Organizational Chart of Medical Standard Branch.



1) The role of national/ state and local pharmaceutical administrative organizations.

Medical Supplies Branch is responsible for the Procurement, Storage and Distribution of pharmaceuticals, medical supplies and equipments for all health facilities in Papua New Guinea.

It is also responsible for the preparation and implementation of legislation controlling Medicines & Cosmetics Act & Regulation, Poisons and Dangerous Substances Act and Dangerous Drugs Act; and liaison with international agencies with respect to matters, which are the responsibilities of Medical Supplies.

2) List of laws/regulation governing the pharmaceutical affairs

The pharmaceutical affairs in Papua New Guinea is governed by a list of laws and regulations (National Drug Policy, Medicine and Cosmetic Act 1999 and it's regulation 2002).

The National Drug Policy is a guiding document for legislative reforms, staff development and management improvements used to help control and regulate and the availability, quality, safety and rational use of drugs in order to improve health of the people of Papua New Guinea.

The Medicine and Cosmetic Act 1999 is the governing laws of pharmaceutical affairs in PNG while the Regulation emphasizes on the enforcement of the act in detail.

Medical Supplies Branch in consultation with the Licensing Authority approves drugs and medical supplies to be imported for both Government Health Facilities and Private Importers and Wholesalers of Pharmaceuticals in Papua New Guinea. Papua New Guinea does not have manufacturing plants or factories therefore all pharmaceuticals and medical supplies are imported from other countries. Under the provision of the Medicines and Cosmetics Act 1999 (Section 9 (1) (a)), the Licensing Authority can authorize or approve drugs to be manufactured in a particular premise if PNG has manufacturing plants in the future.

The Medical Supplies Branch under the provision of the Medicines and Cosmetics Act 1999 also regulates Pharmacists and Pharmacy Technicians, Pharmaceutical

Establishments' such as: Hospital Pharmacies, Community Pharmacies, Pharmaceutical Importers and Wholesalers, Pharmaceutical Exporters etc. in Papua New Guinea.

It is also responsible for regulating pharmaceuticals (medicines), cosmetics, devices etc. in the country. The drugs or medicines are categorized into: Prescription Only, Pharmacy Only and Over the Counter (OTC) medicines. It is also responsible for regulating cosmetics and even counterfeit drugs in the country.

The Medical Supplies Branch does not directly control and regulate 'Traditional Medicines' in the country and currently there is also no legislation in place governing Traditional Medicines in the country. However, a Policy on Traditional Medicine in PNG has been drafted, approved and printed.

Pharmaceutical Inspection and Guidance.

- Pharmacy Board of Papua New Guinea0j have appointed inspectors who inspects pharmacy outlets, pharmaceutical importers & wholesalers, exporters etc. to ensure they comply with GMP and the PNG Medicines and Cosmetics Act 1999 and its Regulation of 2002.

- In Papua New Guinea there are no drug manufacturing plants and therefore no GMP inspection is carried out. However, there is a Checklist for the inspection of premises intended to be used for pharmacy, import and wholesale, export etc. Companies normally apply for the license to operate for: Pharmacy, Import & Wholesale, and Export License etc. These checklists are used to evaluate the

premises intended for the above activities. If they meet all the standard requirements they are granted the above licenses.

- In addition, when Tender of Pharmaceuticals and medical supplies are evaluated for procurement, suppliers are asked to submit their GMP documents and other necessary documents from their manufacturers. Pharmacists use these documents to qualify or disqualify a supplier or manufacturer when they bid in tenders.

vi) Classification of Pharmaceuticals and Medicinal Products.

For example in Japan, pharmaceuticals and medicinal products are classified into three categories; medicines for ethical use, over –the –counter (OTC) drugs, and quasi-drugs. Almost all ethical medicines are listed on the National Health Insurance (NHI) price list, and are reimbursed by the NHI system.

OTC drugs are not reimbursed by the medical insurance systems. OTC drugs are defined as medicines that have a mild action and a high degree of safety if used correctly. They can be purchased directly from pharmacies or other type of licensed drugstores or outlets and used by consumers at their own discretion. OTC drugs are further roughly divided into OTC drugs and "HAICHI HANBAI" drugs (Medicines distributed directly to households). They are governed by the Pharmaceutical Affairs Law.

Most preparations of vitamins and minerals are classified as OTCs, Quasi-drugs or foodstuffs like dietary supplements and functional food products such as FOSHU (foods for specific health use) are governed by the Food Sanitation Law.

In Papua New Guinea, pharmaceuticals and medicinal products are classified into three categories: Prescription Only, Pharmacy Only and Over-the- Counter (OTC) medicines. Prescription Only Medicines are medicinal products that can only be dispensed or supplied by a pharmacist on a prescription given by a medical practitioner, dentist or veterinary surgeon; Pharmacy Only Medicines are medicinal products that can be sold or supplied without prescription issued by a medical practitioner, dentist or a veterinary surgeon, but under the supervision of a pharmacist; and Over-the-Counter Medicines are medicinal products that can generally be sold over the counter without the supervision of a pharmacist.

vii) Licensing system of factory and registration system of drug

Papua New Guinea does not manufacture drugs or any pharmaceuticals because there is no manufacturing plants or factories in the country. For this reason, there is no licensing system for factories in the country.

However, the National Department of Health has started drug registration in 2006 and has initially started with the registration of Antibiotics. Here, interested applicants for drug registration usually obtain application forms for drug registration from the medical supplies office, fill in the applications, than submit their technical documents and samples for product registration. The applications are than screened and accepted only when all

the requirements are met. Next, the technical documents (dossiers) are evaluated first internally by the internal drug registration committee comprising of allthe nine (9) pharmacist within the medical supplies branch. Onced passed by the internal drug registration committee, the dossiers than move on to be evaluated by the external committee. This external committee is made up of doctors who are experts in the medical and pharmaceutical fields both within the department of health as well as the school of medicine and health sciences. Once the technical documentations as well as samples are evaluated and seen that all the requirements are met, the products are than endorsed for registration and issuance of license by the pharmacy board..

So far the department has already received 593 antibiotics for registration from different pharmaceutical manufacturer/suppliers. From these, only 37 antibiotics have fully met all the requirements for registration and have been registered. The other therapeutic categories of drugs and cosmetics are yet to be registered. Currently there are approximately 15,000 medicinal products circulating in the country.

4) Pharmaceutical inspection including quality control check system

5) Good Manufacturing Practice (GMP)

In Papua New Guinea there are no manufacturing plants for pharmaceuticals, instruments, equipments etc. Because of that GMP is not practiced in the country, especially for drugs. PNG only import drugs and medical supplies from other drug manufacturing countries such as India, Malaysia, China etc. for its consumption. Maybe in the future when the

country has enough expertise, technologies and capital then the country can start thinking of establishing its drug manufacturing plants or factories. This is when GMP can be practiced.

6) Post Marketing Surveillance system (PMS)

As stated above, there is no Pharmaceutical Plants in Papua New Guinea therefore no manufacturing of drugs and no post marketing surveillance is done in PNG.

However, one Post Marketing Surveillance was recently done in PNG on ARCO (artemisinine 125mg + naphthoquine 50mg) tablets manufactured by Kunming Pharmaceuticals of China. ARCO was tested for its safety and efficacy, ADR etc. by Professor Francis Hombanje of the Divine Word University (PNG).

As already mentioned above Papua New Guinea does not manufacture drugs or any pharmaceuticals because there is no manufacturing plants or factories in the country. PNG only import from other drug manufacturing countries such as India, Malaysia, China etc. for its consumption

7) Sale and Distribution of drugs (ethical and OTC)

8) Additional requirements for biological (vaccines) and antibiotics such as national test system (if any)

5. Present situation and future plan (ex. National plan, introduction of GMP concept, etc.) in the national drug policy including essential drugs and traditional medicine.

A. History of the Traditional (Herbal) Medicines in Papua New Guinea (PNG).

Traditional Medicine includes medicaments prepared from plants, animals and minerals. Traditional Medicine is the total combination of knowledge and practice, whether explicable or not, used in diagnosing, preventing or eliminating a physical, mental or social disease and is based mainly on past experience and observations handed down from generation to generation, either verbally or in writing (WHO definition).

Traditional (Herbal) Medicines existed even before 'Modern Medicine' was introduced in PNG. That is, our ancestors have been practicing or using traditional medicines even before modern medicine was introduced. PNG has a lot of traditional medicinal plants, which was used by our ancestors, and some are still being used today in our rural villages and even urban areas. Currently there is no proper record of traditional medicines and the dates our ancestors invented and began using them.

Traditional or Herbal Medicine forms an important and integral part of medicinal practices in PNG. However, there is little recognition of and documentation on the commonalities, identities and uses of these plants. The national health services would benefit if this field of medicine was further explored and incorporated into the formal health care system.

Traditional medicine also includes non-medical practices, such as bone setting, spiritualism, incantations, divinations, mental therapy and baths. However, witchcraft, sorcery or related dangerous practices must not be recognized as part of traditional medicine and not incorporated into the formal health care system.

Traditional Medicine in PNG is non-codified i.e. there is no formal recognition or written text; sources of information are inaccessible and scattered; they are utilized by both Villagers and Urban dwellers. Therefore, the National Health Plan recognized that traditional healers have a role to play in the delivery of health care in PNG.

A Policy on Traditional Medicine in PNG has been drafted and is currently in the process of being printed.

B. History of the National Plan on Pharmaceutical Services in PNG.

The PNG Department of Health has for many years provided a comprehensive low cost medical service to the people of the country, particularly those in the rural area. By low cost we mean that at the time of the service the recipient pays very little, if anything, for consultation and treatment. The health system including the cost of administration, staff and medical supplies is funded under the annual budget from consolidated revenue.

The Medical Supply Branch of the National Department of Health was established after World War II to provide a comprehensive medical supply service to the entire country. In

its very early years, medical supply service based its operation on a catalogue derived from military. Through time, the catalogue grew to include a comprehensive range of generic drugs, most of which these days would be called “Essential Drugs”. PNG Department of Health is pioneer in this field as well as other areas such as Treatment Guidelines.

As early as the 1960’s, Medical Supply Branch was purchasing generic drugs on the international market, which is common place now, but revolution then. This activity elicits considerable comment from the multinational drug companies strongly opposed to the idea, and international agencies who watched the development with interest. It came to be generally regarded that PNG has, in principle, one of the most cost effective, and efficient, medical procurement and distribution system in the world.

It should be noted that not only does Medical Supply Branch now handles drugs, but also vaccines, dressings, hospital furniture and equipment, pathology and laboratory requisites, x-ray equipment and consumable and dental requirements.

However, with the growth of urbanization most of the business in the private practitioners and pharmacies now comes from Papua New Guinea nationals, not expatriate.

The demands and expectations of the general population on the health system have increased. The population is better educated, which increases expectations. Communications and roads have improved. Demands for health services have therefore increased because people have a greater awareness of the impact of health care, and the infrastructure allows easier access. Together with these factors, the population has been

increasing very rapidly since independence in September 1975, outstripping budgetary growth, adding more pressure.

There are other pressures on the health system. After independence, there was an exodus of health professionals and administrative standards. There were too few qualified people in Papua New Guinea to take over, and those could often receive poor handovers, and little experience in these position.

Political and social changes after independence were almost far reaching, and included such dramatic events as almost complete and rapid decentralization of the health system, which went hand in hand with formation of provinces had control of their own Department of Health, with the National Department providing consultancy and advisory services. Fortunately, the medical supply remained under the National Department of Health which supplies were held in check. Economies of scale were maintained, even if the administrative functions suffered.

In recent times, political events have served to further undermine the operation of Medical Supplies Services, attracting bad publicity and calls for reform. Frequent changes of Government, financial constraints and staff shortages are the main contributing factors.

It is, then fair to say that factors outside the control of Medical Supply Branch have severely impacted upon the ability of the Service to fulfill its chapter.

6. Drug supply system and drug price mechanism including local products, imported and exported drugs

Drug Distribution System.

- All drugs and medical supplies are procured from other countries such as China, India, Thailand, Malaysia etc. When the supplies arrive, they are stored in the Government's six (6) Area Medical Stores and then they are distributed to hospitals and health centres in the country. Medical supplies are also delivered to the Provincial Transit Stores and then they are further distributed to their health facilities. The Health Department has engaged a freighting company to distribute drugs and medical supplies on a timely manner to hospitals and health centres in Papua New Guinea to avoid shortage of drugs and medical supplies.

Drug Price Mechanism.

- All drugs are imported from other countries. PNG has a free market and Government does not control price of drugs.

7. Pharmacopoeia

- Does your country have its own pharmacopoeia?

- If not, what kind of pharmacopoeia do you refer to as an official pharmacopoeia?

  - Papua New Guinea does not have a Pharmacopoeia of its own. PNG uses the British Pharmacopoeia (BP), British Pharmaceutical Codex (BPC), Martindale etc. for reference purposes only.

8. List of reference

List report, materials and publications that were quoted or used as references in the information of this country report. This list of reports/materials/publications should include titles, writers, years published, publishers, and places of publication.

5. Essential Drug List.

- Papua New Guinea has the *Medical and Dental Catalogue* as the country's Essential Drug List. All items listed in the Medical and Dental Catalogue are purchased or procured by the National Department of Health for all Government and Mission Hospitals, Health Centres and Aid Posts in the country.

- The Medical and Dental Catalogue (MDC) contains approximately 2, 654 items. The MDC is divided into the following sections:

Section 1- Drugs and Medicinal Preparations: 420 items

Section 2- Dangerous Drugs: 12 items

Section 3- Serological Products: 40 items

Section 4- Dressings: 42 items

Section 5- Hospital Sundries: 490 items

Section 6- X-Ray Supplies and Equipments: 61 items

Section 7- Laboratory Supplies and Equipment: 569 items

Section 8- Minor Instruments and Equipments: 321 items

Section 9- Dental Items: 699 items.

6. Difficulties and constrains in Manufacturing Control of Essential Drugs (e.g. GMP, etc.) that you have been facing these days and clear directions in the future.

7. Current situation concerning Counterfeit and Substandard Drugs and its Countermeasures.

Currently Papua New Guinea does not have a big problem with counterfeit and substandard drugs and no counterfeit or substandard drugs have been detected yet. However, some antimalarial drugs were reported to be counterfeit or substandard so samples of all antimalarial drugs used in the country were collected from selected Area Medical Stores, hospitals and health centres in the country. These samples were sent to

Therapeutic Goods Administration (TGA) in Australia and we are still waiting for the results.

8. Overview of relationship with Overseas Assistance Organization.

The relationship with Overseas Assistance Organizations such as JICA, JICWELS, WHO etc. have helped greatly in many areas such as; human resource development, provision of equipments, provision of experts and volunteers, provision of aid, grants etc. This has also helped greatly in the financial, economic, social, health and human resource development of Papua New Guinea and other developing countries.

9. Overview of Technical Assistance Programmes in the fields of Pharmaceuticals, GMP, Quality Control organized by International Organizations, NGOs etc. including details of programmes; Programme Name/ Duration/ Organizer/ Aims/ Outline.

WHO, JICA and other International Organizations have been sponsoring and organizing workshops and training programmes in the fields of Pharmaceuticals, GMP, Quality Control etc. for developing countries and this has greatly improved their human resource

development. For example, in October 2006, I attended a training workshop organized by WHO in Manila, Philippines. The workshop was on Consultation on Financing of Essential Medicines. The workshop was organized by WHO Regional Office for the Western Pacific Region. The workshop was held from the 4th – 6th October 2006. My other colleagues also have attended similar workshops on Pharmaceuticals, Rational Drug Use, Quality Control etc., which were organized by WHO and other International Organizations. Some of the Training Programs or Workshops they attended were:

i) Training Program on Counterfeit Medicine Control and Law Enforcement.

Organized by: Therapeutic Goods Administration (TGA) in Australia.

Duration of training: 17th – 28th October 2005.

ii) Workshop on Implementation of the Regional Strategy for improving access to Essential Medicine in the Western Pacific Region held in Manila- Philippines.

Organized by: World Health Organization (WHO) Regional Office in Manila.

Duration of Workshop: 17th – 19th November 2004.

iii) Pacific Regional Workshop on Intellectual Property and access to medicines. "Appropriate National Responses". Held in Nadi, Fiji.

Organized by: Third World Network in Malaysia, WHO, UNDP and Commonwealth Secretariat.

Duration of Workshop: 19th – 21st June 2006.

10. REFERENCES

1. PNG National Department of Health- Monitoring, Research and Evaluation Branch.

2. World Health Organization.

3. Nursing Council of Papua New Guinea.

4. Medical Board of Papua New Guinea.

5. University of Papua New Guinea- School of Medicine and Health Sciences.

6. PNG National Department of Health- Medical Supplies Branch.

The Study Programme

for the Pharmaceutical Affairs Experts

Philippines

COUNTRY REPORT

STUDY PROGRAMME

FOR

PHARMACEUTICAL AFFAIRS EXPERTS

SUBMITTED:

SHARON ROSE P. GARCIA, MSc

Food Drug Regulation Officer III

DEPARTMENT OF HEALTH

Center for Health Development - Zamboanga Peninsula

Upper Calarian, Zamboanga City

PHILIPPINES

THE PHILIPPINES

1. Geographical and political featuresI

The Philippines is a tropical country of 7,100 islands lying in the Pacific Ocean off the coast of Southeast Asia. The islands have a total land area of 300,000 square kilometers. The two largest islands are Luzon in the north and Mindanao in the south. Between these islands lies a group of small to medium-sized islands called the Visayas. Manila is the capital city. Metropolitan Manila, which is made up of 12 cities and five municipalities, is the biggest urban center in the country.

The country is mountainous with narrow strips of lowland along the coast and some broad inland plains. Tropical forests used to cover most of the Philippines, but very large areas are now devoid of forest leading to soil erosion and flash floods. The country has an extensive coastline and many fine bays and harbors. A wide variety of tropical plants and animals can be found in its mountains, rivers and lakes and along its coastal areas. Except for a few plants, the medicinal values of this flora remain to be fully tapped.

Philippines, due to its population as of 2004 of 82,636,689, make one of the world's most populous countries. The population density is 249 people per square kilometer, but this is unevenly distributed throughout the islands.

The Philippines is the only predominantly Christian country in Asia. The majority of Filipinos are Roman Catholics. There are at least 110 ethno linguistic groups. The indigenous peoples account for about 18 percent (13 million) of the population. Most Filipinos are bilingual, speaking both English and Filipino or any of the other local languages. The presence of a well-established educational system accounts for the high functional literacy rate of 83.3 percent. In urban areas, where the people have easier access to educational facilities, including mass media, the functional literacy rate is higher compared to in rural areas.

Although the functional literacy rate is high, folk beliefs, misconceptions and practices detrimental to health are still rampant. Socio-cultural barriers to health are prevalent and more apparent in indigenous communities.

The family is the basic unit of the Filipino society. It is usual to find extended families where the members include not just the husband, wife and their children but also grandparents, parents, siblings and other relatives. Families are close knit, strongly influenced by tradition and have a sense of loyalty to family and the community. Special events like the births of a certain child and deaths as well and religious affairs like fiestas bring families together. The family support systems are very strong, especially in times of need.

Under the Constitution, the Philippines are a democratic and republican state with three branches of government (executive, legislative and judicial). The executive power is vested in the President who is elected directly by the people. The President is also the head of the state and commander-in-chief of the armed forces. The Cabinet members assist the President in executing laws, policies and programs of the government.

The local government units (LGUs) comprise the political subdivision of the Philippines. These are made up of 78 provinces headed by governors, 82 cities and 1,525 municipalities headed by mayors and 41,939 barangays or villages headed by barangay chairmen. LGUs are granted local autonomy under the Constitution. Legislative power in these LGUs is vested in their respective local councils. The country is also divided into 16 administrative regions. One is the Autonomous Region for Muslim Mindanao (ARMM) headed by a governor. In other regions, offices of national agencies are under the respective regional directors. The Bureau of Food and Drugs in Alabang, Muntinlupa, represents the main office where overall management, direction, supervision, and control over the Bureau stands. On the other hand, the regional offices also have BFAD section headed by the regional health directors. Although all the licenses underwent final evaluation in terms of documentary requirements still it has to be indorsed by the regional health directors.

The economy traditionally depends on agriculture, forestry, mining and fishing. One of the thrusts of the administration is to strengthen agricultural production to attain food security. This will positively affect the health and nutrition of the Filipinos.

The economic growth is partly due to the deployment in other countries of Filipino workers. This sector, the overseas Filipino workers, has greatly helped the Philippine economy. Their health as well as that of their families needs to be addressed. The leading imports include machinery, equipment, petroleum, chemicals and raw and semi-processed materials. The major trading partners of the Philippines are United States, Japan, the European community and the ASEAN neighbors. The country still depends on imported health care products like drugs, vaccines, equipment and medical supplies.

DEPARTMENT OF HEALTH
REPUBLIC OF THE PHILIPPINES

Vision: The leader of health for all in the Philippines.

Mission: Guarantee equitable, sustainable and quality health for all Filipinos, especially the poor, and to lead the quest for excellence in health.

The Bureau of Food and Drugs

VISION: The Bureau of Food and Drugs is an internationally recognized center of regulatory excellence safeguarding the health of Filipinos. .

MISSION: To protect public health and ensure the safety, efficacy, purity, and quality of all the products it regulates through the effective and efficient implementation of national policies consistent with international best practices.

HISTORICAL BACKGROUND

The origin of the Food and Drug Administration ((FDA), Now the Bureau of Food and Drugs (BFAD) can be traced to the year 1947, the following year after the Philippine Independence.

By virtue of Executive Order No. 94 s. 1974, the Drug Inspection Division and the Division of Laboratories of the Department of Health (DOH) were created. The division of Laboratories was later transformed into an Office of Public Health Research Laboratories (PHRL) by virtue of Executive Order No. 392 s. 1950.

PHRL was composed of various divisions dealing with national disease problems like malaria, venereal diseases and schistosomiasis and Central (manila) and Regional Health Laboratories for food and Drug, water and soft drinks.
In 1958, after a series of reorganization, PHRL was abolished and its place was created the Bureau of Food and Drug Testing.

In 1961-1962, in the light of the tremendous progress in the food and pharmaceutical industry, the late Department of Health (DOH) Secretary Francisco Duque, Sr. created a Subcommittee on Food and Drugs to initiate an administration bill to Congress to enact a law that would ensure the safety, purity and quality of foods, drugs and cosmetics being made available to the public. The Subcommittee was chaired by the then Undersecretary for special Health Services, Dr Rodolfo Canos. Thus, on June 22, 1963, Republic Act No. 3720 was passed into law known as the "food, Drug and Cosmetic Act." To carry out the provision of R.A. 3720, the food and Drug Administration (FDA) was created and offices and laboratories were constructed in the DOH San Lazaro Compound, Sta. Cruz, Manila. The Food and Drug Administration became operational with the President of its first FDA Administrator, Ms. Luzonica M. Pesigan and Deputy Administrator, Mr. Emilio Espinosa . By the virtue of R.A 3720, the powers, functions and duties of the Division of Food and Drug Testing of the Bureau of Research and Laboratories (BRL) engaged in food and Drug control together with all their equipment, supplies, records, files, and balance of appropriations were transferred to the FDA.

With the Integrated Reorganization Plan of 1973, the Narcotics Division of the Bureau of Internal Revenue, Department of Finance, was transferred to the FDA, Department of Health as one of its Divisions.

In 1982, Executive Order No. 851 abolished the FDA and created the Bureau of Food and Drugs (BFAD). Ms. Catalina C. Sanchez was appointed the first Director of the BFAD. In 1987, the Bureau moved to its new site in Alabang, Muntinlupa City and acquired new facilities including state-of-the-art analytical instruments and a modern experimental animal laboratory with the $12M grant from the Government of Japan International Cooperation Agency (JICA). This new BFAD in Alabang became operational on April 30, 1987. In 1987, RA 3720 was amended by Executive Order 175 to the new title "Foods, Drugs and Devices and Cosmetics Act."

On the retirement of Mrs. Sanches, Dr. Cecile P. Gonzales (February 01, 1989-January 31, 1991) took over, followed by Dr. Quintin l. Kintanar (March 13, 1991-January 4, 1999); Dr. William D. Torres (January 5, 1999-August 31, 2002), with the Deputy Director for Drugs, Dr. Kenneth Hartigan-Go (June 1, 1999-June 10, 2001) and the lateral transfer of Mrs. Adelisa C. Ramos, Director III of the DOH Nutrition Service as Deputy Director for Food (November 6, 2000- present). On September 1, 2002, **Professor Leticia Barbara B. Gutierrez** was appointed Director of the Bureau until 15 June 2009. Currently BFAD is headed by Acting Director **NAZARITA T. TACANDONG**. BFAD is now renamed as FOOD AND DRUG ADMINISTRATION by virtue of Republic Act 9711. The crafting of the implementing rules and regulations is in progress.

2. STATISTICAL DATA

HEALTH INDICATOR

Indicator	Year	Data
1. Area (in 1000 sq. Km)	2005	300,00sq. Km
2. Estimated Population*	2005	
Male : 42,401,391		
Female : 41,839950		
Both Sexes : 84,241,341		
3. Annual Population Growth Rate	2000-2005	2.32%
4. Percentage of Population		
- less than 15 years old	2004	38%
- over 65 years old	2004	3.5%
5. Urban Population	2001	44,734,419.72
6. Rate of Natural Increase of population (%)	2000-2005	4.3%
7. Crude birth rate (per 1000 population)*	1995	24.09
8. Crude Death rate (per 1000 population)*	1995	5.66
9. Life expectancy at birth (years)*	1995	
- Total		
- Male		67.83 years
- Female		73.08 years
10. Infant mortality rate (per 1000 live births)	2000	15.7
11. Maternal mortality rate (per 1000 live births)	2000	1.0
12. Child mortality rate under 5 years old	2000	15.7
13. Percentage	2002	
- Urban area		94%
- Rural area		83.2%

Sources:

*N. 2, 7-9 : 1995 Census-Based National and Regional Population Projection**

10-11 : 2005 Philippine Health Statistics

Indicators	Data	
14. Five main diseases causing morbidity	No. of cases (2003)	Rate/100,00
• Acute Lower Respiratory Tract Infection & Pneumonia	674,386	861.2
• Diarrhea	615,692	786.2
• Bronchitis/Bronchiolitis	604,107	771.4
• Influenza	431,216	550.6
• Hypertension	325,390	415.5
15. Five leading causes of morbidity	No. of cases (2002)	Rate/100,00
• Diseases of the Heart	60,417	79.1
• Diseases of the Vascular System	48,271	63.2
• Malignant Neoplasm	36,414	47.7
• Pneumonia	32,637	42.7
• Accidents	32,355	42.4

B. Medical Care

1. Number of Hospitals (in 2003 or the year in which the latest data is available)

		Number
- Number of Government Hospitals	(2004)	694
- Number of Public Hospitals	(2004)	421
- Number of Private Hospitals	(2004)	1450
- Clinics	(2004)	483
- Health Centre	(2004)	RHU: 41,458

2. Number of Health Manpower (With 3- year interval towards the year in which the latest data is available)

- Physician (year)	***Number***
1997	***1876***
2000	***2174***
2004	***2983***

- Pharmacist (year)	***Number***
1997	***1447***
2000	***1622***
2004	***1769***

- Dentists (year)	***Number***
1997	***1571***
2000	***1052***
2004	***1235***

- Nurses (years)	***Number***
1997	***11,693***
2000	***5784***
2004	***9471***

- Midwives (year)	***Number***
1997	***4018***
2000	***1738***
2004	***1258***

- (Licensed) Pharmaceutical Manufacturers (years)	***Number***
1997	***249***
2000	***225***
2004	***238***

- (Licensed) Traditional Medicine Manufacturers (year)	***Number***
1997	***No data available***
2000	***10***
2004	***17***

- (Licensed) Drug Importer (year)	***Number***
1997	***291***
2000	***392***
2004	***402***

- (Licensed) Wholesalers (year)	***Number***
1997	***1127***
2000	***1773***
2004	***2562***

- Pharmacy/ies (year)	***Number***
1997	***1345***
2000	***1670***
2004	***1053***

- Drugs Stores (other than pharmacies) (year)	***Number***
1997	***9545***
2000	***12,329***
2004	***17,402***

- Prescription Items Registered (year)	***Number***
1997	*No data available*
2000	***8035***
2004	***15629***

- OTC Products Registered (year)	***Number***
1997	*No data available*
2000	***8035***
2004	***3674***

- Traditional Medicines Registered (year)	***Number***
1997	*No available data*
2000	**12**
2004	**30**

- Cosmetics Registered (year)	***Number***
1997	*No data available*
2000	**6094**
2004	**7951**

C. Educational Information for Pharmacist in your country

a) System of Education

Primary School	:	4 years system
Age at enrollment	:	7 years old
Secondary School	:	2 years system
High School	:	4 years system

b) System of university or college education (Age at graduation: 21 years old)

University or college years	:	4-5 years
Professional education	:	4 years
Practical Training	:	30 weeks
Duration of Training by each facility	:	5 weeks
Hospital Pharmacy	:	5 weeks
Pharmacy	:	5 weeks
Pharmaceutical Company	:	5 weeks
Others	:	- weeks

c) National examination system for pharmacist in your country

Academic Exams	:	2 days
Clinical Exams	:	N/A days

None

d) Requirement to obtain pharmacist's License

d) - 1 must be a graduate of Bachelor of Science major in pharmacy

d) - 2 passed the examination given by the Professional Regulation Commission

d) - 3 must be 21 years of age

e) Graduates number of Pharmaceutical university or college: Average of 1,500/year

f) Percentage of the alumni's progressive (as of: 2002)

Hospital	25%
Community Pharmacy	55%
Government Organization	10%
Enterprise	5%
Others (Academe)	5%

3. HISTORICAL DEVELOPMENT OF PHARMACEUTICAL SERVICES

A. HISTORY OF THE TRADITIONAL (HERBAL) MEDICINES IN THE PHILIPPINES

For the DOH-BFAD, regulations as to the registration of Herbal and/0r Traditional drugs both local and imported are strictly implemented. All these herbal and/or traditional drugs are presently recognized in the Philippine National Drug Formulary. Moreover, the registration of herbal and/or traditional drugs is required to be supported by pharmaceutical data's, pharmacologic documentation, and quality control specifications as determined by BFAD.

The Philippine government through the Department of Health has created the Philippine Institute of Traditional and Alternative Health Care, an institution which will promote the development traditional alternative system of medicine which can offer safe, effective health care that is accessible, affordable and acceptable to the majority of the Filipinos. At present, BFAD has recognized the ten Medicinal Plants since November 14, 1992 during the leadership of Dr. Juan M. Flavier. The ten medicinal plants Lagundi (5 leave Chaste tree), Yerba Buena (Peppermint), Sambong Blumea Camphor), Tsaang Gubat (A shrub), Ulasimang Bato (Peperomia pellucida-a wild fruit in the Philippines), Bawang (Garlic), Niyug-niyogan (Burma creeper), Bayabas (Guava), Akapulko (Ringworm bush of shrub), and Ampalaya (Bitter Gourd).

B. HISTORY OF THE NATIONAL PLAN ON PHARMACEUTICAL SERVICES

The formulation of National drug Policy (NDP) was the product of a long process of consultations and deliberations that came out in response to a felt need which was conveyed to the government by people from various sectors of society.

On April 30, 1987, during the inauguration of the Bureau of Food and drugs in Alabang, muntinlupa, the former President Corazon C. Aquino announced the birth of the NDP and the government's commitment to its implementation of Philippine national drug policy (PNDP).

It was on September 13, 1988 when the Republic Act 6675, otherwise known as the Generics Act of 1988, was passed in congress and enacted into law. When the Philippine National Drug policy (PNDP) Program, was formulated in 1987, the Generics Law served as its legislative framework for implementation.

It was in 1993 that the Philippine-Australian National Drug Policy Cooperation project was formerly launched.

The people's need to have essential drugs that are safe, efficacious and of good quality at reasonable and affordable cost with emphasis on rational drug use is the core of the PNDP.

At present, the PNDP Program is set on five pillars with its main concern is to bring about the availability and affordability of safe, effective and good quality drugs for all sectors of the country especially for the poor who need them the most, but who can least afford them. These five pillars with an acronym, P Q R S T, form an integral unit, mutually complimentary and supportive of each other.

The ***first pillar is people empowerment.*** The main goal is to assist people exercise an informed choice in the market place concerning purchase of cost-effective medicine. Today, many public hospitals run out of drugs. People buy medicine in their own pockets.

The ***second pillar emphasizes on quality assurance.*** This involves the assurance of drug quality, safety and efficacy. Since then, Philippines have in battle to the proliferation of sub-standard products and drugs of unknown quality and dubious quality.

The ***third is the rational drug use.*** To provide accurate and objective information on health promotion and disease prevention and management that will guide health providers and consumers on the proper use of medicines.

Fourth pillar is the strengthening of self reliance wherein it aims to promote self reliance in local production of certain strategic essential products and drugs. There is continued domination of foreign drug companies.

The ***last pillar tackled on tailored procurement***. To assure cost-effective drug procurement and supply for DOH and other government agencies. Philippines aim on the efficiency of government procurement as well as compliance of the national and local government with the NDP.

Executive Order No. 851 was superseded by Executive Order No. 119, s. 1987 that again reorganized the Bureau of Food and Drugs (BFAD) on the basis of Administrative Order(A.O.) No. 30 1987, Provisions to Implement the Reorganization of the Department of Health."

The functions and operations of the Department of Health. BFAD was expanded with an added Division, the Policy, Planning, and Advocacy Division. He joining of the National Drug Policy workforce with that of BFAD further strengthened the Bureau to meet new challenges in serving the interest of the Filipino people consistent with the Philippine National Drug Policy and the National Health Policy.

In the joint effort also of the regional BFAD offices, DOH believes that the NDP can help our people. Its main concern now is to concentrate on the internal strengths to overcome difficulties and realize the DOH main goal-to serve the people.

C. History of GMP

As defined by WHO, Good Manufacturing Practice is the part of quality assurance which ensures that products are consistently produced and controlled to the quality assurance standards appropriate to their intended use and as required by marketing authorization or product specification. With the development of the quality control technology, it has been encouraged that the quality be incorporated during the manufacturing process. In this regard, the WHO has recommended to its entire member that GMP be implemented in every country since 1969.

In 1974, the Philippines have formulated its own version of good Manufacturing Practice with an Administrative Order No. 220 s. 1974. This order prescribes the conditions and requirements for good manufacturing practice, which applied to buildings and facilities, equipment, personnel and documentation.

In 1999, pursuant to the provisions of RA 3720 otherwise known as foods, Drugs, Devices and Cosmetics Act, as amended and in consonance with the development in science, Technology, industry and public health interest, Administrative Order No. 220 s. 1974, Current Good Manufacturing Practice was amended with the adoption and implementation of Administrative Order No. 43-A s. 1999 otherwise known as Current Good Manufacturing Practice Guidelines for Drugs.

In 2002, Administrative Order No. s. 2002 otherwise known as Current Good Manufacturing Practice Guidelines for Cosmetics Products was also adopted for implementation.

The Bureau of Food and Drugs (BFAD) is the regulatory agency responsible for ensuring licensed pharmaceutical and cosmetic establishment meet the GMP requirement to assure good quality. For the bureau to continue implementing GMP guidelines several trainings abroad has been an opportunity for our regulatory chiefs. Regional meeting of GMP experts in the pharmaceutical sector was conducted in Hanoi last December 2004. The main concern is on the legislative framework. Assessing the said legislative framework and why there is a need to assess has been given emphasis.

The past months, BFAD regulatory chiefs and other food and drug regulatory officers have attended PIC/S Training in other countries in the interest of the Bureau to join the Pharmaceutical Inspection Convention (PIC). PIC/S is the abbreviation and logo used to describe both the Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) operating together in parallel. The need to form the PIC Scheme became necessary when it was realised that an incompatibility between PIC and European law did not permit individual EU countries that were members of PIC to sign

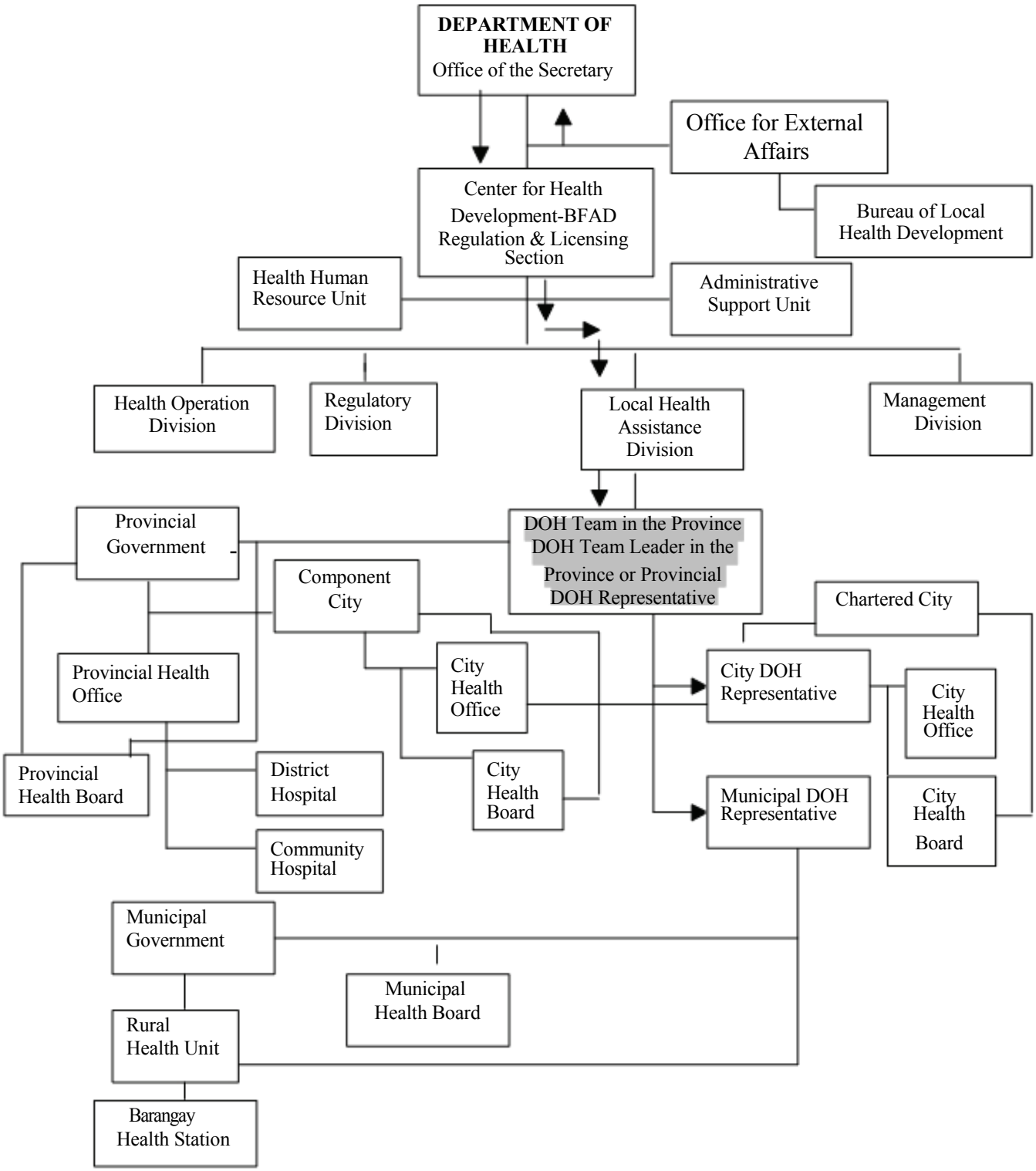
agreements with other countries seeking to join PIC. Only the European Commission was permitted to sign agreements with countries outside Europe, and the Commission itself was not a member of PIC.

PIC and the PIC Scheme, operating together as PIC/S, provide an active and constructive co-operation in the field of GMP (Good Manufacturing Practice). The purpose of PIC/S is to facilitate the networking between participating authorities and the maintenance of mutual confidence, the exchange of information and experience in the field of GMP and related areas, and the mutual training of GMP inspectors. Fortunately, Philippines are among the eight countries that shows interest in joining. As to date, the BFAD is currently on the process of formulating, drafting and soon to final Quality of System Manual for GMP inspectorates not only for the BFAD main but also that of the regional BFAD offices.

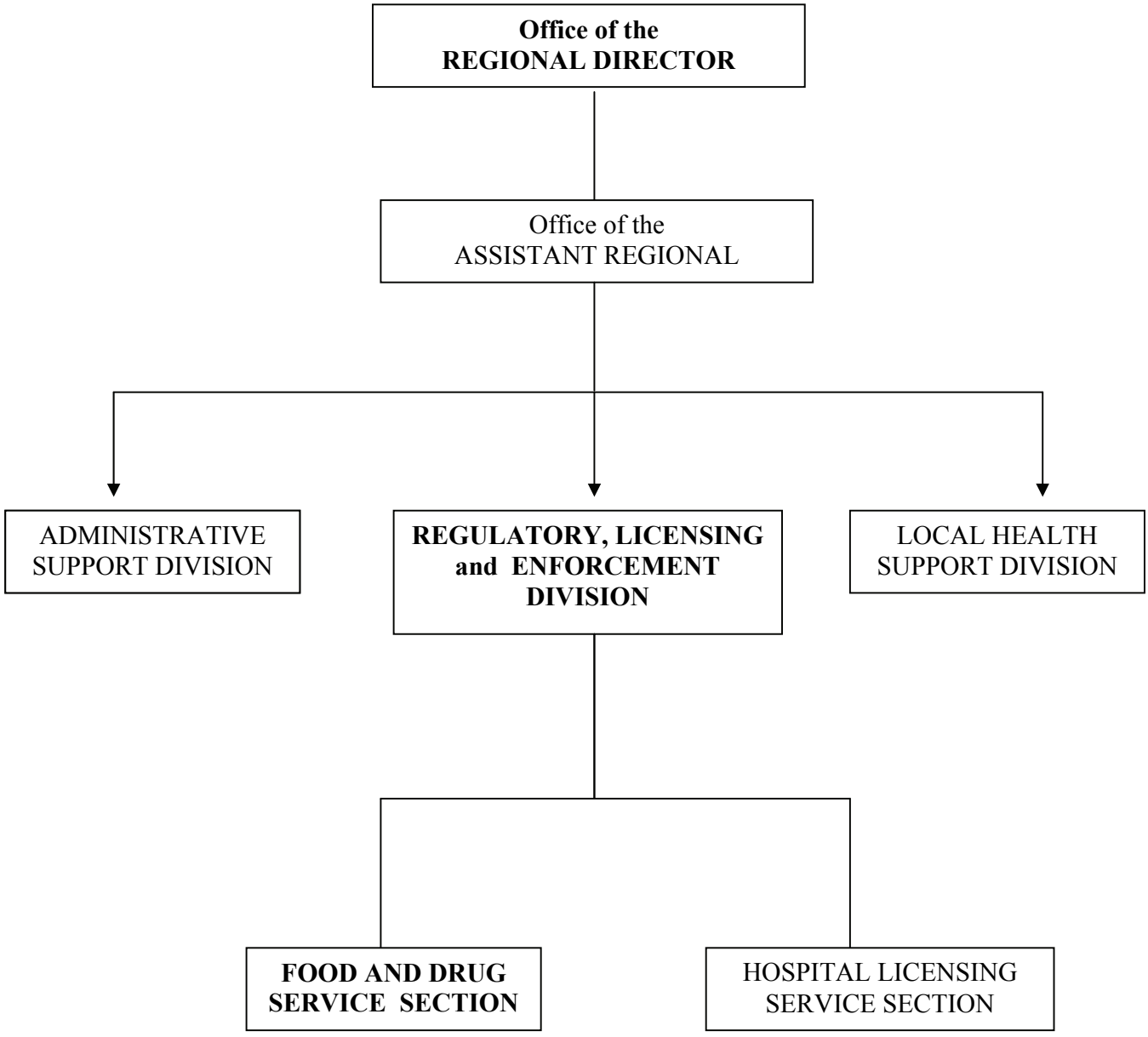
The food and drug regulation officers in the region have taken part in acquiring the necessary expertise to monitor the covered establishments being licensed by BFAD. Joint inspection from the main and regional level is on-going. Comprehensive audit inspection within the regional FDROs is likewise being strengthened thru full involvement of the entire regional health office. Additional FDRO's is also one of the thrusts of the regional directors to be able to assess and monitor GMP compliance to all drugs manufacturing and the like.

4. PHARMACEUTICAL AFFAIRS ADMINISTRATION

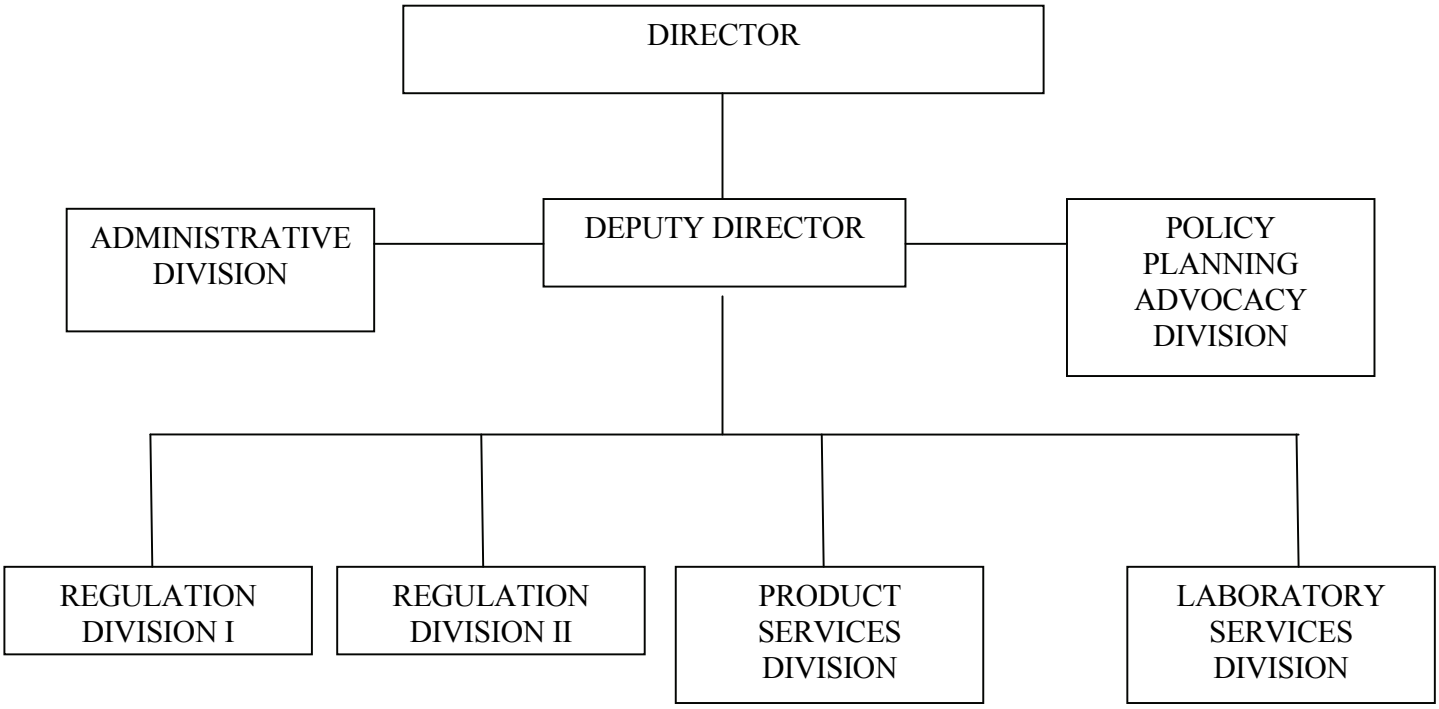
1) A. Flow of Authority from the DOH to the Lowest Level of Health Units



DEPARTMENT OF HEALTH
CENTER FOR HEALTH DEVELOPMENT



B. BFAD ORGANIZATIONAL CHART



- ***RA 9711 (Food and Drug Administration Act of 2009) approved on 18 August 2009 strengthens BFAD.***

LEGAL BASES FOR REGULATIONS:

1987 Philippine constitution, Section 12, Article XIII:

"The State shall establish and maintain an effective food and drug regulatory system"

Republic Acts

- R.A. 3720 (1963) -Food , Drug and Cosmetic Act later amended by EO175 otherwise known as Foods, Drugs, Devices and Cosmetic Act
- R.A.6675 (1988) - Generics Act
- R.A.7394 (1992) - Consumer Act
- R.A. 9165 (2002)- Comprehensive Dangerous Drugs Act which superseded R.A. 6425 Dangerous Drugs Act of 1972
- R.A. 8203 (1996) - Special Law on Counterfeit Drugs
- R.A. 5921 (1951) - Pharmacy Act as amended by E.O. 174 s. 1987
- P.D. 881 (1976) - Household Hazardous Substances Decree
- R.A. 7581 (1992) - An Act Promoting Salt Iodization Nationwide and for Related Purposes (ASIN Law)
- R.A. 8976 (2000) - An Act establishing Food Fortification Program and for other Purposes (Food Fortification Law)

- R.A. 7432 (1993) - Senior Citizens Act
- E.O. 51 (1986) - Philippine Milk Code of Marketing of Breast Milk Substitute (milk Code)
- E.O. 302 (2004) - Declaring and Adopting the Philippine Pharmacopoeia as the Official Book of Standards and Reference for Pharmaceutical products and Crude Plant Drugs in the Philippines.
- AO 153 s. 2004 cGMP on Food - Guidelines on the operation of Food Manufacturers
- AO 152 s. 2004 Prescribing Regulations for Irradiated Food
- AO -Guidelines on the Registration of Herbal Food Products & Herbal Dietary Supplements (B0 142-A s.2005)

2) The Role of National / State and Local Pharmaceutical Administrative Organizations.

- Develops plans, programs, and strategies for regulating processed foods, drugs, medical devises, cosmetics, in vitro diagnostic reagents and household hazardous substances.
- Formulates rules, regulation and standards for licensing and accreditation of processed foods, drugs, medical devices, cosmetics, in vitro diagnostic reagents and household hazardous substances.
- Conduct licensing and accreditation of processed food, drugs and other related products.
- Provides technical, consultation and advisory services and develops capability of field offices on licensing and enforcement of laws, rules and regulations pertaining to processed foods, drugs and other related products.
- Monitors, evaluates and ensures compliance of manufacturer, distributors, advertisers and retailer of processed foods, drugs and other related products with health rules and regulations and standards of quality.
- Advises the Secretary and the Undersecretary of Health on matters pertaining to regulation of processed foods, drugs and other related products.
- The regional health offices shall be responsible for the field operations of the department and for providing efficient and effective health and medical services through its supervision and control of all Department agencies located in the region.

- The Provincial Health Office, located in each of the province of the country, shall exercise supervision and control over district health offices, municipal hospitals, medicare hospitals, and other Department agencies in the province except those otherwise placed under the Department proper or directly under the Regional Health Office which is now known as the Center For Health Development.

3) CLASSIFICATION OF REGULATIONS

3.1 PRODUCT REGULATIONS

- **Republic Act No. 3720:** Food, Drug and Cosmetic Act later amended by EO 175 otherwise known as Foods, Drugs and Devices and Cosmetics Act - an act ensure the safety, and purity foods and cosmetics and the purity, safety, efficacy and quality of drugs and devices being made available to the public vesting the bureau of Food and Drugs with authority to administer and enforce the laws pertaining thereto, and for other purposes.

- **Republic Act No. 8203**: The Special Law Counterfeit Drugs- it is the policy of the state to protect and promote the right to health of the people and still health consciousness among them. It further declared the policy of the state that in order to safeguard the health of the people, the State shall provide for their protection against counterfeit drugs.

- **Republic act No. 6675:** Generics Act of 1988- it is an act to promote, require and ensure the production of an adequate supply, distribution, use and acceptance of drugs and medicines identified by their generics names.

3.2 PROFESSIONAL REGULATION

- Republic Act No. 5921: Pharmacy Law- an act regulating the practice of pharmacy and setting standard of pharmaceutical education in the Philippines and other purposes.

3.3 HEALTH PROMOTIONS AND REGULATIONS

- Health Establishments and Regulations

- **Republic act 4426-** an act requiring the licensure of all hospitals in the Philippines and authorizing the Bureau of Licensing and Regulations.

- **Administrative Order 55**-(for laboratory clinics) - revised rules and regulation in the licensing of laboratory performing HIV testing. The licensure of laboratory clinic is done by the bureau of Research and Laboratory.

- **Administrative Order 56 s. 1989**- Licensing requirements for securing BFAD license to operate.

- **Administrative Order No. 43-A s. 1999**- and amendment of A.O. 220 s. 1974, Current Good Manufacturing Practice. With the development in the science and technology, industry and public health interest, the current Good Manufacturing Practice Guidelines for Drugs was adopted and implemented.

- **Administrative Order No. 90 s. 2002**: Current Good Manufacturing Practice Guidelines for Cosmetics Products- lenient guidelines for cosmetics as compared with A.O. 43-A s. 1999.

- TRADITIONAL MEDICINES

- **Republic Act 8423** - an act creating the Philippine Institute of Traditional Medicine and Alternative Health Care to accelerate the developments of traditional and alternative health care in the Philippines.
- **Administrative Order 12 s. 1993**- Traditional Medicine Program for Promotion and development of traditional medicines that has been found safe and effective.

- HEALTH ECONOMICS

- Section 2.3 BFAD Regulation No. 5 s. 1987 and A.O 65 s. 1989 - No Pharmaceutical product classified by BFAD as a Prescription or Ethical Drug shall be advertised or promoted in any form of mass media except through medical journals, publications and/or literature solely intended for medical and allied professions.

- Article 116 of Republic Act No. 7394 or the Consumer Act of the Philippines - xxx. That any sales promotion campaign using medical prescriptions in any part thereof or attachment thereto for raffles or a promise of reward shall not be allowed, nor permit be issued thereof.

- Section 4 of BFAD Regulation No. 5 s. 1989 - Press releases, editorials, health columns and features and public service announcements on health and medicines shall not specify brand/trade names. Generic names are, however, permissible. For prescriptios drugs, it should be clearly stated that this product can be bought only with a prescription and a doctor's advise shall be sought.

- A.O 119 of s. 2000 (item no.1) - Consistent with the rational drug use policy, the promotion of OTC drug to the public will only be allowed if its known adverse effects are also cited. Moreover, it is the intention of RA 6675 or the Generic Acts of 1988, to promote drug safety by minimizing duplication medications and/or use of drugs with potentially adverse drug interactions.

3.4 RESEARCH AND INDUSTRIAL DEVELOPMENT

The DOH work hand in hand with the academe, pharmaceutical industries, private sectors and other government agency as PCHRD (Philippine Council for Health Research and Development) for the research and development of drugs such as herbal medicines. PCHRD will recommend to the Department of Budget deserving health research and development proposal for government funding.

3.5 EDUCATIONAL DEVELOPMENT

- **Pharmacy Education**

The practice of pharmacy in the Philippines began only after the arrival of the Spaniards in 1521. The official pharmacy started in 1871 at the University of Santo Tomas with a five-year curriculum. In 1899, the course had ceased and in 1901it has resumed and the curriculum was reduced to four years. In 1954, the curriculum was developed to five years and finally in 1984 the degree in science in Pharmacy was reduced again to fours years due to the integration of some subjects. To date, there are about 24 colleges offering this course.

4) MANUFACTURING (IMPORT) APPROVAL OF DRUGS, ETC.

The manufacturing (import) approval of drugs is one of the responsibilities of the Bureau Of Food and drugs. Establishments engaged in the manufacture and distribution of drugs shall first secure a license to operate (LTO) from the Bureau's Regulation Division I for importer/distributor and Regulation Division II for Manufacturers. Food Drug Regulation Officers will conduct inspection on establishment applying for a license. If the establishment complies with the licensing requirements, a license to operate will be issued.

Since unregistered products are not allowed in the Philippine market, this must be registered first with the Bureau's Product Service Division. Applicants are advice to submit an application for registration and other supporting documents for preliminary evaluation and representatives samples for laboratory analysis. (Note: Routine/random sampling is also conducted by GMP Auditors during their visit to the manufacturing facilities aside from the samples summated by the applicants). After collation of results, if it passes the analysis, BFAD will issue a Certificate of Product Registration (CPR).

Last 2001, President Gloria Macapagal Arroyo pledge to reduce the cost of essential drugs by at least 50%. The Department of Health has organized the GMA-50 Project to spearhead the achievement of this objective. In partnership with the Department of Trade and Industry (DTI) procured essential drugs through the Parallel drug importation program. The said imported drugs were registered with BFAD.

5) PHARMACEUTICAL INSPECTION AND GUIDANCE

In the Philippines, there are about 119 drug inspectors stationed all over the country. There are 40 inspectors (particularly on drugs) from the National Capital Region (main office) and 128 inspectors detailed in the different regions. In the National Capital Region, drug inspectors are divided into two (2) divisions:

Regulation Division I- drug inspectors are responsible for the inspection of drugstores, nonprescription drug outlets, Chinese drugstores, hospital pharmacies and distributors (importer/exporter, wholesaler) of food, drug, cosmetics, medical device and household hazardous substances.

Regulation Division II- drug inspector are responsible for the inspection of establishments that deals with the manufacture and repacking of drug, cosmetic, medical device and household hazardous substance, moreover, traders are also under the jurisdiction of the Regulation Division II.

The regional health offices have their own regulation, licensing and enforcement division where the Food and Drug Services Section belongs, implementing BFAD rules and regulation.

The Food and Drug Services Section of the DOH Regional Offices is technically under the supervision of the BFAD Central Office. The regional offices then have extension offices in the provinces. The regional offices and extensions offices are handled by Food Drug Regulation Officers (FDROs). The provincial FDROs conduct inspection/licensing of regulated establishments (drug manufacturers, drug distributors, retail drugstores, hospital pharmacies and food manufacturers) and monitoring of health products to ensure quality, efficacy and safety.

Inspectors under the Bureau of Food and Drugs are all government officials and are mostly pharmacists except for the food inspectors.

FDROs conduct an on the spot inspection on all licensed establishments and for establishments applying for a license. Based on the actual inspection, if the establishment is non-compliant to BFAD rules and regulations, the establishments are not recommended for the issuance of BFAD license to operate and not to distribute the products in the market. The company are required to submit a commitment letter with time frame for their compliance to the deficiencies noted. Once deficiencies are complied, follow-up inspection is made and a license can then be issued (for opening) or renewed (for old applicants).

6) PHARMACEUTICAL INSPECTION AND GMP

The Bureau of Food and Drugs is the regulatory agency under the Department of Health responsible for ensuring that the products distributed in the market by licensed establishments met the basic GMP requirements based on A.O. 43 S. 1999, Current Good Manufacturing Practice Guidelines for Drugs.

6.1 List of GMP Inspection and Guidance:

- Administrative Order No. 43 s. 1999 - Current Good Manufacturing Practice Guidelines for Drugs
- Administrative Order No. 90 s. 2002 - Current Good Manufacturing Practice Guidelines for Cosmetics
- Administrative Order No. 153 s. 2004 - Revised Guidelines for Current Good Manufacturing Practice in Manufacturing, Packing, Repacking, or Holding Food.

7) POST MARKETING SURVEILLANCE (PMS)

One of the functions of the Bureau of Food and Drugs is Post Marketing Surveillance (PMS). PMS is a close observation of drug effects, whether beneficial or adverse, following the marketing of a drug. The Bureau ensures that all product marketed are regulated by the agency and conforms to its standards and specification. One way of surveillance is by routine sampling of products in the market and during the actual manufacture or at the company's finished goods warehouse. This is done during the inspection. Samples are taken to the laboratory for testing; appropriate action is advised by the Legal Division depending on the result of analysis.

QUALITY CONTORL SYSTEM OF DRUGS AND COSMETICS
"QUALITY ASSURANCE LOOP"
Safety, Efficacy, Qualit

Assuring the quality of drugs and cosmetics is a continuous process and is not limited to one (1) division of the Bureau of Food and Drugs.

The Licensing Division assures of the establishment to GMP, GLP and GSP.

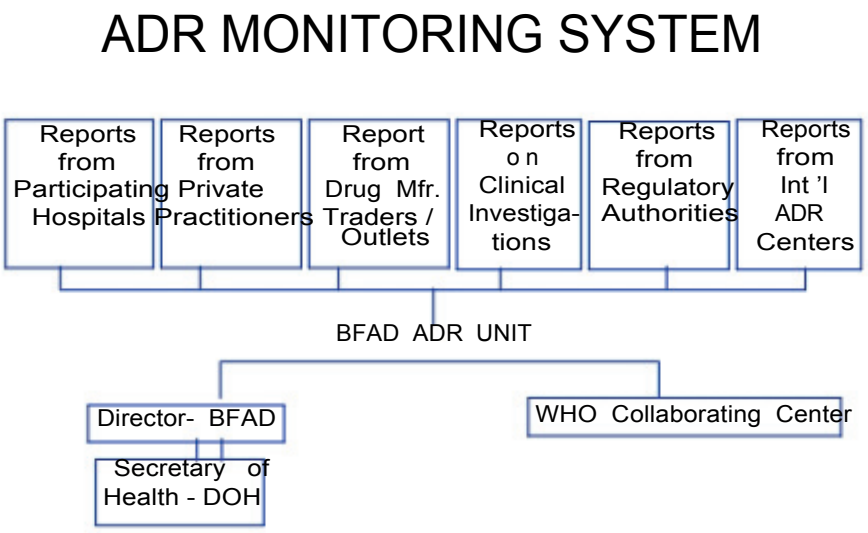
The Product Services Division assures that the product meet the criteria for safety, efficacy, and quality.

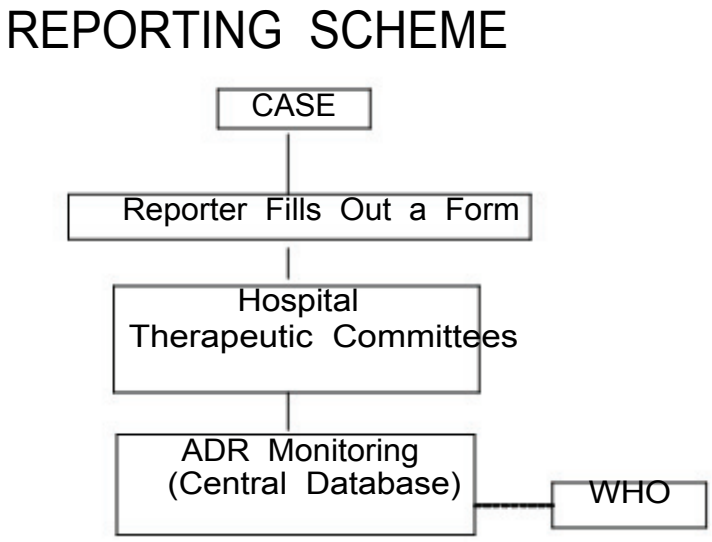
The Laboratory Services Division (LSD) verifies compliance of the product with the psychochemical, microbiological and toxicological tests.
Samples tested by LSD include products randomly collected from the market or from the manufacturers as well as traders. The Inspection Section of Regulations Divisions I and II conduct the post marketing monitoring through random sampling of products in the market and in the manufacturers as well as traders.
The Legal Information and Division monitors through sales promotion and advertisements the product's labeling information.

8) EFFORT FOR DRUG SAFETY

Collection and Evaluation of ADR Data

Collection and evaluation of adverse drug reaction data is one of the responsibilities of the Bureau of Food and Drugs. Food-Drugs Regulation Officers from the Regulation Division I - assigned to monitor Adverse Drug Reaction. The group collects data from sources such as report from hospitals or drug manufacturers. Reports are evaluated. Products found to have adverse reaction are endorsed to Product Services Division for further evaluation and revision of drug literature.





9) PHARMACOPOEIA

The Philippine Pharmacopoeia Project

The Bureau of Food and Drugs, embarked on a project to prepare and publish the Philippine Pharmacopoeia which will be utilized on the national official reference book for standards of purity and quality of pharmaceutical substances and product. The Philippine Pharmacopoeia will consist of two parts: part I will contain the General Considerations and the Official Monographs of Chemical/Pharmaceutical Substances and Products, while Part II will contain the Official Monographs of selected Philippine Medicinal Plants and Products. A Philippine Pharmacopoeia Committee, composed of representative from different fields of pharmacy, chemistry and medicine was created to ensure the success of the project.

To provide preliminary guidance and direction to the project, technical assistance has been requested from the Government of Japan through the Japan International Cooperation Agency. (JICA)

To date, under Executive Order No. 302 dated 29 March 2004, the Philippine Pharmacopoeia (PP) 1st edition 2004 and any supplement thereto, has been declared and adopted as the official book of standards and references for the determination of the identity, purity, and quality of pharmaceutical products and crude plants drugs in the Philippines.

10) PRODUCTION AND TRADE OF DRUGS AND OTHER PRODUCTS

All establishments in the Philippines that are engaged in the manufacture of drug products are registered with the Bureau of Food and Drugs. These manufacturers distribute their products locally or to be exported in foreign country. These importers are licensed with the Bureau.

11) DRUG DISTRIBUTION SYSTEM

Drug distribution is done by a licensed Drug Distributor (importer, exporter, and wholesaler) and by a licensed Drug Manufacturer and Drug Trader. Usually, the drugs Distributors are authorized by Drug Manufacturers and Traders to distribute their products. Distribution Agreement between each client is provided. (Note: Antibiotic products must first be batch certified aside from being registered prior to distribution in the market).

Documentation System such as records of delivery receipts and invoices are required between the distributor and the supplier (Drug Manufacturer or Drug Trader). Each distribution records must indicate the necessary data such as the name of the product, description of the product as its dosage form and strength, expiry date, date of manufacture and the lot or batch number. Storage condition and handling must also be specified, such record is needed for easy traceability in case of a product recall.

For the drug distribution of drugs in all government hospital, the regional health offices thru the DOH has certain list of accredited suppliers allowed in to join in the bidding. All manufacturers/suppliers are all BFAD licensed holders. The local government units have their own system of procuring essential drugs. Provincial health hospital has their own therapeutic committee to check on the procurement of drugs and medicines following the Philippine National Formulary as mandated by E.O 49 s. 2003-directs the mandatory use of Philippine National drug Formulary (PNDF) as the basis for procurement of drug products by the government.

12) DRUG PRICE MECHANISM

In the Philippines, high prices of drugs and other products do not only alarm the public but also the government. High prices are usually based by manufacturers on the cost of imported raw materials, taxes, labor fee, etc. For this, the government has created Republic Act 7581 on June 7, 1992, otherwise known as the "Price Act." The Act provides protection to consumers by stabilizing the price and supply of the basic necessities and prime commodities and by prescribing measure against undue price increase especially during the emergency situation.

The Bureau of Food and Drugs and the National Drug Policy conducts monthly monitoring of prices of drugs, especially essential drugs.

In answer to the high cost of drugs, the Republic Act 9502 "Cheaper Medicine Act" was enacted in 2008.

13) STABLE SUPPLY OF VACCINES

The Philippines has only one manufacturer of vaccines - the Biological and Vaccine Production Division which is directly under the Department of Health. Currently the agency has produced the BCG vaccine. The vaccines are already imported to supplement the needs of the people.

14) Re - examination of Drugs (if any) - *No available Data*

15) Classification of Pharmaceuticals and Medicinal Products

In the Philippine setting, drugs are categorized as;

- Prescription / Ethical Drugs
- Over-The-Counter
- Household Remedies
- Vaccines and Biologicals
- Herbal
- Veterinary
- Medical Devices
- In vitro Diagnostic Reagents
- Cosmetics
- Household Hazardous Substances

An essential drugs list which is a concept promoted by the WHO and refers to those drugs which cure the vast majority of illnesses and should be available to all persons are the ones listed in the National Drug Formulary of the Philippines (NDF). The NDF is a list of medicines officially recognized and approved by the Department of Health (DOH). This formulary is being prepared by the National Drug Committee and when completed will be regularly revised and updated. All drugs listed in the NDF shall be reimbursed by the Philippine Health Insurance (PHILHEALTH). On the other hand, those OTC are not reimbursed by PHILHEALTH.

OTC drug in the Philippines is also referred to as Non-Prescription drugs. This is defined as any Pharmaceutical product that can be dispensed without the written order of a duly-licensed physician, dentist or veterinarian, for the use of the consumers for the prevention or symtomatic relief of minor or self-limiting ailments.

Food supplements are not allowed to have therapeutic claims and also being registered to BFAD.

5. ESSENTIAL DRUGS

The Philippine National Drug Formulary (NDF) contains the essential list of drugs, which are the most needed for the health care of the majority of the population. It enumerates the kind of drugs that can cure most common ailments or diseases and the most needed health care that should be made available and affordable to all people. The essential drug list of the Philippines is in its 5th edition which contains 557 drugs: 365 in the core list and 307 in the complimentary list.

CORE OR MAIN LIST - A list of drug for the health care needs of the majority of the population: the listed drugs should therefore be made available at all items in adequate amounts and in appropriate dosage forms at the lowest possible cost. They are of utmost importance and are basic, indispensable and necessary for the health needs for the population

COMPLIMENTARY LIST- a list of drugs for treating rare disorders or in exceptional circumstances: alternative drugs when drugs in the main list are known to be ineffective or inappropriate for a given individual: alternative drugs when drugs in the main list cannot be made available: drugs with special pharmacological properties.

CRITERIA FOR INCLUSION OF DRUGS IN THE PHILIPPINE NATIONAL DRUG FORMULARY

a.) the drug is needed for the prevention and treatment of conditions not already covered in the existing list:
b.) the drug is more effective and/or less toxic than a drug listed for the same indication:
c.) the drug's at least as effective and safe and of lower cost than the drug listed for the same indication: and
d.) The drug is seemed essential for a specific DOH health program/project.

CRITERIA FOR DELETION OF DRUGS FORM THE PHILIPPINE NATIONAL DRUG FORMULARY

a) A more effective or equally effective but less toxic drug becomes available:
b) In the light of further knowledge, the therapeutic efficacy of the drug is found to be unsatisfactory or questionable:
c) Toxicity/suspected toxicity or potential for abuse and dangerous interaction prove to out weight its therapeutic value:
d) The drug has fallen into disuse and is no longer available:
e) The drug is no longer deemed cost-effective to other therapies; and
f) The drug is a fixed- dose combination which does not satisfy the requirements of A.O. 96 s. 1990.

6. **DIFFICULTIES & CONSTRAINTS IN MANUFACTURING CONTROL OF ESSENTIAL DRUGS (e.g. GMP, etc.) that you have been facing these days & clear directions in the future.**

From the continuous implementation of the GMP in the Philippines, BFAD still finds Drug Company not in compliance to the guidelines. Due to the economic crisis arising from the country, more drug company has opted to just have their product toll manufactured. The issue of the local pharmaceutical lab cannot easily cope up with the advanced technology of the multinationals. The knowledge, skills and capability of the personnel in every manufacturing facility can be pirated by other laboratories or the opportunity to go other countries. Other, manufacturing companies still has not improved or established quality management system. The proliferation of the counterfeit drugs by unknown fly by night manufacturers still exists.

On the part of the implementing agency both in the BFAD main and BFAD regional health offices, the main problem is the insufficient number of Food Drug Regulation Officers particularly in the regions. The expertise is not fully acquired due to the limited budget of the BFAD main to conduct seminars to re-echo the latest updates on the GMP inspections. Insufficient numbers of vehicles to locate and reach some drug manufacturing facilities.

The Bureau is very strict not to issue license to operate to drug manufacturers not complying GMP. The continuous coordination of BFAD main to the BFAD regional has been done using the zonal approach and continuous training of FDROs. Thus, making it sure that all the FDROs fully understand the latest updates GMP. The latest PIC/S seminar done by the main is an added solution. This will provide harmonized guidelines in the country.

Other solutions, being considered by the Bureau are the additional plantilla, technical training and technical competency enhancement, and competitive salary standards. With the approval of Republic Act 9711, there will improved and strengthened Food and Drug Regulatory Agency.

7. **CURRENT SITUATION CONCERNING COUNTERFEIT AND SUBSTANDARD DRUGS AND ITS COUNTERMEASURES**

While Philippines are on the verge of increasing technology, BFAD has difficulty in recognizing genuine from counterfeit products. Many of the fast moving drugs especially those from multi-nationals are being counterfeited. This problem is not only happening in the national capital regions but also in the provinces. The project of the government to allow the imported drugs coming from Pakistan to be sold in the existing licensed drug retail outlets has been one of the problems. This is so due to the fact that some would take advantage by incorporating those imported drugs and medicines not registered in BFAD and has not passed PITC.

PITC is the responsible agency allowed to import these drugs and medicines. This imported drugs and medicines are previously available at all government hospital. It has been expanded due to the government's program to provide affordable, accessible and quality medicines in all communities.

BFAD on the other hand, has on-going activities that include collaboration with the pharmaceutical sector thru the conduct of monthly meetings of the Technical Working Group on Counterfeit Drugs, saturation drive, product monitoring, regional audit inspection, random collection and purchases of pharmaceutical products for laboratory testing, investigation and validation of phone-in complaints received thru hot line and call center.

The strategy on saturation drive involves all Food and Drug regulation Officers in the inspection of licensed and unlicensed drugstores, sari-sari stores, in an identified vicinity of locality. This is done simultaneously within one-day to prevent the spread of information on the presence of the FDROs.

Monitoring of counterfeit drugs in various places nationwide giving priority to areas where information of prevalent counterfeiting from confidential sources is the main priority thrust of BFAD.

8. OVERVIEW OF RELATIONSHIP WITH OVERSEAS ASSISTANCE ORGANIZATION

The financial grant given by the World Health Organization (WHO) to the Bureau of Food and Drugs in the Agreement for Performance of Work (APW) has boost BFAD commitment to the cause of ensuring the availability of safe, quality and efficacious drugs. The support allowed the FDROs to conduct intensified surveillance on counterfeit drugs nationwide.

The coordination of PIC/S secretariat Geneva will enable BFAD to facilitate the networking between participating authorities and the maintenance of mutual confidence, the exchange of information and experience in the field of GMP and related areas, and the mutual training of GMP inspectors. This will also provide the framework for all necessary exchange of information and experience and help us achieve coordination on mutual training for inspectors and for other technical experts in related fields. BFAD effort to continue common efforts for the development, harmonization and maintenance of GMP, and to extend the co-operation to other competent authorities having the national arrangements necessary to apply equivalent standards and procedures with a view to contributing to global harmonization.

9. OVERVIEW OF TECHNICAL ASSISTANCE PROGRAMMES IN THE FIELD OF PHARMACEUTICALS, GMP, QUALITY CONTROL ORGANIZED BY INTERNATIONAL ORGANIZATIONS, NGOs, etc

WHO - How to monitor counterfeit drug in the market. The support allowed the FDROs to conduct intensified surveillance on counterfeit drugs nationwide.

PIC/S Secretariat Geneva - To lead the international development Implementation and maintenance of harmonized GMP standards and quality systems of inspectorates in the field of medicinal products.

JICA - the yearly training being offered by the JICA is a major step in BFAD strengthening process especially on the Good Manufacturing Practice (GMP) and Pharmaceutical Affairs Experts.

10. LIST OF REFERENCES

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The Study Programme

for the Pharmaceutical Affairs Experts

Thailand

Country Report

Thailand

Study Programme for Pharmaceutical Affairs Experts

(No. J09-00794)

Ms. Daranee Pencharoen

Head of New Drug Section

Drug Control Division

Food and Drug Administration of Thailand

Name: Ms. Daranee Pencharoen

Position and Name of Organization: Head of New Drug Section, Drug Control Division, Food and Drug Administration of Thailand.

Name of Country: Thailand

1.Geographical and political features

1.1 Location, Territory and Boundary

The Kingdom of Thailand is situated in the continental Southeast Asia, just north of the equator and is part of the Indochina Peninsula.

Thailand covers an area of about 514,000 square kilometers. It is the third largest country among the Southeast Asian nations, after Indonesia and Myanmar.

In the North, bordered by Myanmar and the Lao People's Democratic Republic.

In the South, bordered by Malaysia and the Gulf of Thailand.

In the East, bordered by the Lao People's Democratic Republic and Cambodia.

In the West, bordered by Myanmar, the Andaman Sea, and the Strait of Malacca.

1.2 Topography and Climate

Thailand can be topographically divided into three different areas: the plain areas are mostly in the Central Region of the country, the highland areas are mostly in the Northeast, and the mountain areas are mostly in the North and the Southeast.

Thailand has three types of climate as follows:

- Tropical rain climate in the coastal areas in the East and the South, with heavy rainfall all year round and tropical rain forests.
- Tropical monsoon climate in the Southwestern and Southeastern coasts with monsoons and a very high average annual rainfall.

- Seasonal tropical grassland or savannah climate with a lot of heavy rains in the Southwest monsoon season and dryness in the cold season covering most regions of the country, particularly the Central Region, the North and the Northeast.

  Prevailing winds include the southwesterly monsoon from about mid- May through October and the northeasterly monsoon from November through February.

1.3 Population, Language and Religions

The population of Thailand is 66.9 million (October 2009); almost all residents (98.1%) are of Thai nationality and the rest are of other nationalities such as Chinese, Myanmar and Lao.

For communication purposes, the Thai language is officially and commonly used for speaking and writing, while English tends to play a greater role particularly in the business sector.

Most of Thai people are Buddhists (94.5%), followed by Muslims (4.5%) Christians (0.7%) and others.

1.4 Education

Education in Thailand is provided mainly by the Thai government through the Ministry of Education from pre-school to senior high school. A free basic education of twelve years is guaranteed by the constitution, and a minimum of nine years' school attendance is mandatory.

Formal education consists of at least twelve years of basic education and higher education. Basic education is divided into six years of primary education and six years of secondary education, the latter being further divided into three years of lower and upper secondary levels. Kindergarten levels of pre-primary education, also part of the basic education level, span 2-3 years depending on the locale, and are variably provided. Non-formal education is also supported by the state. Independent schools contribute significantly to the general education infrastructure.

Administration and control of public and private universities are carried out by the Ministry of University Affairs.

1.5 Political system

The politics of Thailand are currently conducted within the framework of a constitutional democratic monarchy, whereby the Prime Minister is the head of government and a hereditary monarch is head of state. The judiciary is independent of the executive and the legislative branches.

According to the constitution, the three major independent authorities holding the balance of power are executive, legislative and judicial. The King has little direct power under the constitution but is a symbol of national identity and unity. The head of government is the Prime Minister. Under the present constitution, the Prime Minister must be a Member of Parliament. Cabinet members do not have to be Members of Parliament. The legislature can hold a vote of no-confidence against the Premier and members of his Cabinet if it has sufficient votes.

1.6 Literacy rate and GNP

The literacy rate among Thai population aged 15 and over rose from 78.6% in 1970 to 93.5 % in 2005. It is estimated that the literacy rate will be as high as 97% in 2010. The Gross National Product (GNP) per capita at current market prices of Thailand in the year 2007 was 124,831.6 baht.

2. Statistical data

1) Population

66.9 million (Male 32.9 million, Female 34.0 million) (data on October 2009)

2) Vital statistics

a) Rate of vital statistics (per 1,000 population) (per 1,000 live births*)

	Live birth rate	Death rate	Infant death rate*
Data	12.4	6.3	7.3
Year	2008	2008	2008

b) Five main diseases causing morbidity

	2003	2004	2005	2006
Group of diseases	percentage	percentage	percentage	percentage
1 Respiratory tract diseases	40.2	44.8	45.0	44.3
2 Musculoskeletal disease	14.9	11.8	12.2	11.4
3 Gastrointestinal diseases	10.3	9.1	9.3	9.4
4 Cardiovascular disease	6.3	5.2	5.9	6.3
5 Endocrine system diseases	4.4	3.1	4.4	4.1

c) Five leading causes of death

	2002	2004	2006	2008
Causes	number	number	number	number
1 Malignant neoplasm, all forms	45,834	50,818	52,062	55,403
2 Accident and poisonings	34,568	36,855	37,433	34,851
3 Disease of the heart	5,361	16,766	17,775	18,820

4 Hypertension and cerebrovascular disease	16,640	21,756	15,284	15,596
5 Pneumonia and other diseases of lung	13,185	16,462	13,766	14,542
6 Human immunodeficiency virus (HIV) disease	15,597	11,473	6,551	4,683

d) Life expectancy

	Male	Female	Total
Data	70.59	77.54	74.06
Year	2005-2010	2005-2010	2005-2010

3.Medical care policy

a) Estimated number of patients who received medical treatment on the specified date (not yearly total)

	Government hospital	Public hospital	Private hospital	Others hospital
Data	N/A	N/A	N/A	N/A
Year	N/A	N/A	N/A	N/A

b) Number of hospitals by establishing organ

	Government hospital	Public hospital	Private hospital	Clinics
Data	999	1	317	16,800
Year	2007	2007	2007	2006

c) Number of health manpower

	Physicians	Dentists	Auxiliary medical personnel*	Nurses (RN, CN, PHN)
Data	22,651	4,653	13,146	105,398
Year	2007	2007	2007	2007

*: as lab. Technician, X-ray technician, et al.

d) Number of Pharmacists

Data	6,288	7,413	7,940	8,565
Year	2002	2004	2006	2007

e) Number of drug manufacturers/ plants

Data	174	171	165	168	167
Year	2002	2004	2006	2008	2009

f) Number of traditional medicine manufacturers/ plants

Data	883	912	881	1,002	1,013
Year	2002	2004	2006	2008	2009

g) Number of drug importers

Data	641 (modern drugs)	177 (traditional drugs)
Year	2009	2009

h) Number of drug wholesalers

Data	15,939 (modern drugs)	1,986 (traditional drugs)
Year	2009	2009

4. Pharmaceutical affairs administration

1) Administrative organization

The Food and Drug Administration is a department under the Ministry of Public Health (see Figure 1). It is divided into ten divisions and three units as shown in Figure 2. There are about 663 workforces (data in 2006). Most of them (60%) are pharmacists and food technologists. The rest of them are nutritionists, lawyers, public- relation officers, etc. The top administrators are Secretary-General and three deputies Secretary General.

The Drug Control Division is responsible for all kinds of control activities involving licensing to manufacture, import, export and sell pharmaceutical products and granting registration certificates for pharmaceutical products to ensure their quality and legality. The division conducts research and determines principles, regulations, and measures regarding the safety, efficacy and quality of drugs. It promotes and supports the manufacture, import, and sale of quality drugs. The division carries out the inspection and surveillance on drugs and drug advertising to ensure their legality. It also provides information and technical advice and develops data resources for drug information service.

The organizational structure of the Drug Control Division is shown in Figure 3.

The functions of the division can be divided into 3 major parts: pre-marketing control, post-marketing control and development of the work system and national drug policy.

1. Pre-marketing Control
   - 1.1 Consideration of authorization to operate a modern or traditional drug manufacturing, importing or selling facility
   - 1.2 Consideration of registration of modern and traditional drugs
   - 1.3 Consideration of authorization of drug media advertising to the public or healthcare professionals.
   - 1.4 Consideration of the notification of pharmaceutical chemicals which are active ingredients.
   - 1.5 Consideration of the other approvals regarding medicines, e.g. authorization to manufacture or import sample drugs for registration, issue of certificates of pharmaceutical products/ certificates of free sales (CFS/CPP), certificates of veterinary

biological product lot release and approval of import according to the Ministry of Commerce's announcements.

2. Post-marketing Control

   Inspection and surveillance of drugs and of facilities and drug advertising are necessary to ensure the quality, efficacy, safety and legality of drug products in the market.

3. Development of the Work System and National Drug Policy

   The Drug Control Division acts as coordinator in the making of national policy regarding drugs in order to determine the direction of drug development as a whole and the translational of policy into practice.

2) List of laws/regulation covering pharmaceutical affairs

After several years of endeavoring, the Drug Act 1967 (B.E. 2510) was promulgated to supersede the 1950 Drug Act. The Drug Act 1967 has been employed for almost three decades. This brought in quite substantial improvement in all aspects of pharmaceutical control in the country. Up to now, there were four more revisions subsequently emerged in order to cope with the over changing situation of pharmaceutical industry and the globalization of international pharmaceutical trade.

The current laws and regulations for pharmaceutical control are as follows:

1. Drug Act 1967 (B.E. 2510)
2. Drug Act (2nd revision) 1975 (B.E.2518)
3. Drug Act (3rd revision) 1979 (B.E.2522)
4. Drug Act (4th revision) 1984 (B.E.2527)
5. Drug Act (5th revision) 1987 (B.E.2530)

These Acts contain provisions on definitions, authorities of the designated officers, role and responsibilities of business operators and personnel, registration and licensing, enforcement, offenses and penalties.

The activities under the above Acts are conducted under the supervision of Drug Committee which will give consent, advice and make recommendation to the Minister of Public Health regarding control and enforcement measures, issuances of notifications, licensing and registration, or other

related issues concerning pharmaceutical products. The Drug Committee has been appointed every two years. The committee is also authorized to approve pharmaceutical registration and to withdraw or suspend the licenses. There are 23 regular members in the committee;14 of them are positional appointed from related organizations; the other nine members are drug experts. The committee can then appoint subcommittees to assist them in the technical viewpoint. Presently, twenty subcommittees have been appointed; these are:

1. Subcommittee on review and approval for registration of modern medicines(new drugs) for human use
2. Subcommittee on review and approval for registration of modern medicines(new generic drugs) for human use
3. Subcommittee on review and approval for registration of modern medicines(generic drugs) for human use
4. Subcommittee on review and approval for registration of modern medicines(biological products) for human use
5. Subcommittee on review and approval for registration of traditional and herbal medicines
6. Subcommittee on review and approval for registration of modern medicines for use
7. Subcommittee on re-evaluation of registered medicines for human use
8. Subcommittee on surveillance of safety of drug utilization
9. Subcommittee on review and approval of drug advertisement
10. Subcommittee on establishment of good manufacturing practices(GMP) requirements
11. Subcommittee on approval of manufacturing or importing medicines for clinical studies
12. Subcommittee on establishment of requirements for bioequivalence studies
13. Subcommittee on GCP inspection of clinical studies
14. Subcommittee on establishment of guidelines on problem-solving of pharmaceutical raw materials and products for veterinary use
15. Subcommittee on evaluation and approval of pharmaceutical quality and testing for compliance with quality standards
16. Subcommittee on licensing approval of manufacturers, importers, distributors and drugstores
17. Subcommittee on policy development and promotional of biological products
18. Subcommittee on establishment of requirements for biological products

19. Subcommittee on the exemption of certificates of free sale in the registration of certain products
20. Subcommittee on approval for registration of growth hormone products

3) Licensing system of factory and registration system of drug

Licensing system

The Drug Act requires that any persons, who wish to sell, manufacture or import pharmaceutical products into the kingdom must obtain licenses from the licensing authorities. The Drug Control Division is the licensing authorities. The Drug Control Division is the licensing authority for manufacture, import and selling of pharmaceutical products in Bangkok metropolitan and its territories. Provincial Health Offices are the licensing authorities for manufacture and import of traditional drugs and sale of pharmaceutical products in other provinces.

Application for a license must be submitted to the licensing authority. Buildings and facilities will then be inspected. A license will be given after the inspection has confirmed that the applicant has adequate capabilities of conducting such business, and he/she can secure appropriate facilities and personnel for that purpose. There are different categories of licenses as the following:

- License to manufacture modern drugs
- License to sell modern drugs
- License as a wholesaler of modern drugs
- License to sell ready-packed modern drugs which are neither in the categories of dangerous nor specially-controlled drugs
- License to sell ready-packed modern veterinary drugs
- License to import modern drugs
- License to manufacture traditional drugs
- License to sell traditional drugs
- License to import traditional drugs

Drug Registration System

The registration process is necessary to ensure efficacy, safety and effectiveness of the pharmaceutical products freely sold in Thailand. Only the authorized licensees are qualified to apply for pharmaceutical product registration certificates. The manufacturing plant, in which a pharmaceutical product is manufactured, is subject to inspection for compliance GMP (Good Manufacturing Practices). According to the Drug Act, the granted certificate is valid to the validity of its authorized licensee.

The process of drug registration is carried out through two channels, which differ in degree of control and dossier submission: modern drugs and traditional drugs.

Modern drugs include chemical and biological entities. Modern drugs are classified according to the purpose of regulatory assessment into 3 categories, differing in the type of dossiers required of them. These are new drugs, new generic drugs and generic drugs.

There are 5 sections of the Drug Control Division responsible for drug registration as the following:

1. New Drug Section is responsible for the registration of new drugs and new generic drugs for human use.
2. Generic Drug Section is responsible for the registration of generic drugs for human use.
3. Biological Product Section is responsible for the registration of biological products for human and veterinary use.
4. Veterinary and Pharmaceutical chemical Section is responsible for the registration of veterinary drugs (not include biological products and traditional and herbal drugs)
5. Traditional and Herbal Medicine Section is responsible for the registration of traditional and herbal drugs for human and veterinary use.

New Drugs include products with new chemical entities, new indication, new combination, new delivery system, new route of administration, new dosage form (of new drugs) and new strength (of new drugs)

New Generic Drugs are medicines with the same active ingredients, dosage forms and strengths as those of new drugs registered after 1991.

Generic Drugs include products with the same active ingredients and dosage forms as those of new drugs registered before 1991.

Biological Products mean any products of biological origin, prepared with biological processes, derived from human blood and plasma, or manufactured by biotechnology, consisting of substances of higher molecular whose purity, potency and composition cannot readily and reliably be determined by chemical or physicochemical analysis. (e.g. Vaccines, blood products, modified animal tissues, high-molecular weight hormones, allergens, products of genetic engineering or other newer biotechnological techniques.)

Veterinary Drugs mean drugs intended for use in the diagnosis, treatment, relief, cure or prevention of animal disease or illness.

Traditional Drugs mean drugs intended for use in the practice of the traditional medicine (the practice of medicine by dependence on the knowledge acquired from a textbook or through learning which is not on a scientific basis)

Drug Registration Process

The registration process of all categories of drugs involves 2 steps:

1. Application for permission to manufacture or import of drug samples.
2. Application for product registration approval

The diagram showing the registration process is shown in Figure 4.

There are two registration tracks for new drug and new generic drug registration.

Track 1: Standard Review: This track applied to all drugs other than those allowed under Track 2.

Track 2: Accelerated or Priority Review: This is a fast track registration. This track has been created for

- Drugs for public health problems/life threatening e.g. Anti-HIV, Anti-cancer.
- Drugs which are manufactured for export.

Application for permission to manufacture or import of drug samples

The applications have to be submitted at one stop service center of Thai FDA.

Documents to be submitted:

1. Application form: Manufacturer/Importer Name and Address, License to manufacture/import number, Product Name and Description, Drug Formula(active ingredient(s) only), Packaging, Quantity of drug sample to manufacture/import
2. Labels
3. Leaflets

Application for product registration approval

The applications have to be submitted at the specific sections of the Drug Control Division according to the drug category.

Documents to be submitted:

In Thailand, the ASEAN Common Technical Requirements (ACTR) and ASEAN Common Technical Dossier (ACTD) has been fully implemented for the registration of new drugs, new generic drugs, generic drugs and biological products since 1 January 2009 (B.E. 2552). Thai FDA created 5 books for the industry as follows:

1. Manual/Guidance on New Drug Registration (ASEAN Harmonization)
2. Requirements and Documents to be submitted for New Drug Registration (ASEAN Harmonization)
3. Manual/Guidance on New Generic Drug Registration (ASEAN Harmonization)
4. Manual/Guidance on Generic Drug Registration (ASEAN Harmonization)
5. Manual/Guidance on Biological Product Registration (ASEAN Harmonization)

New Drugs

The dossier requirements for this type of registration are the most demanding compared to other types.

There are 4 parts of documents to be submitted (ACTD).

Part 1: Administrative Data and Product Information

Part 2: Quality Document

Part 3: Nonclinical Document

Part 4: Clinical Document

The ASEAN Common Technical Requirements (ACTR) of the Quality Part is as follows:

1. Drug Substance

2. General Information, Manufacture, Characterization, Control of drug substance, Reference Standards, Container Closure System, Stability
3. Drug Product

   Description/Composition, Pharmaceutical development, Manufacture, Control of excipients, Control of Finished Product, Reference Standards, Container Closure System, Stability, Interchangeability

The ASEAN Common Technical Requirements (ACTR) of the Nonclinical Part is as follows:

1. Pharmacology

   Primary Pharmacodynamics, Secondary Pharmacodynamics, Safety Pharmacology, Pharmacodynamics Drug Interactions
2. Pharmacokinetics

   Absorption, Distribution, Metabolism, Excretion, Pharmacokinetics Drug Interactions, Other Pharmacokinetic studies
3. Toxicology

   Single dose toxicity, Repeat dose toxicity, Genotoxicity, Carcinogenicity, Reproductive and developmental toxicity, Local tolerance, Other toxicity studies, if available

The ASEAN Common Technical Requirements (ACTR) of the Clinical Part is as follows:

1. Bioavailability (BA) and Bioequivalence (BE) Studies
2. Studies Pertinent to Pharmacokinetics using Human Biomaterials
3. Human Pharmacokinetic (PK) Studies
4. Human Pharmacokinetic (PD) Studies
5. Efficacy and Safety
6. Post Marketing Data (if available)
7. References

The requirements of each parts are classified by types of new drugs.

Once a new drug passes the product assessment process and market authorization is granted, it is registered as “conditional approval”. This means that the drug can be sold only in hospitals and other medical service institutes (both government and private sector) under supervision of physicians and at the same time the safety monitoring program (SMP) has to be conducted by the drug company. The SMP will be run for at least 2 years period. After the monitoring period, the company will have to

submit all safety data (both local and foreign drug experience information) to FDA to review with the expert and if satisfactorily would get an “unconditional approval”. Then, the drug can be distributed through normal market channels. Afterward, post marketing surveillance will be continued by voluntary spontaneous adverse drug reaction monitoring system.

New Generic Drugs

There are 2 parts of documents to be submitted (ACTD).

Part 1: Administrative Data and Product Information

Part 2: Quality Document plus bioequivalence study report (or therapeutic equivalence study) to provide evidence of equivalency with the original product.

Generic Drugs

The dossier requirements for this type of registration are the least complex among all modern drugs. There are 2 parts of documents to be submitted (ACTD).

Part 1: Administrative Data and Product Information

Part 2: Quality Document

Bioequivalence study reports are required for some generic drugs (antiretroviral drugs, postcoital contraceptives and sustained release dosage form)

Biological Products

For the purpose of assessment and registration, biological products are classified into new drugs, new generics and generic drugs, in parallel to the scheme used for registration of chemical entities.

Traditional Drugs

The registration of drugs for this group is much simpler than that of the modern drugs. The dossier requirements are as follows: application form, drug sample, drug formular and manufacturing process, labeling and packaging, certificate of analysis of microbial contamination.

Veterinary Drugs

The following documents are required: application form, drug sample, pharmacological and toxicological study (if any), clinical trials, safety and efficacy study (if any), complete drug formula, drug literature, labeling and packaging.

Table 1 Number of pharmaceutical products registered in Thailand (data on April 2009)

Types of drugs	Human use		Veterinary use		total
	manufacture	import	manufacture	import	
Modern drugs	19,462	5,544	2,040	1,714	**28,760**
Traditional drugs	11,407	856	116	6	**12,025**

Source: Drug Control Division, Food and Drug Administration of Thailand.

4) Pharmaceutical inspection including quality control check system

There are 3 main offices responsible for pharmaceutical inspection.

1. Thai FDA

   1.1 Post-Marketing Inspection Section

   - inspect all modern pharmaceutical manufacturers.
   - inspect traditional pharmaceutical manufacturers in Bangkok area.
   - inspect pharmaceutical importers/pharmacies in Bangkok area.

   1.2 Import and Export Inspection Division

   - monitor and surveillance the health products at the custom and ports (sea ports/airports).

   1.3 Rural and Local Consumer Health Products Promotion Protection Division

   - collaboration and supervision the Provincial Health Offices to monitor and surveillance the health products in the province.

2. Provincial Health Offices (local monitoring and surveillance agency)

   - monitor and surveillance the pharmacy/importer/ traditional pharmaceutical manufacturer located in the province.

3. Department of Medical Science

   - perform the analysis/test for the health products which is sampling by the Thai FDA.

Thai FDA monitors the quality as assurance program of pharmaceutical products in the market by collaboration with Department of Medical Sciences (DMS). The results of analysis from

DMS would be complied and the recommendation would be made for the authorities to take over some actions in order to correct the existed efficiencies. There are 5 types of inspection program: regular inspection (planned), follow-up inspection, suspected or petition inspection, established inspection and GMP evaluation inspection.

5) Good Manufacturing Practice (GMP)

Quality assurance of pharmaceutical product safety and efficacy before marketing can undoubtedly be achieved through Good Manufacturing Practice. Inspection of pharmaceutical manufacturers and sampling of pharmaceutical samples from manufacturers, importers or retail pharmacies for analyses by the regulatory authorities cannot effectively solve the cause of tha encountering problems. Pharmaceutical manufacturers, importers and distributors must establish their quality system according to the GMP guidelines to ensure that the pharmaceutical products have and always maintain the quality as claimed.

Thai FDA has started campaigning on GMP compliances since 1984. A project on development of local manufacturing standards in pharmaceutical industry is therefore stipulated in the Sixth (1987-1991) and also in the Seventh (1992-1996) 0f the National Economic and Social Development Plan. The aim of the project is to promote and support pharmaceutical manufacturers on implementing Good Manufacturing Practice. A current code of Thai Good Manufacturing Practice was published in 1987 as the FDA recommended guideline.

Activities that have been carried out towards accomplishment of the goal are as follows:

1. Organizing a national seminar on GMP once a year and periodically training programs for both government and private personnel.
2. Production and dissemination of technical documents, slides and videos on upgrading and training technical skills of personnel in pharmaceutical industry.
3. Conducting regular GMP monitoring and auditing with recommendations to pharmaceutical manufacturers if violation to Good Manufacturing Practice is found.
4. Revision of ministerial regulations to make GMP compulsory in pharmaceutical industry.
5. Audit and evaluation of pharmaceutical manufacturers according to GMP compliances.

Since 1992, it has been compulsory that drugs purchased under the allocated government budget must be from GMP certified manufacturers. In addition, the FDA has requested collaboration

from retail pharmacy stores to do the same. In 2003, GMP for modern pharmaceutical product has become to the law for the first time on March 2003. As the result, every modern pharmaceutical manufacturer must comply with GMP. GMP code is developed in accordance with the WHO GMP guideline.

GMP for traditional pharmaceutical manufacturers has adopted from ASEAN guideline 1993 (GMP Guidelines for the Manufacture of Herbal Medicinal Products). At present, there are 14 of 987 traditional pharmaceutical manufacturers received GMP Certificate.

PIC/S Regulatory Up date for Thailand

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP. ASEAN member countries has been already signed ASEAN Sectoral MRA for GMP Inspection of manufacturers of medicinal products on 10 April 2009, which in its principal, the ASEAN member state have to adopt PIC/S GMP guide or equivalent GMP code and the inspection service has adopted PIC/S quality system requirements. Thai FDA has submitted application to PIC/S since 2006. At present, Thai FDA is under the process of PIC/S assessment and the Thai GMP's regulation has been revising, adopted the PIC/S Guide, which will be finished within the end of 2009.

6) Post Marketing Surveillance system (PMS)

Inspection and surveillance of drugs and of facilities and drug advertising are necessary to ensure the quality, efficacy, safety and legality of drug products on the market. Inspection of manufacturing sites for GMP compliance, monitor advertisement and products in the market for substandard, adulteration, counterfeiting, misleading, exaggerating and hazard to the public are routinely carried out. Medicines that are unregistered will be recalled and those that may present hazards to consumers will be destroyed. In addition, the registered drug products are periodically re-evaluated.

The monitoring about side effects or adverse drug reactions from drug users has been performed by center namely the National Adverse Drug Reactions Monitoring Center (NADRM), established by FDA, collecting, analyzing and compiling all evidences related to adverse drug reactions, by applying the principal and knowledge of epidemiology and statistics. The main purpose

is to find out the degree and causes of problems on drugs and report these events, make comments and solutions to the drug committee and FDA to determine.

7) Sale and distribution of drugs (ethical and OTC)

The drug distributors could be divided to 3 levels as follows:

Level 1 (National level): The drug manufacturers , importers and the Government Pharmaceutical Organization distribute drug to government and private hospitals, health centers and drug stores. Thai FDA who is responsible for distribution of narcotic drug and some psychotropic substances are also included in this level.

Level 2 (District level): Wholesalers including drugstores situated in each province distribute drug to drug stores and clinics.

Level 3 (Consumer level): The drug products are distributed to consumer via distributors such as government and private hospitals, drug stores, clinics etc.

Ethical drugs

1. Psychotropic substance schedule 2: The sale restricted to psychotropic substance schedule 2. Only hospitals can purchase directly from FDA – Ministry of Public Health.
2. Psychotropic substance schedule 3 and 4: The sale restricted to psychotropic substance schedule 3 and 4 license holder. A first grade pharmacist should be on duty. Psychotropic substance schedule 3 and 4 supplies to the public that is on prescription only. Monthly and yearly purchase and sale report should be submitted to FDA - Ministry of Public Health.
3. Narcotic drug scheduled 3: The sale restricted to Narcotic drug scheduled 3 license holders. A first grade pharmacist should be on duty. Narcotic drug scheduled 3 supplies to the public, which is on prescription only. Monthly and yearly purchase and sale report should be submitted to FDA - Ministry of Public Health.
4. Special controlled drug: A first grade pharmacist shall be on duty at the premises selling modern drugs. Sale to public is on prescription only. Daily purchase and sale record required.

5. Dangerous drug: A first grade pharmacist should be on duty at the premises selling modern drugs, at all time, while the premises are open for operation. Daily purchase and sale record required.
6. Non dangerous drug: A first grade pharmacist, second grade pharmacist, a person engaging in the medical profession, a person engaging in the modern medical practice, in the branches of dentistry, obstetrics and nursing should be on duty at the premises selling modern non dangerous drugs.

OTC drugs

At present, drugs for household remedies can be purchased in the stores without prescription and pharmacist suggestion.

8) Additional requirements for biological (vaccines) and antibiotics such as National Test System (if any)

Special restriction imposed on biological products is the control at lot level. A certificate of lot release for biological products issued by the Thai Department of Medical Science (in case of locally-manufactured and imported products) or by relevant agency in the manufacturing country (in case of imported products) is required before the sale of each batch of biological.

5)Present situation and future plan (ex. National plan, introduction of GMP concept etc.) in the National drug policy including essential drugs and traditional medicine.

The National Policy on Drugs intends to assure standard quality of local productivity, availability, accessibility (or effective distribution) and rational utilization of quality drugs, in terms of therapeutic efficacy and safety of drugs. The policy can succeed by collaborative interactions government and private sectors.

The national policy is aimed at many aspects as follows:

1. Availability and accessibility of quality drugs, in terms of therapeutic efficacy and safety to all at reasonable prices.
2. Encouragement on rational use of drugs in such a way that waste and over-consumption of drugs are minimized.
3. Upgrading and promotion of domestic pharmaceutical industry, leading toward self reliance with emphasis on research and development as well as production for export.
4. Advocating on local manufacturing of raw materials from locally available resources for domestic supply and for export.
5. Support particular studies, for example, research and development activities on disease prevention, general health care and potential therapeutic efficacies, safety and efficient utilization of herbs, herbal medicines and traditional medicines.
6. Campaign on recognition and adoption of the National Essential Drug List in both government and private sectors.
7. Improvement of efficiency in legislative administration, strengthening the enforcement of laws, rules and regulations on drugs in favor of consumer protection.

The Drug Control Division acts as coordinator in the making of national policy regarding drugs in order to determine the direction of drug development as a whole and the translation of policy into practice. Important tasks are as follows:

- Development of the national list of essential drugs
- Promotion of rational drug use
- Amendment of legislation, regulation and notification regarding drugs

- Research and analysis
- Improvement of the strength, capacity and sustainability of the domestic drug industry

The division also works on important projects such as the drug quality assurance project, the promotion of quality system in pharmacy dispensaries project, the support for ASEAN Harmonization on registration of pharmaceutical products.

Development of the national essential drug list (NEDL)

Updating the national essential drug list (NEDL) is a continuous process for the public benefits on accessibility to essential drugs when needed. The national drug committee, chaired by the Minister of Public Health, has appointed a subcommittee, chaired by the Minister's Advisor on Public Health Economics, on March 29, 2007, to revise and update the NEDL 2004 coping up with the current medical and public health situations. The subcommittee has appointed 16 working groups, consisting of over 200 experts, physicians and pharmacists covering the entire areas if medicine profession.

The current NEDL 2008, which has become effective since January 23, 2008, contains three kinds of list: a list to be used in public hospitals and health care units, a list for herbal medicines and a list for hospital formulary.

Promotion of rational drug use

The FDA has adopted a pilot project to promote rational use of drugs, starting with the "Antibiotics Smart Use Project" since August 2006, with some of the budget provided by the World Health Organization. The project is intended to reduce the problems arising from bacterial resistance as well as risks from the use of antibiotics. The project was first implemented in Saraburi to create a model of appropriate prescribing and use of antibiotics in community hospitals and public health centers. Significant strategies in changing the use of antibiotics are as follows:

- Educational measures, which involve training courses in operational areas with media and equipment, consisting of a manual on rational antibiotic use, DVD, technical lectures, posters , pamphlets, VCD, and a newsletter
- Management measures, which involve support of media and equipment
- Social measures, which involves reward, praise and trend setting
- Policy measures : Saraburi Public Health Office's approval and support of the project

The pilot project ended in August 2007. However, the Antibiotics Smart Use has been adapted as practice in other provinces with the collaboration between FDA and other related organizations.

Support for ASEAN Harmonization on registration of pharmaceutical products

The most important thing that has just been emerged in the drug registration process is the ASEAN harmonized registration scheme. The ASEAN working group on this matter established since 1999 has adopted the common technical requirements as well as a dossier used for market approval application. It is mandatory for ASEAN members to implement the ASEAN Common Technical Requirements (ACTR) and ASEAN Common Technical Dossier (ACTD) by the end of the year 2008. Thai FDA issued a notification on the full implementation of the ASEAN Harmonization of Pharmaceutical Product Registration on December 26, 2008. According to the notification, the FDA would accept applications in the full format of ASEAN Harmonization from January 1, 2009.

Development and standardization of drug manufacturer

This is intended as preparation for membership of PIC/S (please see the topic “PIC/S Regulatory Up date for Thailand”).

6)Drug supply system and drug price mechanism including local products, imported and exported drugs

Drug supply system

The quality of domestically produced drugs has much imported as a result, in part, of the promotion of Good Manufacturing Practices (GMP). In 2003, the Ministry of Public Health issued a rule requiring that all pharmaceutical manufacturers have a GMP certification.

During the economic booming period 1988-1996, with the monopolies of new drugs, the proportion of imported drugs had a rising trend. Even after the economic crisis, since 2002, the import trend had been rising steadily, up to 56.3% in 2005. When considering the values of local production and drug imports, the trends rose steadily, except for a slightly downward trend for production in 2005, while the import values rose and surpassed the production values for the same year, the difference being approximately nine billion baht.

In addition to production and dispensing of drugs for domestic consumption, some drugs are exported to other countries, the export values rising from 480.8 million baht in 1989 to 6958.3 million baht in 2006.

In 2005, drug consumption of Thai people accounted for approximately 103,517 million baht in wholesale prices or 186,331 million baht in retail prices, or 42.8 % of the overall national health expenditure. According to the market survey data by IMS company Thailand (in 2006), drugs are distributed through the following channels: drugstores 24%, public and private hospitals 66%, private clinic and Government Pharmaceutical Organization (GPO) 8 % and others 2 %.

Drug price mechanism

The drug pricing in Thailand is controlled through the following mechanisms:

1. Market mechanism allowing free competition among generics, and competition among drugs under the same category.
2. Direct price control under the Price fixing and Antitrust Act, enforce by the Ministry of Commerce.
3. Medium pricing designated for the sale of essential drugs in public facilities. The medium price list is a price control mechanism established by the government for essential drug. The medium price list has been effective from 1986 and guides the

purchasing committees in price negotiations. The government has also established the new policy for procurement of drugs, whereby the hospitals have to use not less than 80 % of the government allocated money to buy the essentials drugs.

4. Patented drug pricing control designed by the Committee on Patented Drug appointed under the 1992 Patent Act.

7)Pharmacopoeia

In the previous day, the official standards for pharmaceutical products are as set forth in the foreign pharmacopoeia only e.g. British Pharmacopoeia, United States Pharmacopoeia. Some problems have been encountered due to the discrepancies between the standards of the pharmacopoeia. Some methods or standards do not fit in with the real situation in Thailand. The Thai Pharmacopoeia Committee has been therefore appointed by the Ministerial Cabinet to establish the Thai Pharmacopoeia (TP) which defines national standards to assure the quality of pharmaceutical products. TP comprises the recommenced methods and specifications that aim primarily at accommodation the needs of the country. TP also provides information of drug safety and stability i.e. information on dose, contraindication, warning etc. for the benefit of dispensing drugs and important information for drugs which tend to decompose in hot humid weather.

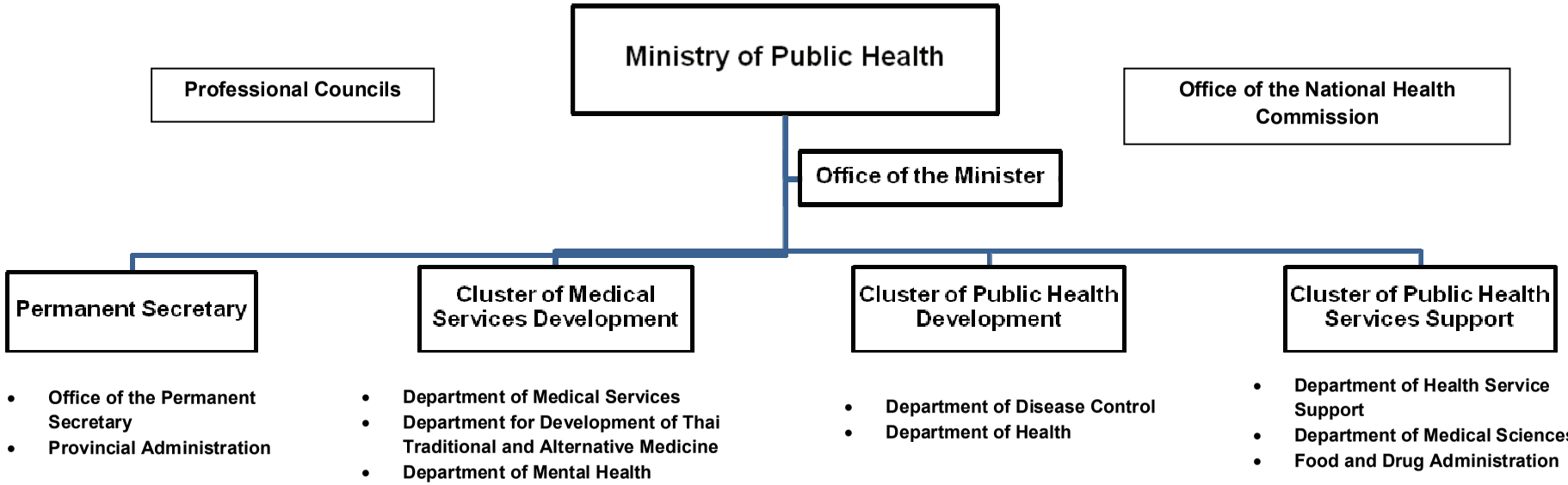
According to the Notification of the Ministry of Public Health 2006, the official Pharmacopoeia for modern drugs is as follows:

1. Thai Pharmacopoeia Volume I Part 1, Part 2 and Supplements
2. Thai Pharmacopoeia Volume II Part 1, Part 2, Part 3 and Supplements
3. Thai Herbal Pharmacopoeia Volume I and Supplements
4. Thai Herbal Pharmacopoeia Volume II and Supplements
5. International Pharmacopoeia 3rd edition and Supplements
6. United States Pharmacopoeia 22nd Revision 2004 and Supplements
7. British Pharmacopoeia 2004 Volume 1-4 and Addenda
8. British Pharmacopoeia (Veterinary) 1998 and Supplements

8)List of References

1. FDA Thailand, Third Edition 2001, Technical Division. The Office of Food and Drug Administration. Ministry of Public Health, Thailand.
2. FDA Thailand, Third Edition (revised in 2004), Technical Development & Foreign Affairs Division. The Office of Food and Drug Administration. Ministry of Public Health, Thailand.
3. The website of Food and Drug Administration Thailand (www. fda. moph.go.th)
4. Thailand Health Profile 2005-2007, Bureau of Policy and Strategy, Ministry of Public Health, Thailand.

Figure 1 Organization of Ministry of Public Health



Agencies under the supervision of MOPH:

- Health system Research Institute
- National Health Security Office
- Praboromarajchanok Institute of Health Workforce
- Development (Act required)
- National Institute of Health (Act required)
- Institute of Emergency Medical Services (Act required)
- Institute of Hospital Quality Improvement and Accreditation(Act required)

State Enterprise:

- Government Pharmaceutical Organization

Public organization (Royal Decrees required)

- Health facilities (Royal Decree enacted for Ban Phaeo Hospital)

Source: Thailand Health Profile 2005-2007, Bureau of Policy and Strategy, MOPH.

Figure 2 Organization of Food and Drug Administration (Source: Technical and Planning Division, FDA)

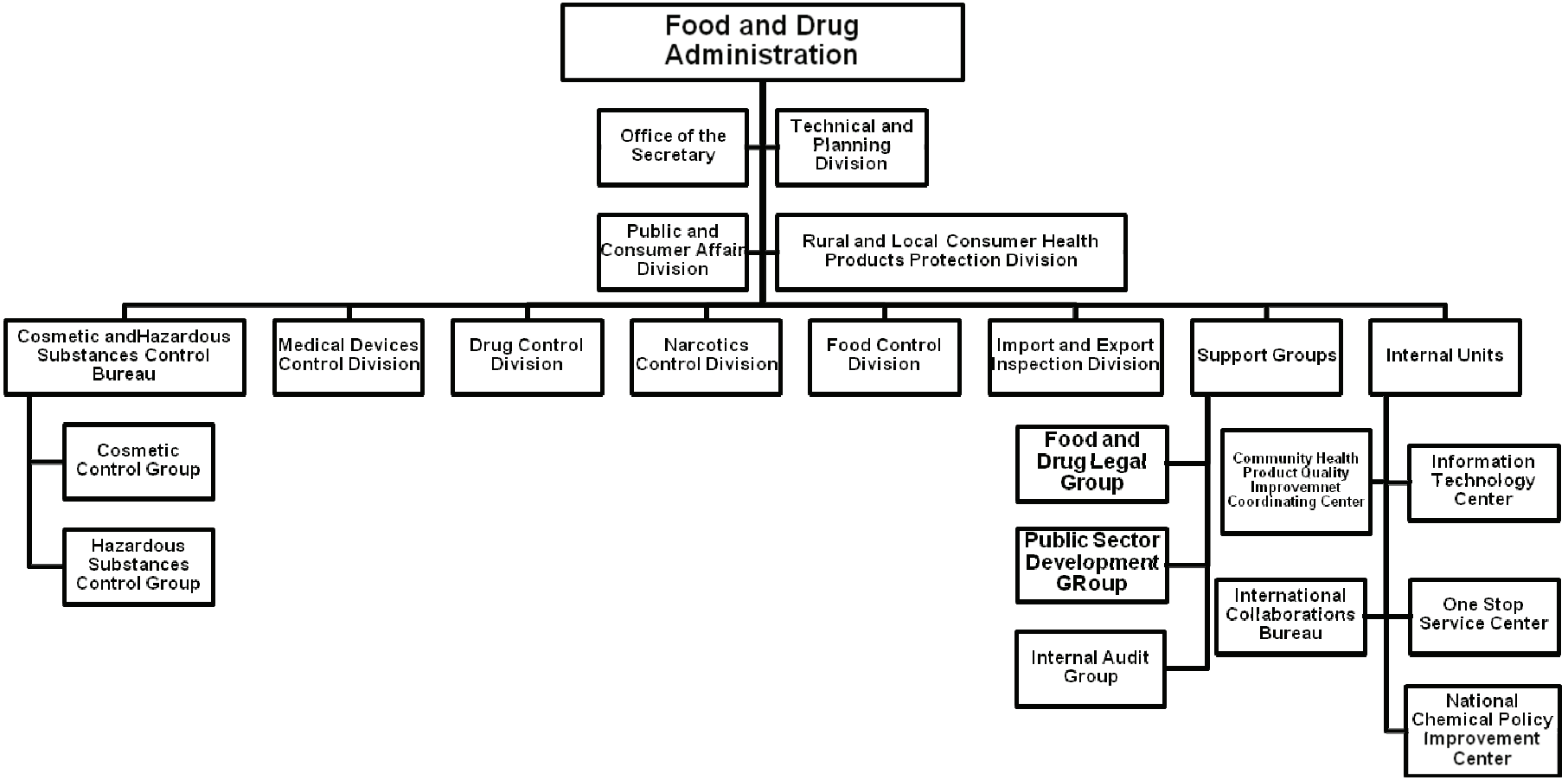
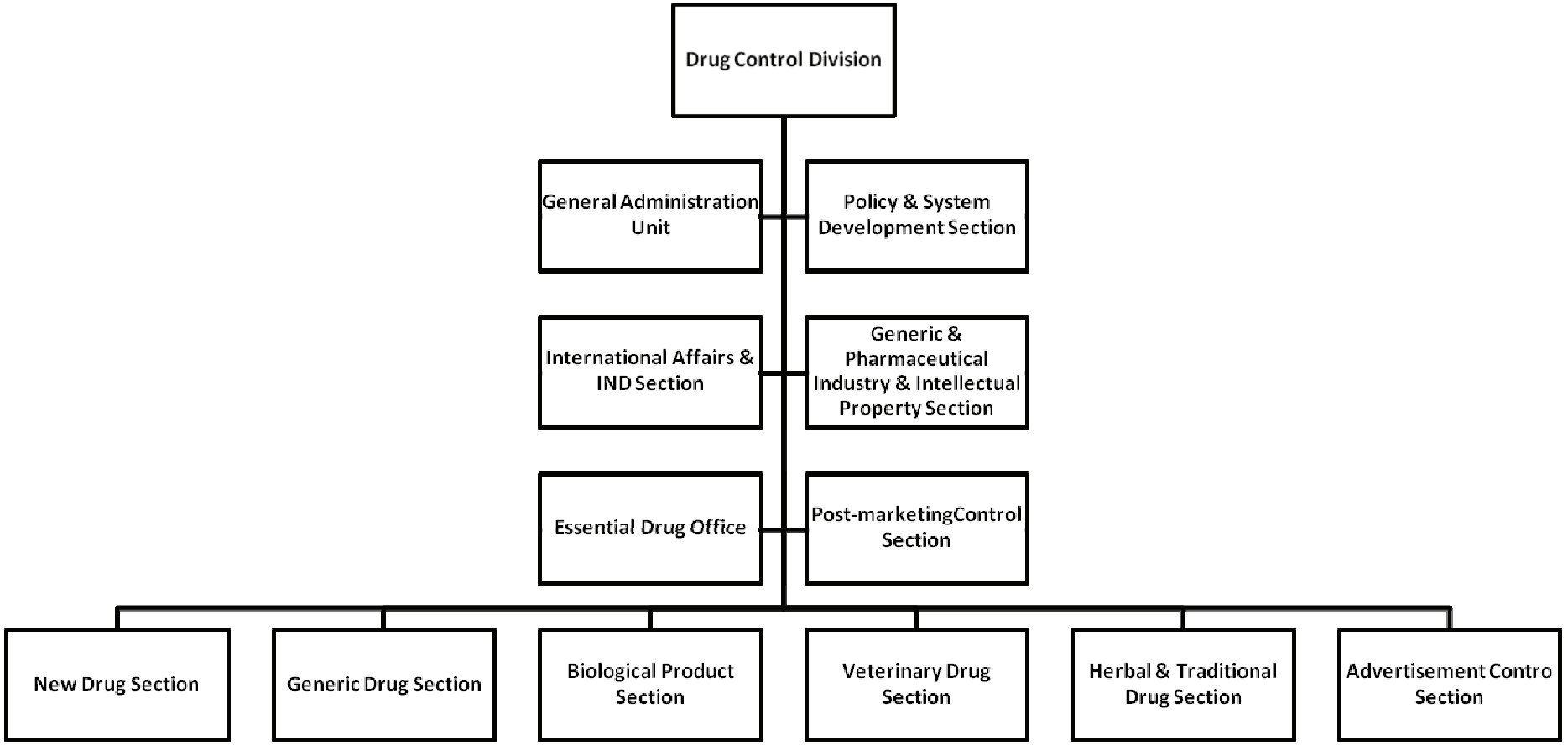
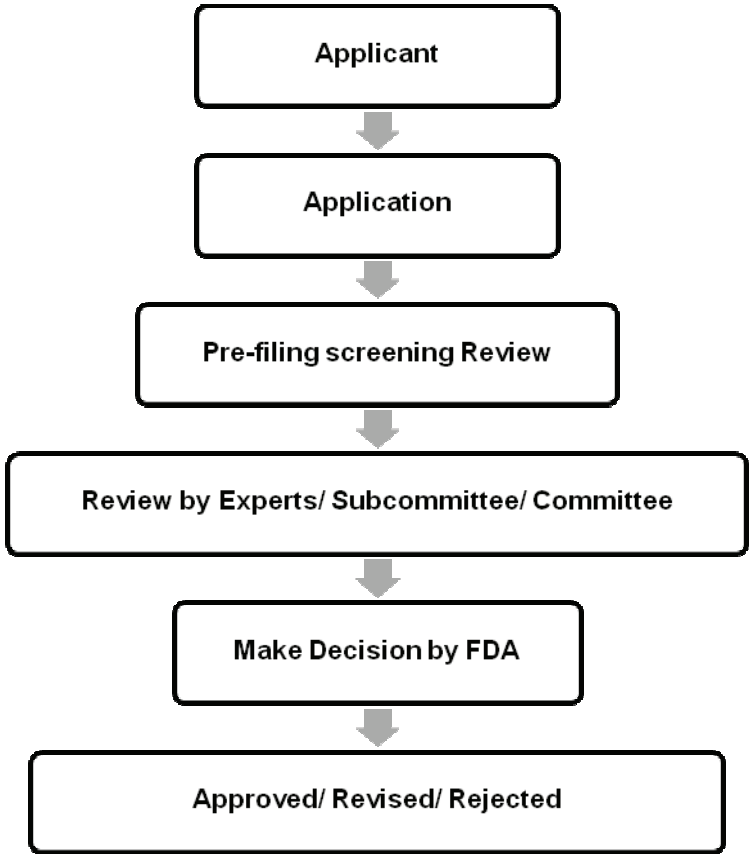


Figure 3 Organization of Drug Control Division



Source: Drug Control Division, Food and Drug Administration.

Figure 4 Drug Registration Process



Source: Drug Control Division, Food and Drug Administration.