The Study Programme
for the Good Governance of Medicines for Pharmaceutical
Regulation Authorities

Country Reports

Japan International Corporation of Welfare Services (JICWELS)

Contents

The Study Programme
for the Good Governance of Medicines for Pharmaceutical
Regulation Authorities

China

Country Report

Position and Name of Organization: Xi'an Food and Drug Administration

Name of Country: China

1. Statistical Data

a) Number of medical professionals

	Physicians	Dentists	Auxiliary medical personnel	Nurses(RN, CN, PHN)
Data	2466094	65000	653588	2244020
Year	2011	2011	2011	2011

b) Number of Pharmacists

Data 363993

Year 2011

c) Number of pharmaceutical manufacturers/manufacturing sites

Data 4678

Year 2011

d) Number of traditional medicine manufacturers/ manufacturing sites

Data About 3000

Year 2011

e) Number of Pharmaceutical importers

Data

Year

f) Number of Pharmaceutical wholesalers

Data 13461

Year 2011

2. Pharmaceutical legislation and regulatory systems

1) What legislation on pharmaceutical administration has been enacted in your country? (Name and outline of the laws)

a) Drug Administration Law of the People's Republic of China

Chapter1 General Provisions

Chapter2 Administration of Pharmaceutical Producing Enterprises

Chapter3 Administration of Pharmaceutical Trading Enterprises

Chapter4 Administration of Pharmaceuticals at Medical Organizations

Chapter5 Pharmaceutical Administration

Chapter6 Administration of the Packaging of Pharmaceuticals

Chapter7 Administration of the Prices and Advertising of Pharmaceuticals

Chapter8 Supervision over Pharmaceuticals

Chapter9 Legal Responsibility

Chapter10 Supplementary Provisions

b) Regulations for Implementation of Drug Administration Law of the People's Republic of China

Chapter1 General Provisions

Chapter2 Administration of Pharmaceutical Producing Enterprises

Chapter3 Administration of Pharmaceutical Trading Enterprises

Chapter4 Administration of Pharmaceuticals at Medical Organizations

Chapter5 Pharmaceutical Administration

Chapter6 Administration of the Packaging of Pharmaceuticals

Chapter7 Administration of the Prices and Advertising of Pharmaceuticals

Chapter8 Supervision over Pharmaceuticals

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c) Good Manufacture Practice

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Chapter3 Organization and Personnel

Chapter4 Building and Facilities

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Chapter14 Supplementary Provisions

d) Good Supply Practice

Chapter1 General Provisions

Chapter2 Quality Management of Drug Wholesale

Management Responsibility

Personnel and Training

Facilities and Equipments

Purchase

Acceptance and Inspection

Storage and Maintenance

Warehousing and Transportation

Distribution and After-sale Service

Chapter3 Quality Management of Drug Retail

Management Responsibility

Personnel and Training

Facilities and Equipments

Purchase and Acceptance

Display and Storage

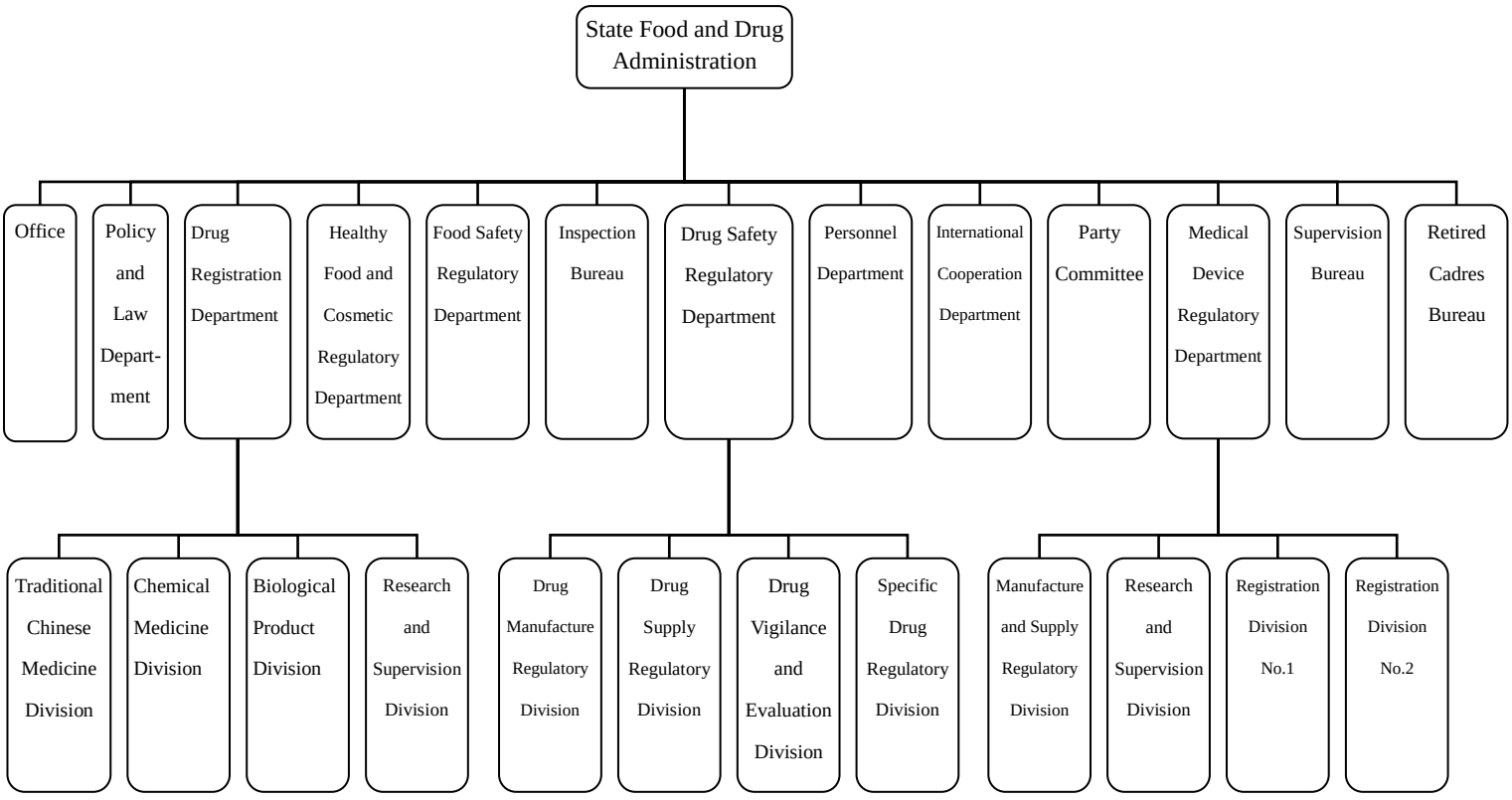
Distribution and Service

Chapter4 Supplementary Provisions

2) Organizational structure; What regulatory framework on pharmaceutical administration are formulated in your country? (Describe the organizational chart at national/state and local levels)

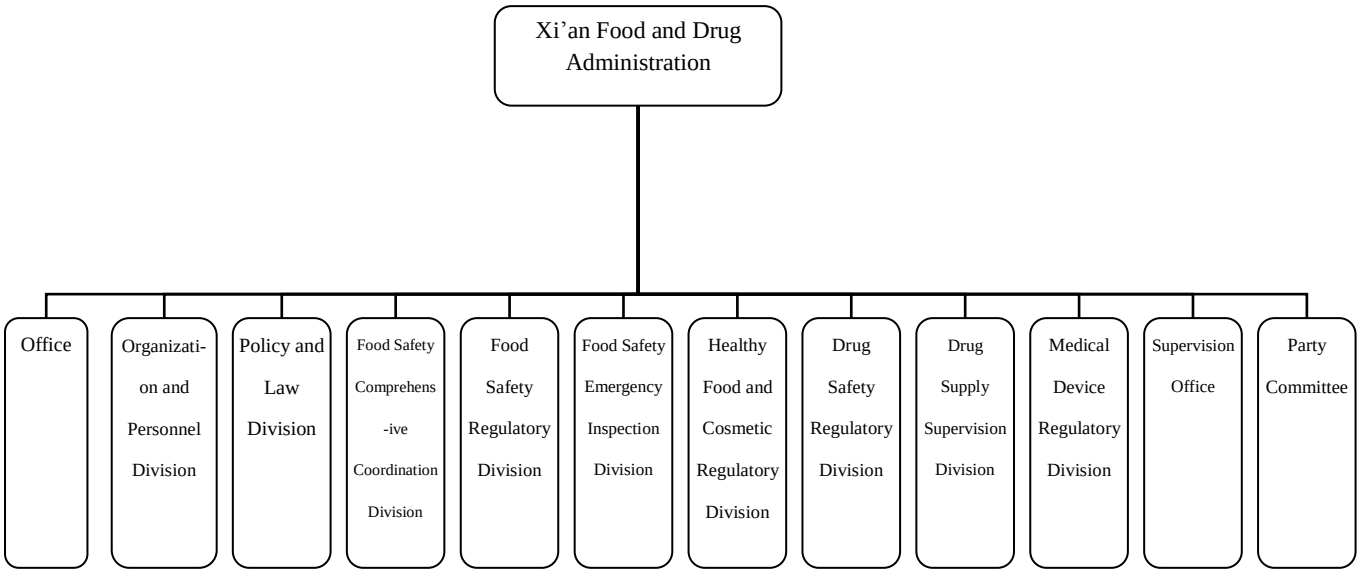
There are four levels of pharmaceutical administration in our country: national level, province level, municipal level and district/county level. Each level of pharmaceutical administration is responsible for the pharmaceutical administration within their administrative regions.

a) National organizational structure:



There are several institutions directly under State Food and Drug Administration: National Institutes for Food and Drug Control, National Pharmacopoeia Committee, Center for Drug Evaluation, Center for Certification of Drug, Center for Drug Reevaluation (National Center for ADR Monitoring), Center for Qualification of Licensed Pharmacist and so on.

b) Local organizational structure:



There are several institutions directly under Xi'an Food and Drug Administration: Drug Inspection Bureau, Food Inspection Bureau, Center for Complaint of Food and Drug and Xi'an Institute for Food and Drug Control.

3) What department/division is in charge of the following pharmaceutical regulatory services respectively? How many officials/staffs are engaged in each service?

a) Licensing of manufacturing site and product qualification/registration

Licensing of manufacturing site: Drug Safety Regulatory Department, about 3000 officials.

Product qualification/registration: Drug Registration Department, about 2000 officials.

b) Regulation on clinical trials conducted in your country

Drug Registration Department, about 2000 officials.

c) Pharmaceutical inspection for compliance with Good Manufacturing Practice (GMP)

Drug Safety Regulatory Department and Center for Certification of Drug, about 4500 officials and near 3000 GMP inspectors.

d) Prevention and control for substandard, spurious, falsely-labelled, falsified, counterfeit medical products

Inspection Department, about 3000 officials.

e) Post-Marketing Surveillance (PMS) for monitoring adverse drug reaction

Center for Drug Reevaluation (Center for ADR Monitoring), about 1500 officials.

f) Sale and distribution of ethical/OTC medicines (including traditional medicines)

At national level: Drug Safety Regulatory Department

At province and municipal level: Drug Market Supervision Division

Totally about 4000 officials.

g) Licensing pharmacist and pharmacy

Center for Qualification of Licensed Pharmacist, about 1500 officials.

h) Public awareness for rational use of medicines

Center for Drug Reevaluation (Center for ADR Monitoring), about 1500 officials.

4) Does your country have its own pharmacopoeia? If not, what kind of pharmacopoeia do you refer to as an official pharmacopoeia?

Yes. Pharmacopoeia of the People's Republic of China, updated every five years. The latest edition is 2010 edition, consisted of three volumes: Traditional Chinese Medicines, Chemical Medicines and Biological Products.

5) Does National Regulatory Authority in your country have any additional requirements for vaccines and other biological products such as National Test System (if any)

Yes. There is a law named Regulation for Batch Release of Biological Products. As referred to the law, before distribution and import, every batch of vaccine and biological product must be examined and verified. The examination is implemented by National Institutes for Food and Drug Control.

3. Present situation and future plan of the National medicine policy, including essential medicine and traditional medicine

The National Medicine Policy consists of several aspects:

1) Essential Medicine. Selection of Essential Medicine is the most important part of National Medicine Policy. The first edition of National Essential Medicine Catalogue was published in 1981. The latest Catalogue is 2009 edition. This catalogue consists of 205 chemical drugs and biological products, 102 traditional Chinese patent medicines and simple preparations and Traditional Chinese Medicine decoction pieces. The essential medicines are of clinical necessity, safety, efficacy, reasonable price and convenience for use.

2) Reasonable Price. It's very important for peoples' affordability.

3) Drug Financing.

4) Supply System.

5) Drug Regulation. It's important to assure the safety, efficacy and quality of drugs.

6) Rational Use of Drugs.

Future Plan: The National Medicine Policy would be developed and improved in the future. The targets include: strengthening the regulation of the whole processes of drugs, improving drug quality and rational use of medicines, promoting the sustainable development of pharmaceutical industry and accelerating the development of Traditional Chinese Medicine. The final target is to protect and advance the public health.

4. Pharmaceutical supply in health system and pharmaceutical pricing mechanism for universal health coverage in your country

Pharmaceutical supply in health system is implemented through a way called drug centralized purchasing. Drug centralized purchasing is implemented in each province. Nonprofit medical organizations must purchase medicines through this way. Drug centralized purchasing in other medical organizations is encouraged. The health regulatory authorities are responsible for drug centralized purchasing in health system. All the information is displayed on the drug centralized purchasing platform.

Generally, there is a national health coverage drug catalogue. The prices of the drugs in this catalogue are fixed by National Development and Reform Commission. Each province has its own health coverage drug catalogue based on national health coverage drug catalogue. The prices of the drugs in the province's health coverage drug catalogue but not in national health coverage drug catalogue are fixed by this province. Other drugs which are not in the catalogues are independent pricing.

The Study Programme
for the Good Governance of Medicines for Pharmaceutical
Regulation Authorities

Laos

Country Report

Good Governance of Medicine for Pharmaceutical Regulation Authorities (J120694)

Food and Drug Department
Lao PDR

1. Statistical data

a) Number of medical professional
(Average number of medical professionals by category (Data year 2009-2010))

Item	Number
- Physicians	1,211
- Dentists	228
- Nurse and midwife	5,322

b) Number of Pharmacists in public sector (Data available in 2010)

Item	Number
- High	366
- Mid	3,975
- Low	182

c) Number of pharmaceutical manufacturer/Manufacturing sites
Data 7
Year 2012

d) Number of traditional pharmaceutical manufacturer/Manufacturing sites
Data 3
Year 2012

e) Number of pharmaceutical importers

Data 45

Year 2012

f) Number of pharmaceutical wholesales

Data 5

Year 2012

2. Pharmaceutical Legislation and regulatory system:

1). Legislation on pharmaceutical administration:

The Legislation establishment is one of thirteen elements (priorities) in the National Drug Policy to assure that the successful implementation of the Drug Policy through using the related, updated appropriate law and regulations. The first Law on Drug and Medical Product endorsed and promulgated in the late year 2000, the law consist 8 sections and 45 articles. Based on this law, many related regulations as listed below had been formulated and revised in order to facilitate the control and management on the quality safety and efficacy of medicine.

1. Revised National Drug Policies, dated on 13/8/2003
2. Regulation number 482/MOH, 19/4/2002 on the pharmacy.
3. Regulation Number 1442/MOH on Establishment of Drug and Medical Equipment Import-Export Company in 2003
4. Regulation Number 1441/MoH endorse 13/08/2003 on Drug Registration in Lao P.D.R
5. Regulation Number 1018/MOH in 2003 on the banned drugs in Laos
6. Regulation No.2580/MOH, on 25/11/2002 on specific controlled medicine and uncontrolled and OTC drugs.
7. Regulation Number 2580/MOH, on 12/11/2003 on Control Cosmetic Products.
8. Regulation number 2581/MOH in2003concerning the Food, Drug and Medical Equipment Advertisement.
9. Regulation Number 2579/MOH, 12/11/2003 concerning Drug and Medical Equipment Donation.
10. Decree of PM Number 155/PM, on 30/9/2003 concerning Natural Medicinal Plant.
11. Regulation on Good Manufacturing Practice No.937 / MOH, 12/07/2004.
12. Regulation on Drug Donation No. 1189 / FDD, 02/01/ 2009.

So far, based on the Scio-economic growth, and integrations to ASEAN harmonization in pharmaceutical areas, the Law on Drug and Medical Product has been revised, endorsed end of 2011. This revised law has been added new five articles regarding Monitoring Quality of Drug and Medical Product (Post-Marketing Surveillance); Classification of Medical Device, Intellectual Property Right Protection; Clinical Trial Test in the Laboratory and ete... the revise Law has 50 articles. The above existing regulation need to be revised.

Lay out of the LAW ON DRUGS AND MEDICAL PRODUCTS

Part I
General Provisions

Article 1 Objective
Article 2 Drug and Medical Product
Article 3 Definition of terms

1. Modern drug
2. Traditional medicine
3. Counterfeit drugs
4. Sub-standard drug
5. Deteriorate drug New drug Medicinal natural resources;
6. Health Supplement;
7. Medical device;
8. Cosmetic product
9. Dangerous chemical
10. Controlled chemical
11. Pharmacist
12. List of essential drugs
13. Generic name
14. Business unit.

Article 4 Policy on Drugs and Medical Products Activities
Article 5 Principles of Drug and Medical Product Activities
Article 6 Scope of Application
Article 7 Internal Cooperation

Part II
List and Classification of
Drugs and Medical Products

Article 8 List of Drugs and Medical Products
Article 9 Classification of Drugs
Article 10 Drugs in Possession
Article 11 (New) Classification of Medical Device

Part III
Drug and Medical Product Business

Section I
The management of Drug and Medical Product Business

Section 3
Intellectual Property

Part V
Clinical Trial Research

Part VI
Toxicology Information Centre and
Collection of Adverse Effects of Drugs and Medical Products

Part VII
Rights and Obligations of Users, and Responsibility of Suppliers of Drugs and Medical Products

Part VIII
Prohibitions

Part IX
Management and Inspection of
Drugs and Medical Products

Article 42 Rights and Duties of Ministry of Health
Article 43 Rights and Duties of Provincial, City Health Department
Article 44 Rights and Duties of District, municipality Health Offices
Article 45 Monitoring and Inspection of Drugs and Medical Products
Article 46 Forms of Inspection

Part X
Policies towards Persons with
Outstanding Achievements and Measures against Violators

Article 47 Policies towards Persons with Outstanding Achievements
Article 48 Measures against Violators

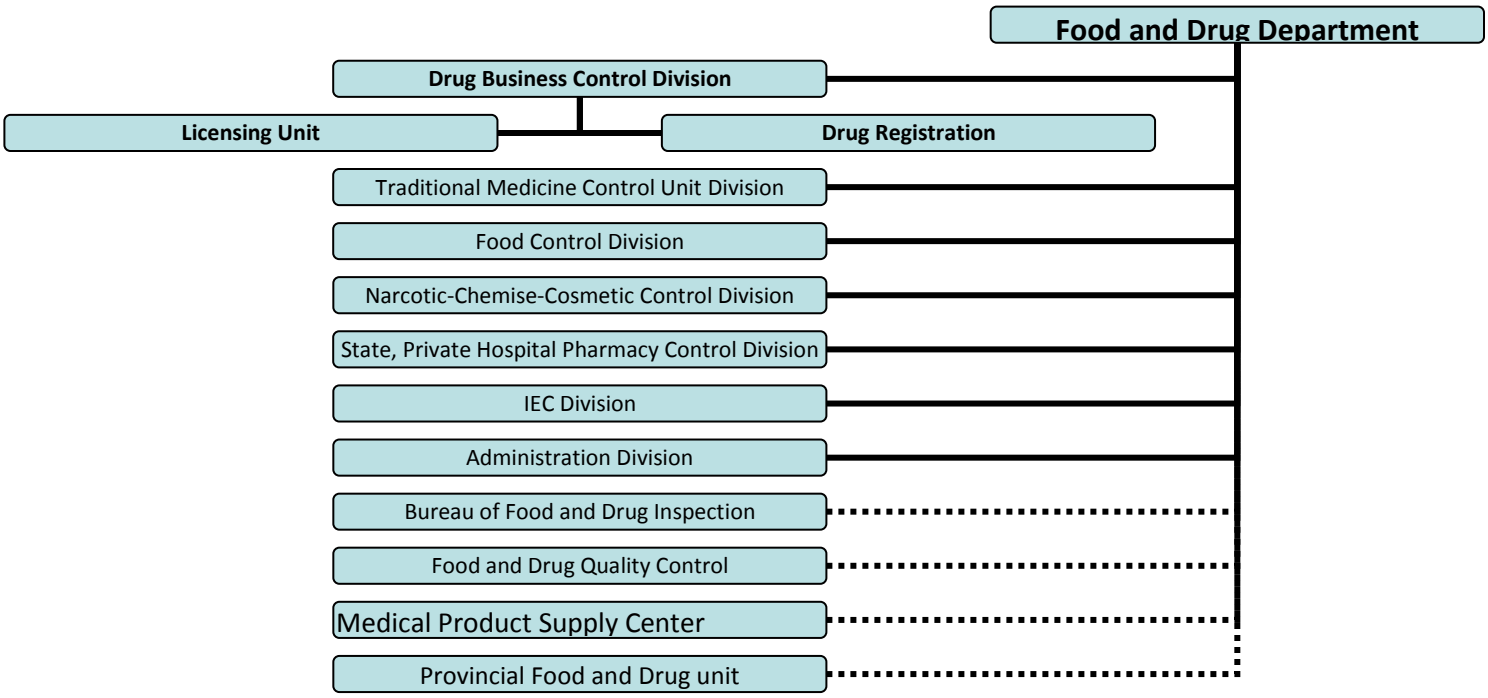
Part XI
Final Provisions

Article 49 Implementation
Article 50 Effectiveness

2). Organizational Structure:

The new organizational structure of the Food and Drug Department (FDD) has been change a little bit since beginning of 2010, in order to ensure the establishment and role of FDD match to current situation. There are seven divisions in the organization chart namely: Drug Business Control Division; Traditional Medicine Control Division; Food Control Division; Narcotic, Chemise, and Cosmetic Control Division; State/Private Pharmacy Hospital Control; Information, Education and Communication Control Unit; Administration Division.

Organizational Structure of the Food and Drug Department



Vision:

- To ensure good quality, safety and efficacy of drug as well as rational use for Lao people.

Mission:

- Develop and implementing strategy and Policy
- Develop, implementing and enforcement of law and regulation governing drug, Medical Devices and Cosmetic
- Pre-marketing and Post marketing surveillances for drug Medical Devices and Cosmetic product
- Strengthening drug quality assurance system including quality control
- Continue education for both public and private providers
- Promotion of rational use of drug amongst health worker as well as communities
- Promotion of local production to comply with GMP internationally.

3). Division is in Charge of the Pharmaceutical regulatory services respectively:

A. Licensing of manufacturing site and product qualification/registration

Licensing and registration is a premarketing authorization activity with belong to the responsibility of Business **Control Division**. Within this Division, the licensing for manufacturing site and the qualification of the product activities are under to control of the **Licensing Unit**, and Product registration is under responsibility of **Drug Registration Unit**. Total member staffs of Business Control Division now are 8 people.

B. Registration on clinical trial conducted country:

Legal provision regarding the Clinical Trial Research is contained in article 31 and 32 of the Law on Drug and Medical Product. The clinical trial of drugs or medical products is the test of the drugs and medical products on animals or human beings in order to prove their effectiveness and safety for the users. The clinical trial of drugs or medical products can be conducted if only it is authorized by the health sector. And the results from the clinical trial of drugs or medical products in the Lao PDR shall be reported to health their relevant sectors. In the case that harmful effects to health are found, the result shall be reported immediately to health sector and other relevant sectors in order to officially remedy or terminate such trial.

So far, there is no any state and private organization in Laos doing the clinical trial research.

C. Pharmaceutical inspection for compliance with Good Manufacturing (GMP).

- GMP compliance inspection post-marketing activity of the quality assurance system of the Food and Drug Department in order to ensure quality safety of medicinal product producing throughout GMP establishment. FDD in collaborating with the Bureau of Food and Drug Inspection (BFDI) do the GMP auditing all manufacturers at least twice years.
- As the MRA in GMP and the five year action plan of FDD, 3-4 local pharmaceutical factories should be complied with GMP standard thus the Ministry of Health composed specific committees (GMP committees) to provide the technical assistance particularly provided regular training on basis of GMP and help establishing documentation for manufacturers.
- So far, FDD in collaborating with BFDI have provided the training to manufacturer in many subjects of GMP and we have 13 GMP committees working as GMP taskforce.

D. Prevention and control of substandard, spurious, falsely-label, falsified, counterfeit medical product:

Post-Marketing Surveillance (PSM) is very crucial of the quality assurance system, and the Monitoring Quality of Medicine (MQM) activity is a part of PSM which implemented since 2003 in collaboration between FDD, BFDI and provincial Food and Drug and with the technical and financial support from NGOs. Each year, some prioritized medicine samples (Anti-biotic, Anti-Malarial, TB, HIV/AIDS) have been taken in country to check the quality in provincial and central Laboratory. The substandard and counterfeit of anti-malarial medicines have been found.

E. Post-Marketing Surveillance (PMS) for monitoring adverse drug reaction:

In year 2000, we organized training course for ADR to the pharmacists and Drug Therapeutic Committee of central and provincial levels whole country, and the ADR forms were developed and distributed to all hospital, but the reporting was not very actively. Thus in the year 2012, the FDD is implementing the pilot project on PV focus on retroviral medicines. So far Drug controls Division responsible for implementation of this activity.

F. Sale and Distribution of ethical/OTC (including traditional medicine)

According to the legislation of Lao PDR drug and medical products sold in Lao PDR must be registered at Food and Drug department Ministry of Health. However exception for registration does exist. Some medicines are waived for registration, e.g. donated medicines, medicines used for research/analysis and medicines used in the embassies. However, some important documents such as medicines registration, GMP compliance and medicine analysis for finished products of related batch certificates need to be provided.

G. Licensing pharmacist and pharmacy:

The Licensing for pharmacist to operate pharmacy is belong to Drug Business Control Division responsible for evaluating the compliance with law and regulation before issuing the license for the pharmacist for instance, we check pharmacist qualification and appropriate room and location of pharmacy . According to the article number 18 of Law and Medical Product, The sale at retail of drugs and medical products shall be conducted by authorized retail pharmacies only.

The conditions and procedures of drugs and medical products retail business operations are determined in the regulation number 482/MOH, 2003.

H. Public awareness for rational use of medicine

Currently, the IEC division takes responsibility for promoting the Ration Use of Medicines. There are 10 indicators for has been developed use us reference and monitoring tool for Prescription among physicians at hospital at central and some district levels; organized the training to the RUM taskforces. The posters on RUM were produced and distribute to all hospitals regularly.

4). Pharmacopeia:

So far Lao PDR has no pharmacopoeia yet, but in quality control test and reference document for the evaluation, we base on JP, USP, and BP as the official pharmacopoeia.

5). Requirement for Vaccine and other biological product of National Regulatory Authority in country.

Not have additional requirement.

3. Present situation and future plant in the National drug policy including essential medicine and traditional medicine.

The Food and Drug Department have established national pharmaceutical framework together with the related institutions which be based on the national drug policy in order to reach the main goal and it elements. The national pharmaceutical strategy have been set up for 5 years, the strategic plan addressed on the law and regulations development, human resource development, improvement of capacity for local

pharmaceutical manufacturers and GMP promotion, post marketing surveillance, improvement of procurement and distribution system, promotion on the use of traditional medicine, rational use of drug… The GMP promotion was set as priority task for pharmaceutical in Laos. There are 7 local factories which not yet complied with the GMP standard of regional level. The Food and Drug Department has nominated GMP inspection committee to inspect and assist local manufacturers in order to reach GMP standard by two sites during the 5 years strategic plan.

4. Pharmaceutical supply in health system and pharmaceutical price mechanism including local products, imported drug

At each health facilities in Laos have been applied revolving drug fund, the procurement practice has been performed by health facility procurement unit. Recently, the Medical Product Supply Center is organization in the Ministry of Health has responsibility for procurement of health products for health facilities in collaboration with provincial level. The pilot project launched with the 4 central hospitals to organize centralization of the procurement based on the items of drug product and medical devices were requested by the hospital. For the procurement at provincial level, there were organized by the procurement committee. The price of drugs was indicated by increasing of 25% of the procurement price. The imported drug have no price mechanism was indicated.

The Study Programme
for the Good Governance of Medicines for Pharmaceutical
Regulation Authorities

Malaysia

GOOD GOVERNANCE OF MEDICINES FOR PHARMACEUTICAL REGULATION AUTHORITIES

POSITION AND NAME OF ORGANIZATION : **SENIOR PRINCIPAL ASSISTANT DIRECTOR**
PHARMACEUTICAL SERVICES DIVISION
MINISTRY OF HEALTH

POSITION AND NAME OF ORGANIZATION : **PRINCIPAL ASSISTANT DIRECTOR**
NATIONAL PHARMACEUTICAL CONTROL BUREAU , MINISTRY OF HEALTH

NAME OF COUNTRY : **MALAYSIA**

1. STATISTICAL DATA

A) Number Of Medical Professionals

	DATA	YEAR
Doctors	36,607	2011
Dentists	4,253	2011
Opticians	2,512	2011
Optometrists	899	2011
Asst. Medical Officers	11,162	2011
Asst. Pharmacy Officers	3,534[a]	2011
Asst. Environmental Health Officers	3,394[a]	2011
Medical Lab. Technologists	5,310[a]	2011
Occupational Therapists	663[a]	2011
Physiotherapists	818[a]	2011
Radiographers	2,167[a]	2011
Nurses	74,788	2011
Dental Nurses	2,528[a]	2011
Community Nurses	22,266	2011
Dental Technologists	1,559	2011
Dental Surgery Assistants	3,279	2011
Traditional & Complementary Medicine Practitioners	13,202[b]	2011

Note:
a: Ministry Of Health only (Government)
b: Refers to registration of local and foreign practitioners

b) Number of Pharmacists

	DATA	YEAR
Public Sector	5,288	2011
Private Sector	3,344	2011
Total	**8,632**	

c) Number Of Pharmaceutical Manufacturers/ Manufacturing Sites

	DATA	YEAR
Pharmaceutical	177	June 2012
Veterinary	3	June 2012
Total	**180**	

d) Number Of Traditional Medicine Manufacturers/ Manufacturing Sites

	DATA	YEAR
Traditional	74	June 2012

e) Number Pharmaceutical Importers

	DATA	YEAR
Pharmaceutical	232	June 2012
Traditional	144	June 2012
Veterinary	1	June 2012
Total	**377**	

e) **Number Pharmaceutical Wholesalers**

	DATA	**YEAR**
Pharmaceutical	924	June 2012
Traditional	175	June 2012
Veterinary	1	June 2012
Total	**1100**	

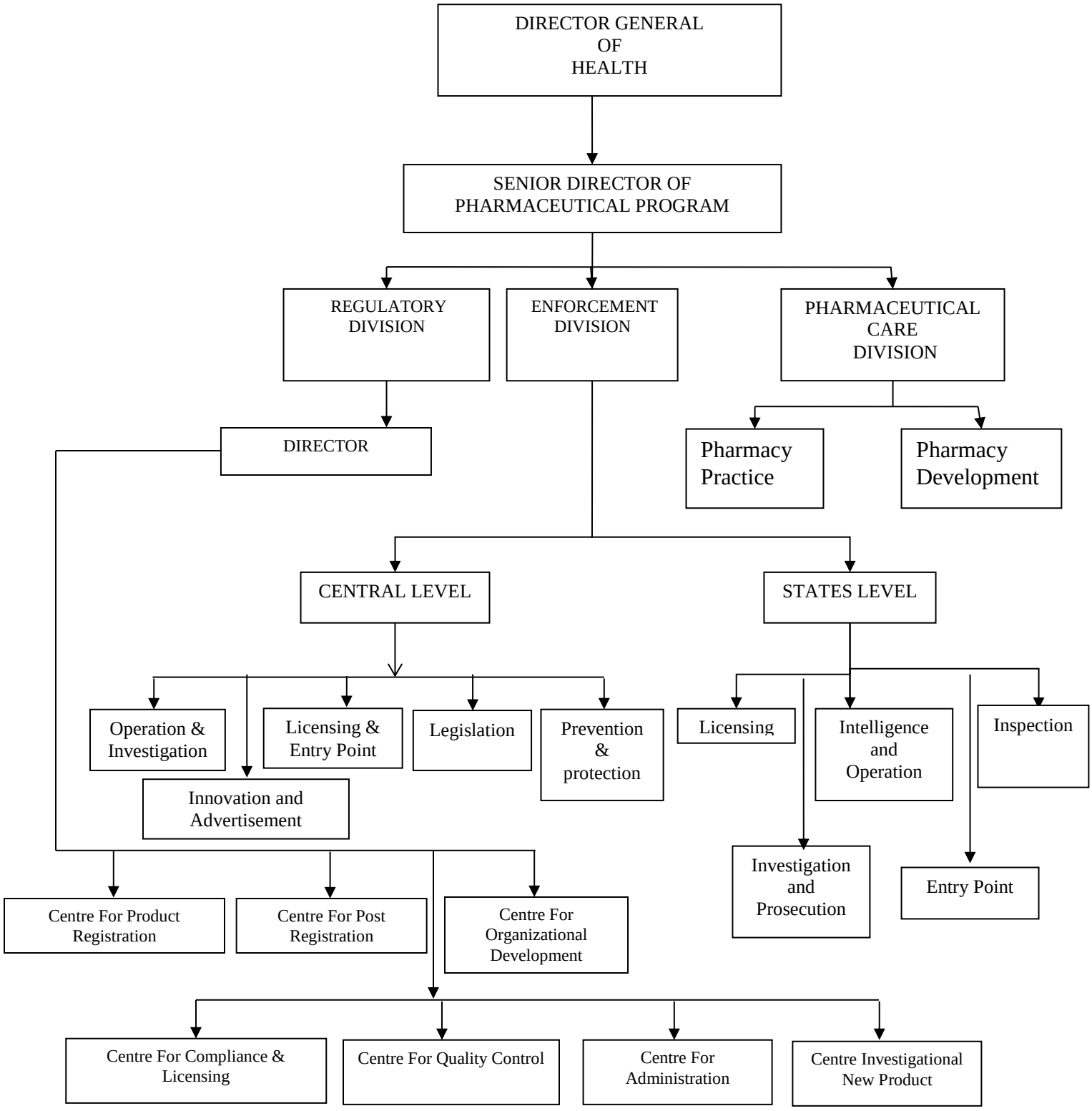
2. PHARMACEUTICAL LEGISLATION AND REGULATORY SYSTEMS

1. Legislation on Pharmaceutical Administration

The following legislations and all their regulations are being enforced by licensing and enforcement activities:

1) Poisons Act 1952 (Revised 1989) & Regulations
    - *An act to regulate the importation, possession, manufacture, compounding, storage, transport, sale and use of poisons.*
2) Dangerous Drugs Act 1952 (Revised 1980)
    - *An Act to make further and better provision for the regulating of the importation, exportation, manufacture, sale, and use of opium and of certain other dangerous drugs and substances, to make special provision relating to the jurisdiction of courts in respect of offences thereunder and their trial, and for purposes connected therewith.*
3) Sale of Drugs Act 1952 (Revised 1989) & Control of Drugs And Cosmetics Regulation 1984
    - *An Act relating to the sale of drugs.*
4) Registration of Pharmacists Act 1951 (Revised 1989) & Regulations
    - *An Act relating to the establishment of a Pharmacy Board and the registration of pharmacists.*
5) Medicines (Advertisement and Sales) Act 1956 (Revised 1983) & Regulations
    - *An Act to prohibit certain advertisements relating to medical matters and to regulate the sale of substances recommended as a medicine.*

2. Organizational Structure



The role of national/state pharmaceutical administrative organizations

The Pharmaceutical Services Division (PSD) is an independent division in the Ministry of Health. The Senior Director of the PSD is directly responsible to the Director-General of Health. Assisting the Senior Director of PSD at the headquarters are three Directors for Enforcement and Licensing, Pharmacy Practice and Organisational Development and Regulatory.

The 14 states have a PSD office at each of the major cities/towns and a Deputy Director of Health (Pharmacy) oversees the administration of the pharmacy services of each state (inclusive of hospital, clinics and enforcement and licensing activities).

The roles of PSD are:

i. Contributes directly to public health by establishing and implementing the national drug registration system besides regulating the pharmaceutical industry through the National Pharmaceutical Control Bureau (NPCB) that assures the quality of medicines in the country.

ii. Protects consumers from hazardous drugs, misleading medicine advertisements and unscrupulous practices through the enforcement of related drug and pharmacy legislation that control the importation, sale and advertisement of drugs and the practices of pharmacy in the country.

iii. Provides comprehensive pharmaceutical care by ensuring efficient selection, procurement, distribution of pharmaceuticals; ensuring rational, cost-effective and optimal use of medicines through effective up-to-date clinical and professional pharmaceutical services in tandem with the current global development.

iv. Consolidates the pharmaceutical sector activities through the implementation of the National Medicines Policy.

3. Pharmaceutical Regulatory Services

Regulatory control of pharmaceuticals

The National Pharmaceutical Control Bureau (NPCB) carries out the regulatory control of pharmaceutical. The function of NPCB is to ensure safety, efficacy and quality of drugs; safety and quality of traditional medicines and cosmetics marketed locally.

of products, investigation on complaints and monitoring of adverse drug reaction.

Roles and Functions of NPCB are:

i. To implement the drug registration / cosmetic notification scheme through evaluation of technical data, laboratory analysis, research and information received from international agencies.

ii. To carry out analytical, pharmaceutical, microbiological and pharmacological tests on drugs and cosmetics to determine quality, efficacy and safety of such products.

iii. To implement the regulatory scheme on quality of pharmaceutical products in the market through random sampling and carrying out analytical tests.

iv. To implement the licensing scheme for pharmaceutical manufacturers, importers and wholesalers including a licensing scheme for clinical trial.

v. To encourage and assist local pharmaceutical manufacturers to upgrade manufacturing standards to levels equivalent to the requirements of Good Manufacturing Practice as recommended by the World Health Organisation (WHO).

vi. To manage the Adverse Drug Reaction Monitoring Program and participate in the WHO International Adverse Drug Reaction Monitoring Program.

vii. To manage the product recall scheme for pharmaceutical products which are found to be substandard or dangerous to consumers.

viii. To disseminate information on policies/news of the Drug Control Authority (DCA) via the newsletter as well as provide service in the aspect of explaining to the public on the process of on-line registration, information on registered products and other queries pertaining to NPCB.

ix. To carry out research on methodology and basic research for the purpose of evaluating quality, efficacy and safety of drugs/ cosmetics.

x. To establish a reference standard system specially for use in this country generally and for neighbouring countries through a scheme of cooperation in the field of pharmaceuticals among ASEAN countries.

xi. To carry out training for pharmaceutical officers, other professional officers and other semi-professional officers who are placed in this institution from time to time through local training scheme or international co-operational scheme.

There are seven centers under NPCB:

No.	Center	Number of Staff
1.	Centre For Administration	18
2.	Center For Product Registration	59
3.	Center For Post Registration	29
4.	Center For Compliance And Licensing	18
5.	Centre For Quality Control	47
6.	Centre For Organizational Development	14
7.	Centre Investigational New Product	11

3(a) Licensing of Manufacturing site and product qualification/registration

Licensing of manufacturing

The Drug Control Authority (DCA) is the executive body established under the Control of Drugs and Cosmetics Regulations 1984.The main task of this Authority is to ensure the safety, quality and efficacy of pharmaceuticals, health and personal care products that are marketed in Malaysia.

This objective is being achieved through the following:

- Registration of pharmaceutical products and cosmetics
- Licensing of premises for importer, manufacturer and wholesaler
- Monitoring the quality of registered products in the market
- Adverse Drug Reaction Monitoring

According to the Controls of Drugs and Cosmetics Regulations 1984, any company that want to manufacture any registered products need to have Manufacturer's Licence with the Drug Control Authority (DCA). A premise with Manufacturer's Licence is allowed to manufacture registered products and to sell by wholesale or supply their products.

Product qualification/registration

The Control of Drugs and Cosmetics Regulations 1984 empowers the DCA to implement the registration scheme in phases i.e.

Phase 1: Pharmaceutical products which contain scheduled poisons as defined in the Poisons Act 1952 (1st November 1985).

Phase 2: Pharmaceutical products that do not contain scheduled poisons, other than traditional medicines (1st August 1988)

Phase 3: Traditional medicines (1st January 1992)

Phase 4: Cosmetics

- hair dyes containing phenylenediamine, toluenediamine, salt and derivatives (1 st August, 1991)
- tooth whiteners containing hydrogen peroxide / carbamide peroxide (1st February,1996)
- all cosmetic products other than listed above (1st February 2002)

Cosmetics registration was replaced by the Notification Procedure as of 1 Januari 2008

Phase 5: Registration - Veterinary (Aug 2007)

Phase 6: Registration beginning with NCE (Jan 2012)

The DCA also ensures that all registered / notified products are labelled according to stipulated labelling requirements.

3(b) Regulation on clinical trials conducted

Clinical trials that is conducted in Ministry of Health (MOH) facility or involve MOH personnel or funded by MOH research grant must be register with National Medical Research Register (NMRR). Registration of clinical trials is very much an international norm and is endorsed by both the International Committee of Medical Journal Editors and the World Health Organization. This is to ensure transparency and to increase public trust and confidence in the conduct of medical research as well as to inform physicians and prospective volunteers about ongoing/future research in which they may wish to enroll.

The registration schemes enable MOH management to document the level of research activity in the MOH, and also to track the progress of the researches it has approved and/or provided support such as funding

3(c) Pharmaceutical Inspection for Compliance with Good Manufacturing Practice (GMP)

According to the Control of Drugs and Cosmetics Regulations 1984, compliance to Good Manufacturing Practice is a pre-quisite for the application of a manufacturing license as well as product registration/ cosmetic notification.

Good Manufacturing Practice (GMP) is a standard that should be followed by manufacturers of registered pharmaceutical/ traditional products and notified cosmetics to ensure that the product manufactured is safe, efficacious and of quality.

Centre for Compliance and Licensing (CCL) of NPCB is responsible for the Good Manufacturing Practice (GMP) inspections of manufacturers of registered products and notified cosmetics to ensure manufacturers compliance towards the current GMP requirements. CCL, with the assistance of the State Pharmacy Enforcement Division, is responsible for ensuring the importers and wholesalers of registered products adhere to the current Good Distribution Practice (GDP) requirements.

Generally, GMP compliance is rated as Good, Satisfactory or Poor. The level of compliance is determined by the weaknesses / non-conformances found during an inspection. The frequency for inspection is determined according to the level of risk of the product manufactured, as well as the latest GMP compliance rating.

3(d) Prevention and control of substandard , spurious, falsely-labeled, falsified, counterfeit medical products.

All products in Malaysia must undergo registration process with the Drug Control Authority. Product means:

(a) a drug in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a medicinal purpose; or

(b) a drug to be used as an ingredient of a preparation for a medicinal purpose.

Registered products will carry a registration number and hologram stickers. The number is uniquely given for each product. The number can be checked through NPCB website where the registered products are listed. A decoder was used to identify the genuine hologram.

Public and private pharmacists were given the awareness on the usage of hologram and decoder to identify the genuine medicines. A total of 1700 private pharmacies were provided with meditag hologram decoder for public use

The State Pharmacy Enforcement Division is responsible for ensuring all products in market are registered products through routine inspections, raiding, and sampling on the premises that sell products. Premises which sell unregistered will be charged in court.

3(e) Post-Marketing Surveillance (PMS) for monitoring adverse drug reaction.

Active product monitoring via the Post Market Surveillance (PMS) program is conducted by the authority to ensure that only safe products are being marketed. The activities consist the following:

1. Screening of product formulation and information
2. Audit on the Product Information File (PIF) for compliance with the regulations
3. Sample collection, testing and monitoring of label compliance
4. Audit of premises to ensure compliance with Guidelines Investigation of complaints
5. Initiation of warning and information sharing system between ASEAN countries
6. Monitoring of adverse reactions reported by Healthcare Professionals or consumers.
7. Monitoring of product advertisement

3(f) Sale and distribution of ethical/OTC medicines (including traditional medicines).

Registered products including OTC medicines and traditional medicines can only be distributed by a licensed wholesaler whose license is issued by DCA but, the sale of these products is not control. Any premise or individual can sell these medicines as long as they are registered.

3(g) Licensing pharmacist and pharmacy.

All pharmacists in Malaysia must be registered with the Board of Pharmacy with a practice certificate renewed annually. A license called Type A license is issued to a pharmacist to import, store and deal generally by wholesale and retail or by wholesale only or by retail only in all poison listed in Schedule 1 of The Poisons Act 1952. Type A license is issued to a pharmacist at a premise by the Enforcement Branch of each state after a satisfactory inspection been conducted. The premise must be registered with the local council/authority or Companies Commission of Malaysia before it can be operated as a business premise.

Pharmacists working with the Government of Malaysia are required to apply for a Type A license but they still need to have a practice certificate renewed yearly.

3(h) Public awareness for rational use of medicines.

Continuous educational activities were conducted for the public in both urban and rural area to empower consumers with knowledge and information towards rational use of medicines. Dissemination of information via electronic and printed media increased the knowledge and awareness or targeted groups.

The Quality Use of Medicine-Consumer (QUM-C) is a strategy to support the forth component of Malaysian National Medicines Policy (MNMP) which is Quality Use of Drugs. The main objective of QUM-C is to educate consumers on the rational use of medicine. This will increase their knowledge and skill so that they are able to make informed decisions. Further objective is to encourage consumers to play a more active part on drug related issues and subsequently be responsible to their own. The activities have been actively carried out as state level so that project impact can be spread out to each and every public stratum.

In year 2009 the Know Your Medicine campaign has been implemented actively and widely at state level in order to ensure awareness activities and information on medicines are well disseminated to the public. The activities conducted are in the form of campaign launchings, seminars, exhibitions, dialogues and radio talks.

The Training of Trainers Workshop has been organized in every state since 2007 to train and lead pharmacist of every state to carry out the activities in a standard and structured manner.

4. Pharmacopoeia

Malaysia has no pharmacopeia of her own. For reference the following pharmacopoeias are used

i) British National Pharmacopoeia

ii) United States Pharmacopoeia

iii) The Martindale.

5. Additional Requirement for vaccines and other biological products

1. Guidelines for the Pharmacovigilance on Safety of Vaccines in Malaysia. These guidelines encompass the operation of the Pharmacovigilance Program on the Safety of Vaccines. The National Immunization Technical Committee is established by the Ministry of Health (MOH) Malaysia to plan, monitor and review strategies, programs, targets and achievements of the immunization programs in the country.
2. Guidelines for application for registration of biological/ biotechnology product:

   The additional requirements for registration of Biotechnology Products, Vaccines and Blood Products

   Comply with WHO requirements for the product as can be found in the WHO Technical Report Series, including:

   - Control of starting materials, including baseline data both on the host cell and on the source, nature and sequence of the gene used in the production. A well-characterized, clean starting material.
   - Control of the manufacturing process.
   - Control of the final product.
   - Stabilisation and storage.
   - Viral Safety Evaluation.

3. PRESENT SITUATION AND FUTURE PLAN OF THE NATIONAL MEDICINE POLICY, INCLUDING ESSENTIAL MEDICINE AND TRADITIONAL MEDICINE

National Medicines Policy (NMP) has been approved to become the country's Medicines Policy in October 2006 with aims to promote equitable access to, and rational use of, safe, effective and affordable essential drugs of good quality to improve health outcomes of the people. The full term review of NMP has been conducted to present the activities accomplished throughout the first term of Malaysian NMP 2006-2012.

The NMP consists of five main components with aim and strategies as below:

Main Component		Aim	Strategy
1.	Quality, Safety and Efficacy of Drugs	To ensure that drugs marketed for patient care are safe, effective and of high quality so as to meet the health needs of the nation	Strengthening the drug regulatory system through a comprehensive drug legislation framework and enhancement of pharmaceutical quality assurance measures.
2.	Drug Availability and Affordability	• To ensure an equitable, adequate and continuous availability of safe, effective and quality essential drugs to the entire population • To ensure continuous access and financial sustainability of essential drugs at prices affordable to all	• Careful selection of medicines, improvement in the management of drug procurement and the supply chain, and through optimal utilization of available financial resources. • Implementing cost-containment measures and developing appropriate and reliable financing mechanisms to ensure equitable access to essential drugs for the population.
3.	Quality Use Of Drugs	To contribute towards quality of care and cost-effective therapy	Training and education for healthcare providers and public, provision of independent and evidence-based drug information establishment of therapeutic committees, development of standards of professional practice, ethical promotion of drugs and provision of relevant legislation

4.	Human Resources Development, Research & Development, Technical Cooperation	To ensure partnership and collaboration of all stakeholders in the healthcare industry conforms to best practices and standards pertaining to medicines at national, regional and international levels.	The aim shall be achieved by: 1. Early and continuous engagement of all relevant stakeholders. 2. Ensuring sustainability of qualified, competent and effective human resource based on needs through: ▪ Training and development ▪ Development and advancement of professional career pathway 3. Sharing of information, expertise, skills and facilities. 4. Developing and updating legislation, regulation and guidelines to sustain the applicability of the policy.
5.	Governance in Medicines	• To have appropriate governance that ensures the provision of safe, effective and affordable medicines within the best practice environment.	• Health professional bodies and relevant stakeholders should have code of conducts and be responsible to ensure compliance by its members with the code • Stakeholders perform in accordance with standard of

		• To ensure all stakeholders are responsible in conducting themselves in an ethical and professional manner • To ensure regulations facilitate and support the provision of safe, effective and affordable medicines	practice developed by appropriate authorities/ relevant professional bodies. Compliance with the standards should be supported by legislation where appropriate. • Relevant legislations/ regulations should be developed and/or reviewed to ensure and efficient and integrated medicines management and supply chain network that protects the public.

4. PHARMACEUTICAL SUPPLY IN HEALTH SYSTEM AND PHARMACUETICAL PRICING MECHANISM FOR UNIVERSAL HEALTH COVERAGE IN THE COUNTRY

Pharmaceutical Supply in Health System

The pharmaceutical service in hospitals and health clinics under the Ministry of Health Malaysia aims to provide comprehensive patient-centred pharmaceutical care.

Pharmacy Ambulatory Services stress on quality use of medicines, promotion of healthy lifestyle and provision of innovative services to give a positive impact in view of the patients' perspectives and expectations. Various activities and drug delivery systems have been introduced to minimize medication errors, promote patients' compliance and assist patients in getting access to their medications.

The Clinical Pharmacy Services have also been expanded to include Medication Therapy Adherence Clinic, Methadone Dispensing and Counseling, Ward Pharmacy Service, Drug Information Service, Clinical Pharmacokinetic Service, Total Parenteral Nutrition Service, Oncology Pharmacy Service and Nuclear Pharmacy Service.

The pharmacy services in primary care facilities include Basic Pharmacy Services: Include prescriptions screening, drug dispensing, patient counseling, procurement, health promotion, health education and drug information. Extension and Expansion of Pharmacy Services; include Medication Therapy Adherence Clinic, Methadone Maintenance Therapy Programme and Home Medication Review

There are also other types of supply systems include:

The Integrated Drug Dispensing System introduced in the year 2005 to facilitate the supply of refill medicines to patients on long term therapy. Through these dispensing systems patients can get their refill medications from any Ministry Of Health facilities of their choice.

Other supply systems: Appointment Card System, Phone & Take System, SMS & Take System, Pharmacy Drive Thru System and Pharmacy Home Delivery System via Courier Service. These dispensing systems aim to reduce patient waiting time and facilitate patients on chronic therapy who received monthly supplies of their medications.

Pharmaceutical Pricing Mechanism for Universal Health Coverage

As drugs price is a contentious issue the government is of the opinion that it should be handled very carefully. The Pharmaceutical Services Division (PSD) has set up a Price Monitoring Unit to conduct price monitoring for the country. Expert was brought to the country to train pharmacists on how to conduct price monitoring.

The price monitoring activities will ensure that as the price of drugs become transparent to prescribers and users, and this will encourage self-regulation by the distributors. At the same time, the authorities are also looking into other mechanisms of drug control.

The Medicine Price Database is being developed. Currently, the medicines price data, comprising of categories as below, are continuously compiled and updated.

i.	Fee Act (Full Paying Patient)	vi	National Essential Drug Price List (Public)
ii	Private Retail Price	vii	National Essential Drug Price List (Private)
iii	Public Wholesale Price	viii	Traditional Wholesale Price
iv	Private Wholesale Price (Controlled Medicines)	ix	Recommended Retail Price (RRP)
v	Private Wholesale Price (OTC)	x	Government Procurement (GP) Price

Newly listed medicines in the Ministry of Health (MOH) Drug Formulary are subjected to price monitoring. To further strengthen this monitoring procedure, firms requested for their medicines to be listed in the MOH Drug Formulary are required to submit their quotation of selling price to MOH facility if the aforementioned medicines have been successfully listed in the MOH Drug Formulary. The medicine price sold to MOH facilities should not exceed the said quotation for at least one a year. After that, any price increments will be monitored by the Medicines Price Determination Unit. The review is done once a year continuously by obtaining feedback from MOH hospitals. In the event where the medicines price is more than the predetermined price, the related firm is obliged to provide explanation regarding this issue and take corrective actions such as credit notes provision or reimbursement in the form of medicines

The Study Programme
for the Good Governance of Medicines for Pharmaceutical
Regulation Authorities

Philippines

REPUBLIC OF THE PHILIPPINES

COUNTRY REPORT

Training on Good Governance of Medicines for Pharmaceutical Regulation Authorities

04 November to 29 November 2012

Food-Drugs Regulation Officer- III
Food and Drug Administration
Department of Health
Philippines

I. The Philippines: Background

The Philippines is located in Souteast Asia and divided by 7,107 various islands and speaks the varied attitude but with a common culture of being hospitable. This is located in between the South China Sea on the west and the Philippine Sea on the east. The major islands are Luzon in the north, the Visayan Islands in the middle, and Mindanao in the south. The total area is about 300,000 square kilometers, including about 298,000 square kilometers of land and about 2,000 square kilometers of water.

The Philippines has a tropical marine climate, with the northeast monsoon, which produces a cool, dry season from December to February, and the southwest monsoon, which brings rain and high temperatures from May to October. Between March and May, hot, dry weather prevails. Manila is the capital city and Baguio City as the summer capital of this country. Temperatures in Manila range from 21˜2˜C to 3C, with an average annual temperature of 27˜C. Temperatures elsewhere in the Philippines have been recorded at more than 37˜C. The average monthly humidity ranges from 71 percent in March to 85 percent in September. Annual rainfall is heavy but varies widely throughout the Philippines, ranging from 965 millimeters in some sheltered valleys and the southern tip of the island of Mindanao to 5,000 millimeters along the mountainous east coasts of the islands of Luzon, Samar, and the northern tip of Mindanao. The Philippines lies astride the typhoon belt and experiences 20 to 25 typhoons a year from July through October, of which five or six may cause serious destruction and death. About 83 percent of the population is Roman Catholic; 9 percent Protestant, including Presbyterian, Methodist, Philippine Independent Church, and Philippine

Church of Christ; 5 percent Muslim; and 3 percent Buddhist and other religions. The constitution guarantees freedom of religion and separation of church and state. But Christianity predominates, and Muslims historically have been marginalized.

The group constituting more than 90% of the population is predominantly Roman Catholic, although the Philippine Independent Church and the Iglesia ni Cristo command significant followings. The hill tribe practice tribal religions and Islam is strongest in the Sulu Archipelago, Southern Palawan, and parts of Southern Mindanao.

The Philippines has two official languages, Pilipino (Tagalog) and English, while in Visayas and Mindanao the common language is Bisaya (or Cebuano speaking). Filipinos has eight major dialects, in order of use: Tagalog, Cebuano, Ilocano, Hiligaynon or Ilonggo, Bicol, Waray-waray, Pampango, and Pangasinense. Filipino, based on Tagalog, is related to Malay and Indonesian and is part of the Malayo-Polynesian subgroup of the Austronesian language family. Filipino is the common language used between speakers of different native languages, which are closely related but not mutually intelligible. English and Pilipino are used in the government and as the medium of instruction in higher education.

This year, Department of Education commenced Grade Seven making it seven years of primary education which is basically free and compulsory; the four-year secondary education program is free but not compulsory. The Philippines has one of the highest literacy rates in Asia. The many colleges and universities include the University of the Philippines (1908) and

the University of Sto. Tomas (1611). Higher education is greatly valued, although the economy cannot absorb all college graduates.

Article II of the 1987 Constitution of the Republic of the Philippines explicitly states that the Filipino political system is both democratic and republican, placing the right to govern with the people. The Philippines has a government that is elected by the people who retain some form of control over the running of the state.

Republican - Article VI of the Philippines Constitution vests "legislative power" in the Congress, giving Congress the power to create laws. The President's power is derived from Article VII of the Constitution, allowing him the authority to appoint Congressmen during recesses as well as the executive departments similar to the President's cabinet in the United States. As commander-in-chief, the Filipino President ensures civilian control of the military.

Democratic - The government of the Republic of the Philippines is elected by the people, and any authority given to the government comes from the people as stated in the Philippine Constitution. Members of the executive and legislative branches of government are elected by the people to serve predetermined terms of office. Article VII mandates that the President and Vice President of the Philippines be elected through a direct election by the people. The President may only serve one six-year term. Members of Congress are elected by the citizens in their individual districts.

All economic activities in the country give yearly a final output of goods and services. This 'GNP per capita' shows the general economic achievement of a country. The figure of the

GNP for the Philippines shows that the country is ranking somewhere in the middle position of all countries in Pacific Asia.

The rich body of indigenous artistic traditions includes folktales, music, and the folk dances made famous by the Bayanihan Dance Troupe. Painting and Sculpture often combine Asian & Western elements. Spanish and English have been the vehicles for such writers as Jose Rizal, N.V.M. Gonzalez, Bienvenido Santos, and F. Sionil Jose.

II. STATISTICAL DATA

II.A. Philippines Demographics Profile as of 2012

Population	103,775,002 (July 2011 est.)
Age structure	**0-14 years:** 34.6% (male 17,999,279/female 17,285,040) **15-64 years:** 61.1% (male 31,103,967/female 31,097,203) **65 years and over:** 4.3% (male 1,876,805/female 2,471,644) (2011 est.)
Median age	**total:** 22.9 years **male:** 22.4 years **female:** 23.4 years (2011 est.)
Population Growth Rate	1.873% (2011 est.)
Net migration rate	-1.27 migrant(s)/1,000 population (2011 est.)
Urbanization	**urban population:** 49% of total population (2010) **rate of urbanization:** 2.3% annual rate of change (2010-2015 est.)
Sex ratio	**at birth:** 1.05 male(s)/female **under 15 years:** 1.04 male(s)/female **15-64 years:** 1 male(s)/female **65 years and over:** 0.76 male(s)/female **total population:** 1 male(s)/female (2011 est.)
Total fertility rate	3.15 children born/woman (2011 est.)
HIV/AIDS - adult prevalence rate	less than 0.1% (2009 est.)
HIV/AIDS - people living	8,700 (2009 est.)

with HIV/AIDS	
HIV/AIDS - deaths	fewer than 200 (2009 est.)
Major infectious diseases	**degree of risk:** high **food or waterborne diseases:** bacterial diarrhea, hepatitis A, and typhoid fever **vectorborne diseases:** dengue fever, malaria, and Japanese encephalitis **water contact disease:** leptospirosis (2009)
Nationality	**noun:** Filipino(s) **adjective:** Philippine
Ethnic groups	Tagalog 28.1%, Cebuano 13.1%, Ilocano 9%, Bisaya/Binisaya 7.6%, Hiligaynon Ilonggo 7.5%, Bikol 6%, Waray 3.4%, other 25.3% (2000 census)
Religions	Roman Catholic 80.9%, Muslim 5%, Evangelical 2.8%, Iglesia ni Kristo 2.3%, Aglipayan 2%, other Christian 4.5%, other 1.8%, unspecified 0.6%, none 0.1% (2000 census)
Languages	Filipino (official; based on Tagalog) and English (official); eight major dialects - Tagalog, Cebuano, Ilocano, Hiligaynon or Ilonggo, Bicol, Waray, Pampango, and Pangasinan
Literacy	**definition:** age 15 and over can read and write **total population:** 92.6% **male:** 92.5% **female:** 92.7% (2000 census)
School life expectancy (primary to tertiary education)	**total:** 12 years **male:** 12 years **female:** 12 years (2008)
Education expenditures	2.8% of GDP (2008)
Health Expenditures	3.8% of GDP (2009)

II.B. VITAL STATISTICS

1. Rate of vital Statistics (per 1,000 population)		
1.1 Infant Mortality Rate	**total:** 18.75 deaths/1,000 live births **male:** 21.21 deaths/1,000 live births **female:** 16.18 deaths/1,000 live births (2011 est.)	
2. Five Main Diseases Causing Morbidity	No. of Cases	Rate/100,000
2.1. Acute Lower Respiratory Tract Infection & Pneumonia	776,562	971.6
2.2. Bronchitis/Bronchiolitis	719,982	900.8
2.3. Acute Watery Diarrhea	577,118	722.0
2.4. Influenza	379,910	475.3
2.5. Hypertension	342,284	428.2
3. Five leading causes of mortality	No. of Cases	Rate / 100,000
3.1. Diseases of the Heart	70,138	17.7
3.2. Diseases of the Vascular System	49,519	12.5
3.3. Malignant Neoplasms	38,821	9.8
3.4. Pneumonia	34,218	8.6
3.5. Accidents	33,617	8.5
4. Life expectancy at birth	**Total population:** 71.94 years **male:** 68.99 years **female:** 75.03 years (2011 est.)	
5. Maternal Mortality Rate	94 deaths/100,000 live births (2008)	
6. Children under the age of 5 years underweight	20.7% (2003)	
7. Physician's Density	1.153 physicians/1,000 population (2004)	
8. Hospital Bed Density	0.5 beds/1,000 population (2006)	
9. Obesity - adult prevalence rate	4.3% (2003)	

2 MEDICAL CARE POLICY

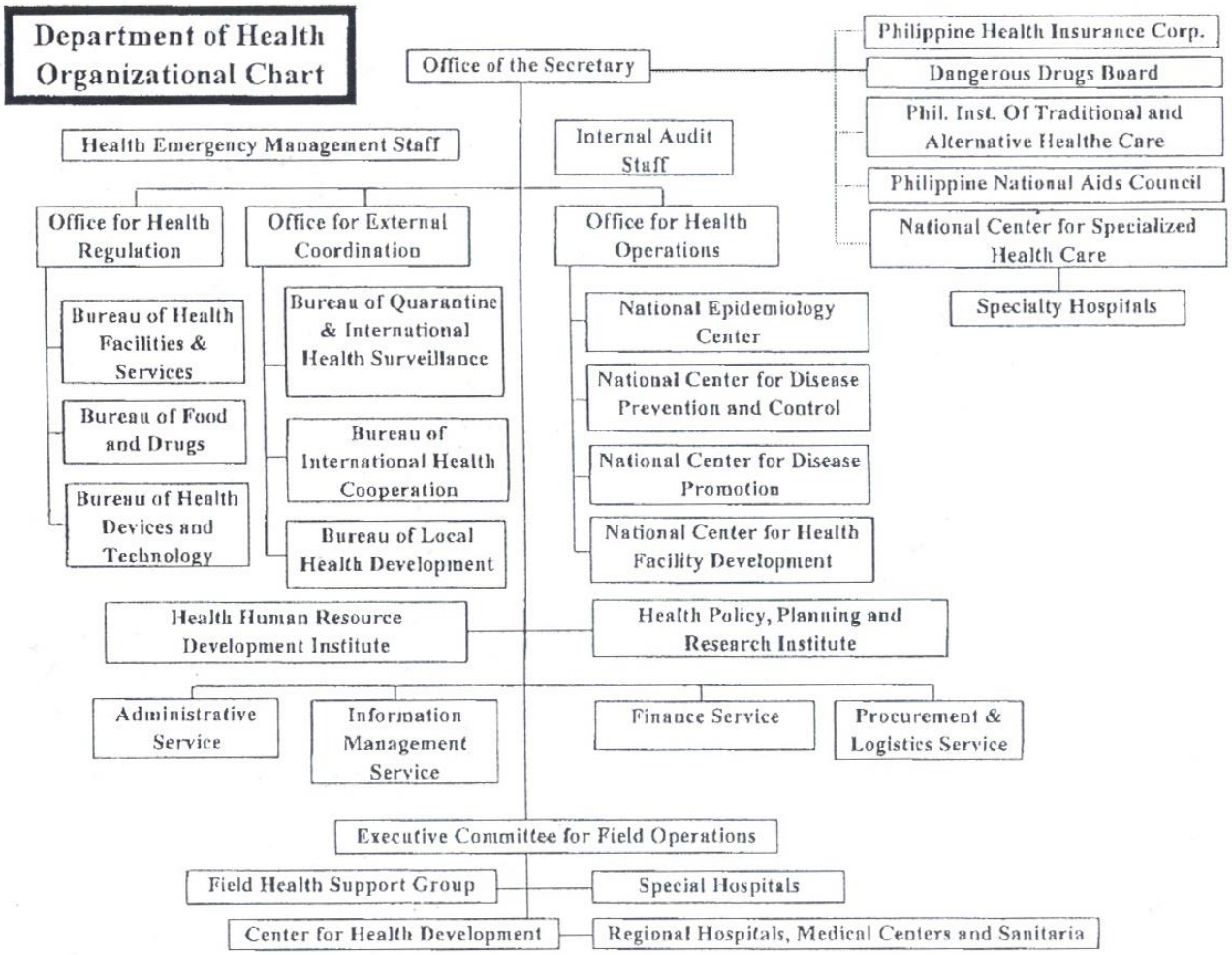
1.1 Estimated No. of Patients who Received Medical Treatment on the Specified Date 3.1.1. Government Hospital 3.1.2. Public Hospital 3.1.3. Private Hospital	
1.2 No. of Hospitals by Establishing Organ (1999-2009) 3.2.1. Government Hospitals 3.2.2. Private Hospitals	721 1,074
1.3 No. of Health Manpower	
3.3.1. Physicians (year)	
2005-2010	106,450
3.3.2. Dentists (year)	
2005-2010	47,337
3.3.4. Pharmacists (year)	
2005-2010	52,312
3.3.5. Nurses (year)	
2005 - 2010	382,624
3.3.6. Medical Technologists (year)	
2005- 2010	49,605
3.3.7. Midwives (year)	
2005 -2010	242
3.3.8. (Licensed)Pharmaceutical Manufacturing (year)	
2012	302
3.3.9. (Licensed) Traditional Medicine Manufacturers (year)	
2012	8
3.3.10. (Licensed) Drug Importers (year)	
2012	748
3.3.11. (Licensed) Wholesalers (Year)	
2012	5,090

3 PHARMACEUTICAL AFFAIRS ADMINISTRATION

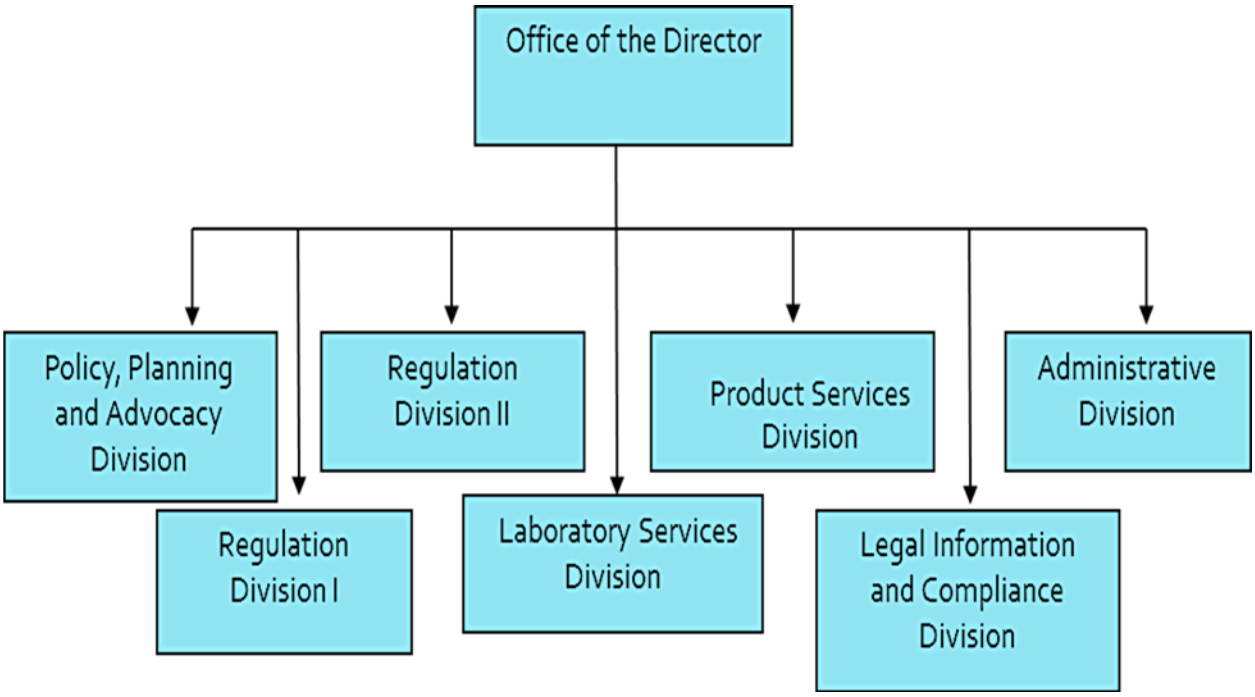
IV.1. ADMINISTRATIVE ORGANIZATION CHARTS
(Please see attached pages)

IV-1.1 DEPARTMENT OF HEALTH

IV-1.2 FOOD AND DRUG ADMINISTRATION


Department of Health
Organizational Chart
Office of the Secretary
Philippine Health Insurance Corp.
Dangerous Drugs Board
Phil. Inst. Of Traditional and Alternative Healthe Care
Philippine National Aids Council
National Center for Specialized Health Care
Specialty Hospitals
Health Emergency Management Staff
Internal Audit Staff
Office for Health Regulation
Office for External Coordination
Office for Health Operations
Bureau of Health Facilities & Services
Bureau of Food and Drugs
Bureau of Health Devices and Technology
Bureau of Quarantine & International Health Surveillance
Bureau of International Health Cooperation
Bureau of Local Health Development
National Epidemiology Center
National Center for Disease Prevention and Control
National Center for Disease Promotion
National Center for Health Facility Development
Health Human Resource Development Institute
Health Policy, Planning and Research Institute
Administrative Service
Information Management Service
Finance Service
Procurement & Logistics Service
Executive Committee for Field Operations
Field Health Support Group
Special Hospitals
Center for Health Development
Regional Hospitals, Medical Centers and Sanitaria

ORGANOGRAM OF FOOD AND DRUG ADMINISTRATION



- **Bureau of Food and Drugs (BFAD)**
  - Republic Act No. 3720 was passed into law known as the " Food, Drug and Cosmetics Act" on June 22, 1963 ; " To ensure the safety, purity, and quality of foods, drugs and cosmetics being made available to the public"
- **Legal Basis**
  - 1987 Philippine Constitution

Sec. 12, Article XIII "*The state shall establish and maintain an effective food and drug regulation system and undertake appropriate health, manpower development, and research, responsive to the country's health needs and problems."*

- **STRATEGIES**
  - Inspection and licensing of establishments dealing with food, drugs, medical devices, cosmetics, *in vitro* diagnostic reagents, and household hazardous substances.
  - Evaluation, testing and registration of products.
  - Approval of product label prior to marketing.
  - Monitoring of quality of products in the market.
  - Evaluation and monitoring of sales promotion and advertisements of regulated products and establishments.
- **FUNCTIONS**
  - Develops plans, policies and programs pertaining to the regulation of processed foods, drugs, and other related products.
  - Provides technical information and assistance to clients and the general public on matters pertaining to food drug, and cosmetics laws, regulations, functions and services.
- **Republic Act No. 9711**
- An Act Strengthening and Rationalizing the Regulatory Capacity of the Bureau of Food and Drugs (BFAD) by Establishing Adequate Testing Laboratories and Field Offices, Upgrading its Equipment, Augmenting its Human Resource Complement, Giving

Authority to Retain Its Income, Renaming it the Food and Drug Administration (FDA), Amending Certain Sections of Republic Act No. 3720, As Amended, and Appropriating Funds Thereof.

3.1 LAWS/REGULATIONS COVERING PHARMACEUTICAL AFFAIRS

3.1.1 PRODUCT REGULATIONS

3.1.1.1 **Republic Act 3720** - Food, Drug and Cosmetic Act later amended by EO 175 otherwise known as Foods, Drugs, and Devices and Cosmetics Act- an act to ensure the safety and purity of food and cosmetic and the purity, safety, efficacy and quality of drugs and devices being made available to the public vesting BFAD with the authority to administer and enforce the law.

3.1.1.2 **Republic Act 6675** - Generics Act of 1988- it is an act to promote, require to ensure the production of an adequate supply, distribution, use and acceptance of drugs and medicines identified by their generic name.

3.1.1.3 **Republic Act 8203** - Special Law on 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.

3.1.2 PROFESSIONAL REGULATIONS

3.1.2.1 **Republic Act 5921** - Pharmacy Act as amended by E.O. 174 s. 1987 - the act regulating the practice of pharmacy and setting standard of pharmaceutical education in the Philippines and other purposes.

3.1.3 HEALTH PROMOTION & REGULATIONS

3.1.3.1 Health Establishments Regulations

3.1.3.1.1 **Republic Act 4226-** an act requiring the licensure of all hospitals in the Philippines and authorizing the Bureau of Licensing and Regulations**.**

3.1.3.1.2 **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.

3.1.3.1.3 **Administrative Order No. 56 s. 1989-** Licensing requirements for securing BFAD License to Operate.

3.1.3.1.4 **Administrative Order No. 43- s. 1999- an 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.

3.1.3.1.5 **Administrative Order No. 90 s. 2002-** current Good Manufacturing Guidelines for Cosmetics Products- linient guidelines for cosmetics as compared with A.O. 43-A s. 1999.

3.1.3.2 **TRADITIONAL MEDICINES**

3.1.3.2.1 **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.

3.1.3.2.2 **Administrative Order 12 s. 1993-** Traditional Medicine Program for promotion and development of traditional medicines that has been found safe and effective.

3.1.3.3 HEALTH ECONOMICS

3.1.3.3.1 **Section 2.3 BFAD Regulation No. 5 s. 1987 and A.O 65 s. 1989-** No pharmaceutical products 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.

3.1.3.3.2 **Article 116 of Republic Act 7394 or the Consumer Act of the Philippines-** 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.

3.1.3.3.3 **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 prescriptions drugs, it should be clearly stated that this product can be bought only with a prescription and a doctor’s advice shall be sought.

3.1.3.3.4 **A.O 119 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 effect are also cited. Moreover, it is the intention of R.A 6675 or the Generic Act of 1988, to promote drug safety by minimizing duplication medications and/or use of drugs with potentially adverse drug reaction.

3.2 LICENSING SYSTEM

4.3.1. PHARMACEUTICAL INSPECTION AND GMP

The Food and Drug Administration is the regulatory agency under the Department of Health, responsible for ensuring that the products distributed in the market by licensed establishments has met the basic GMP requirements based on A.O. 43 s. 1999 and the ASEAN Code of GMP. Through the assistance of AUSAID, a Senior GMP Auditor of Therapeutic Good Administration (TGA) came to Manila to conduct a comprehensive training on GMP and other relevant codes were extensively renewed and discussed. It was in this occasion that drug inspectors realized that the written supplement to the existing guidelines was deemed vital both to the pharmaceutical industry and the regulators since BFAD also envisions to be a world class regulatory agency.

Basic GMP Guidelines:

4.3.1.1. Personnel – should be adequate in number and qualified at all levels and provided with skills and capabilities relevant to their respective functions.

4.3.1.2. Premises – it must be of suitable size, design, construction and location to facilitate proper operation, cleaning and maintenance.

4.3.1.3. Equipment – it shall be of appropriate design, construction, size and suitably located in order to assure product quality, process reproducibility and facilitate cleaning & maintenance.

4.3.1.4. Sanitation & Hygiene – high level of sanitation shall be practiced in every aspect of manufacturing drug products.

4.3.1.5. Storage of Starting & Packaging Materials, Intermediate Bulk Products & Finished Products

4.3.1.6. Production

4.3.1.7. Packaging

4.3.1.8. Finished Product Quarantine & Delivery to Warehouse – the finished product is quarantined before the product is transferred to the warehouse and becomes available for distribution to the market.

4.3.1.9. Quality Control - it is essential part of GMP to provide assurance that products will be consistently of quality appropriate to their intended use.

4.3.1.10. Documentation it is part of management information system, which includes – specifications, procedures, methods and instructions, reports & records & other documents required for planning, organizing & controlling & evaluating the whole activities of drug products manufacturing

4.3.1.11. Self – Inspection – the purpose of self-inspection is to evaluate the manufacturer's compliance with GMP on all aspects of production and quality control

4.3.1.12. Guidelines for Handling of Product Complaint, Product Recall and/or Returned Product – a system for handling each of these shall be designed and include written standard operating procedures, stating who is responsible, the investigation conducted & results

evaluated and actions taken up and shall record all details relevant to the product complaint, product recall or product returned.

4.3.2. PHARMACEUTICAL INSPECTION AND GUIDANCE

In the Philippines, there are about 117 drug inspectors stationed all over the country. There are 36 inspectors from the National Capital Region (central office) and 81 inspectors detailed in the different regions. In the National Capital Region, drug inspectors are assigned in two (2) Divisions:

Regulation Division I - drug inspectors are responsible for the inspection of retail drugstores, non-prescription drug retail outlets, Chinese drugstores, hospital pharmacies, drug distributors (importers, exporters and wholesalers) of food, drug, cosmetic, medical devices and household hazardous substances.

Regulation Division II - drug inspectors are responsible for the inspection of establishments that deals with the manufacture and repacking of foods, drugs, cosmetics, medical devices and household hazardous substances.

Inspectors regularly make on the spot inspection on all licensed establishments and establishments applying for a license. Based, on the outcome of the inspection, if there is non-compliance with CGMP, they will require the establishment to correct the deficiencies noted within the specified period. A follow- up inspection will be made and if there were no changes or corrections done, the inspector will recommend for the suspension of license to operate of the establishment to the Bureau’s Legal and Compliance Division.

4.3.3 POST MARKETING SURVEILLANCE (PMS)

One of the functions of the Food and Drug Administration is Post Marketing Surveillance. PMS is a close observation of drug effects, whether beneficial or adverse, following the marketing of a drug. The Bureau ensures that all products regulated by the agency conform to the standards and its specifications. One way of surveillance is by routine sampling of products in the market during inspection. Samples are submitted to the laboratory for testing. Appropriate actions or product recall is decided by the legal division depending on the result of the analysis.

4.3.4 DRUG DISTRIBUTION SYSTEM

4.3.5 Drug distribution is done by a Licensed Drug Distributor (importer, exporter, and wholesaler) by licensed Drug manufacturer and Drug Traders. Usually, the Drug Distributors are authorized by Drug Manufacturers and Traders to distribute their products. Distribution Agreement between each client is provided. Documentation system such as records of delivery receipts and invoices are required between the distributor and the supplier. Such records are needed for easy traceability in case of a product recall. (Same as to from distributors to retail drugstores/ hospital pharmacies)

No medicine, pharmaceutical or drug whatever nature and kind or devices shall be compounded, dispensed, sold or resold, or otherwise be made available to the consuming public except through a prescription drugstore or hospital pharmacy duly established in accordance with the provision of Republic Act 5921 section 25. Pharmaceutical, drug or biological manufacturing establishments, importers and

wholesalers of drugs, medicines or biological products are authorized to sell their products only at wholesale to duly established retail drugstore or hospital pharmacy.

Every pharmacy, drugstore or hospital pharmacy whether owned by the government or a private person or firm shall at all times when open for business be under the supervision of a registered pharmacist. In cases, when a drug establishment operates in more than one shift, each shift must be under the supervision and control of a registered pharmacist.

Products distributed should always be registered by the Bureau and should have an individual distribution record regardless of dosage strength and availability. The purpose of providing distribution records is to assure a systematic procedure of distribution and a prompt recall from outlets if products are found to be defective and violative.

Proper generic dispensing of drugs and pharmaceuticals in retail outlets should always be evaluated by the pharmacist. Incorrect prescriptions are not to be dispensed and patients/customers should be instructed to secure a proper prescriptions from physicians.

4.4.5 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.

10. PRESENT SITUATION IN THE NATIONAL DRUG POLICY INCLUDING ESSENTIAL DRUGS AND TRADITIONAL MEDICINES

From the continuous implementation of the GMP in the Philippines, FDA still finds some Drug Companies not in compliance to the guidelines. Due to the economic crisis arising from the country, more drug companies opted to just have their products toll manufactured. The issue of the local pharmaceutical laboratories is that they 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 they may have the opportunity to go to other countries. Other manufacturing companies still have 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 FDA Central and Regional Health Offices, the main problem is the insufficient number of food and drug regulation officers particularly in the regions. The expertise is not fully acquired due to the limited budget of the FDA Central to conduct seminars to reecho the latest updates on the GMP inspections. Insufficient numbers of vehicles to locate and reach some drug manufacturing facilities is also a problem.

At the moment, FDA Philippines is on the strengthening process to be able to function as mandated by R.A. 3720, as amended, and RA 9711, to fulfill the vision. The agency is very strict in issuing License to Operate to Drug Establishments and Outlets. The

continuous coordination of the Central Office to the Regions has been done using the zonal approach.

Other solutions, being considered by FDA Philippines are the additional plantilla, technical training and technical competency enhancement, and competitive salary standards.

11. 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 Department of Trade & Industry controls the prices of medicines. The Republic Act 7432 - the Senior Citizen Act gives a 20% discount on all senior citizens card holders.

In 2009, Republic Act 9502, otherwise known as the Universally Accessible and Cheaper Medicines Bill, which reduced the prices of 21 drug products to 50% of their original prices, hence, is making them more affordable and accessible to the consuming public.

The Food and Drug Administration and the National Drug Policy conduct monthly monitoring of prices of drugs, especially essential drugs.

The Department of Health also, through the National Center for Pharmaceutical Access and Management (NCPAM) conducts monthly monitoring of drug prices through electronic Drug Price Monitoring System where in all community and hospital pharmacies both private and government upload the drug prices of essential drugs after registering their drug establishments through the Data Encoder hired by DOH Central Office and assigned in each Regional Offices. (Dept. Order No. 2010-007)

12. PHARMACOPOEIA

The Philippine Pharmacopeia Project is an undertaking of the Department of Health and is being implemented by FDA Philippines, in collaboration with various government and non-government organizations.

Under Executive Order No. 302 dated 29 March 2004, the Philippine Pharmacopeia (PP) 1st edition 2004 and any supplement thereto, has been declared and adopted as the official book of standards and reference for the determination of the identity, purity, and quality of pharmaceutical products and crude plant drugs in the Philippines. Thirty (30) synthetic pharmaceutical products, thirty - one (31) crude plant drugs and twenty - two (22) crude powdered drugs have been identified for monograph development.

The Government of Japan, through the Japan International Cooperation Agency (JICA) extends technical assistance and financial support to the Project.

13. LIST OF REFERENCES

Country Report on the study programme on Manufacturing Control of Essential Drugs, Mary Ann R. Malicse, 2008
National Demographic and Health Survey - 2008
List of Licensed Establishments and their classification under Regulation Division I 2012 – Food and Drug Administration, Philippines.
List of Licensed Drug Manufacturers 2012 – Food and Drugs Phil. Regulation Division II Philippines.
List of accredited Government Hospitals and Private and Other Health Facilities for the Calendar Year 2006 – Department of Health Philippines.
National Objectives for Health Philippines 1999 – 2004, Department of Health Philippines.
National Health Plan 1995 – 2020, Department of Health Philippines
National Health Statistics 2002 – 2004, Department of Health Philippines.
Compilation of Administrative Orders and Memorandum Circulars with Summaries and Annotations 1992 Edition.

出典：平成 24 年度 JICA 集団研修カントリーレポート

- 平成 24 年度 JICA 集団研修「薬事行政」

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