*Regulatory Systems*
*on Ensuring Access to Quality Medicines*

# Country Reports

Japan International Corporation of Welfare Services (JICWELS)

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*Regulatory Systems*
*on Ensuring Access to Quality Medicines*

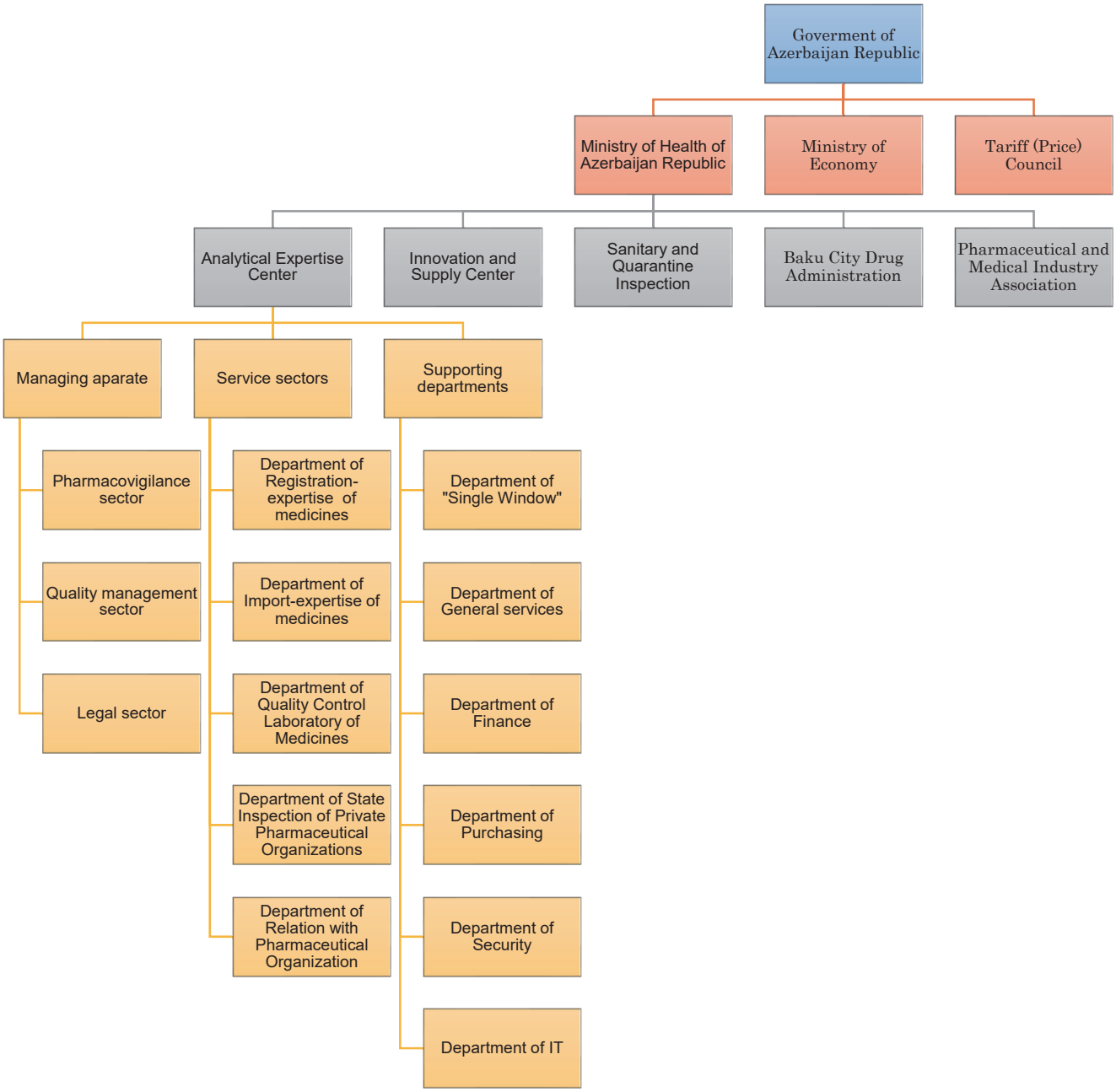
# AFGHANISTAN

*Regulatory Systems*
*on Ensuring Access to Quality Medicines*

# AZERBAIDZHAN

Name: KHALISA AKBAROVA
Country: AZERBAIJAN
Organization/Department/Division: Analytic Expertise Center/Pharmacovigilance

## ① Organizational Chart




- **The Ministry of Healthcare of Azerbaijan Republic**, also known as Ministry of Health of Azerbaijan

Republic is a governmental agency within the Cabinet of Azerbaijan in charge of regulating the healthcare system in Azerbaijan Republic.

- **Ministry of Economy**- issues licenses, permits, certificates and other documents for various entrepreneurial activities.
- **Tariff (Price) Council**- in compliance with relevant legislation regulates prices of pharmaceuticals.
- **İnnovation and Supply Center -** The Innovation and Supply Centre under the MOH organizes procurement for medicines determined by the MOH. Organizes supply of medicines and medical supplies on the basis of the requirements of government healthcare institutions. Participate in determining the needs of medical equipment, instruments, apparatus, devices, devices based on the order of medical institutions.
- **Sanitary and Quarantine Inspection –** issues permission certificate for food supplements and hygiene products.
- **Baku City Pharmacy Administration –** state pharmacies which is located in capital city (Baku) subordinates to this administration.
- **Pharmaceutical and Medical Industry Association –** state pharmacies which is located in out of capital city subordinates to this association.
- **Analytical Expertise Center –** the initiative of the Ministry of Health, for strengthening of state control over the quality, efficiency and security and emerging issues in the activities of the participants in order to regulate the pharmaceutical market. Analytical Expertise Center was established in 2007. Main responsibility of the Center is to provide society with high quality, safe and effective medicines.
- **Pharmacovigilance sector -** sector's main activity is systematic monitoring of adverse drug reactions and risk-benefit balance to ensure the safe use of the medicines, gathering information, registering, evaluating, archiving, establishing contacts between the parties and taking the necessary measures to minimize the damage caused by drugs.
- **Department of Registration-expertise of medicines -** The State Department of Registration of the Analytical Expertise Center of the Ministry of Health acts as a structural unit.
  In accordance with his duties, performs the following functions:

  1. Implementation of state registration of medicines;
  2. Approval of the state registration of medicinal products (extension);
  3. Recall of state registration of medicinal products (cancellation);
  4. Addition of changes to files and documents of registered medicines;
  5. Holding of the state register of medicinal products that passed state registration in the territory of the Republic of Azerbaijan;
  6. Preparation of regulatory documents related to the circulation of medicinal products;
  7. Elucidation of belonging to medicinal products of products received for State Registration;

- **Department of Import-expertise of medicines** – Controls the import of medicines and medical goods in the territory of the Azerbaijan Republic.
- **Department of Quality Control Laboratory of medicines** – The Laboratory of Quality Control of Medicinal Preparations (LQCMP) of the Analytical Expertise Center, used in the world practice of some

countries, as well as in Azerbaijan, was established to control the quality of drugs imported legally and illegally into our Republic and with the goal of protecting the health of the population.

- **Department of State Inspection of Private Pharmaceutical Organizations –** is responsible for periodically inspection of private organizations where pharmaceutical activities are performing.
- **Department of Relation with Pharmaceutical Organization -** The main purpose of the department's activity is to control the safety and quality of medicines in circulation in the territory of the Republic of Azerbaijan. Also, evaluates of compliance of pharmaceutical enterprises with the requirements of normative-legal acts on the basis of appeals received from the Ministry of Health.

## ② Legislation on pharmaceutical administration

–Please briefly bulletined major laws/acts

◆National Level

・ Law on "Protection of Population Health" June 26, 1997 administered by the Ministry of Health

・ Law on "Medicinal Products" December 12,2006 administered by the Ministry of Health

・ Regulation of State Registration and Register Compilation of Medical Products|" July 13,2007 administered by the Ministry of Health

・ Law on "Licenses and Permits" March 15,2016 administered by the Ministry of Economy

◆Local Level

・ Decision of Board of MoH of Azerbaijan Republic on approval of some normative legal acts regulating pharmaceutical activity administered by the Ministry of Health

- Requirements for manufacturing, carriage and strorage of medicines.
- Requirements for wholesale of medicines
- Requirements for Pharmacies and Rules on sale of medicines from pharmacies

・ Rules for state Registration and registery of medicines adminstered by the Ministry of Health.

◆PIC/S No

## ③ Regulatory Services

◆Pharmaceutical Manufacturing

・ There are 4 licensed pharmaceutical manufacturers in Azerbaijan. In 2018, domestic manufacturers held 3.8% of the market share by value produced. Azerbaijan Republic imports 96.2% of all pharmaceutical and medical devices used in the country. Domestic manufactures are certified by a manufacturing license; this is the national analogue of GMP. There are no multinational pharmaceutical companies that manufacture medicines locally.

Manufacturing capabilities are presented in table below:

| | |
|---|---|
| Research and Development for discovering new active substances | No |
| Production of pharmaceutical starting materials (APIs) | No |
| The production of formulations from pharmaceutical starting material | Yes |
| The repackaging of finished dosage forms | Yes |

・ Decision on approval of some normative legal acts regulating pharmaceutical activity (Requirements for manufacturing, carriage and strorage of medicines) administered by the Ministry of Health

◆Drug Import/Export

・Ministry of Economy issues licenses to wholesalers and importers for drug importing and exporting. Wholesalers and importers who are permitted by the Ministry of Economy are allowed to conduct import and export of pharmaceuticals and medical devices. Beside of private sector, government too import pharmaceuticals and medical devices for the public sector. For the public sector drugs are imported mainly through the İnnovation and Supply Center, which is responsible in distributing drugs and related items to government sector hospitals. Legal provisions exist requiring authorization to import medicines. Laws exist that allow the sampling of imported products for testing. Legal provisions exist requiring importation of medicines through authorized ports of entry. Regulations or laws exist to allow for inspection of imported pharmaceutical products at authorized ports of entry, one sample from each imported batch is inspected. All the drug imports to Azerbaijan Republic should be registered under Department of Registration-expertise of medicines established under AEC of the Ministry of Health and all drug importers are held responsible for ensuring that all drugs that are brought to the Azerbaijan Republic are manufactured in accordance to GMP.

・ Law on "Licenses and Permits" March 15, 2016 administered by the Ministry of Economy

・ Law on "Medicinal Products" December 12, 2006 administered by the Ministry of Health

◆Marketing Authorization

・ In Azerbaijan, legal provisions require marketing authorization (registration) for all pharmaceutical products on the market, however exceptions/waivers for registration do exist. Medicines for humanitarian purposes, rare medicines, medicines used to cure diseases that require specific treatment and WHO prequalification medicines without public registration in Azerbaijan may be imported only for non-commercial use. Mutual recognitions mechanisms are not in place. Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products. By 01.06. 2018, there were 4,449 pharmaceutical products registered in Azerbaijan. There are legal provisions requiring the Medicines Regulatory Authority (MRA) to make the list of registered pharmaceutical products publicly available and update it regularly. This register is updated every year. The updated list can be accessed through http://www.pharma.az. Medicines are always registered by their INN (International Non-proprietary Names) or Brand name + INN. Legal provisions require a fee to be paid for Medicines Market Authorization (registration) based on applications and the registration fee for applications can be accessed through http://www.pharma.az.

・ Law on "Medicinal Products" December 12, 2006 administered by the Ministry of Health

・ Regulation of State Registration and Register Compilation of Medical Products" approved by degree of the Cabinet of Ministers, on July 13, 2007 №108 administered by the Ministry of Health

◆Drug Distribution (including drug selection, procurement, sale)

・**Public Sector Procurement** - Public sector procurement in Azerbaijan is both centralized and decentralized. Public sector request for tender documents and public sector tender awards are publicly available. Procurement is based on the prequalification of suppliers. The Innovation and Supply Centre under the MOH organizes

procurement for medicines determined by the MOH for the capital and medicines for all programs (programs available on www.health.gov.az only in Azeri) for the country and carries out centralized tendering. Regions of Azerbaijan organize local procurement for medicines.

・**Public Sector Distribution-**The government supply system department in Azerbaijan has a Central Medical Store (CMS) at National Level which is under the Innovation and Supply Centre. There are no public warehouses in the secondary tier of the public sector distribution. Medical goods are directly delivered from CMS to health facilities. There are national guidelines on Good Distribution Practices (GDP). A licensing authority that issues GDP licenses exists. The licensing authority does accredit public distribution facilities. The CMS is GDP certified by this licensing authority, it is not ISO certified.

・**Private Sector Distribution-**Legal provisions exist for licensing wholesalers and distributors in the private sector. To obtain a license as a wholesaler or a distributor it is necessary to comply with the national GDP. A list of GDP certified wholesalers and distributors exist in the private sector.

・**Selection and rational use of medicines** - A National Essential Medicines List (EML) exists. Selection of medicines for the EML is undertaken through a written process. A mechanism aligning the EML with the Standard Treatment Guidelines (STGs) is in place. All the public health facilities have a copy of the EML and the STGs. There is a public or independently funded national medicines information center providing information on medicines to prescribers, dispensers and consumers. There is a national program or committee, involving government, civil society, and professional bodies, to monitor and promote rational use of medicines.

・Decision of Board of MoH of Azerbaijan Republic on approval of some normative legal acts regulating pharmaceutical activity administered by the Ministry of Health.

- Requirements for manufacturing, carriage and strorage of medicines.
- Requirements for wholesale of medicines
- Requirements for Pharmacies and Rules on sale of medicines from pharmacies.

◆Medicine Safety (post-marketing)

In Azerbaijan, the Pharmacovigilance Department of the Analytical Expertise Center of the Ministry of Health is responsible for the safety of drugs and does post marketing surveillance. Analytical Expertise Center Pharmacovigilance sector's main activity is systematic monitoring of adverse drug reactions and risk-benefit balance to ensure the safe use of the medicines, gathering information, registering, evaluating, archiving, establishing contacts between the parties and taking the necessary measures to minimize the damage caused by drugs.

・At the present time, Azerbaijan provides changes in the Law on Medicines and will approve new national regulations for pharmacovigilance activities which will be harmonized to European Union (EU) system administered by the Ministry of Health.

◆Relief System for Adverse Drug Reactions

・In an event of an adverse drug reaction (such as serious, expected, unexpected and ineffectiveness) a healthcare professional, MAH or the patient can report the details of adverse drug reactions (ADR) to the National PV located at Analytical Expertise Center of MOH, where details of adverse drug reactions are collected from government hospitals and government medical institutions, private medical institutions and from the patients.

・At the present time, Azerbaijan provides changes in the Law on Medicines and will approve new national

regulations for pharmacovigilance activities which will be harmonized to European Union (EU) system administered by the Ministry of Health.

④ **Drug Pricing**

・Tariff Council in compliance with relevant legislation establish prices of pharmaceuticals. In 2015, the it adopted the mechanism which determines the prices for medicines that passed state registration and includes methods for calculating wholesale and retail prices for the medicines. The Tariff Council identifies base prices by referring to at least 5 out of 10 references countries (Turkey, France, Italy, Spain, Portugal, Greece, Poland, Hungary, Bulgaria and Slovenia). In determining the cost of medicines, the Council relies on the lowest price established in these countries. The Ministry of Economy controls observance of established prices.

- "Procedure for regulation of prices of state registered medicines and implementation of monitoring over these prices" approved by Order No. 209 of the Cabinet of Ministers of the Republic of Azerbaijan dated June 3, 2015.
- "Instructıons on the methods of calculation of medicine prices" approved by Decision No. 4 of the Tariff (price) Council of the Republic of Azerbaijan dated July 21, 2015.
- Annex No. 1 to "Instructions on the methods of calculation of medicine prices" approved by Decision No. 4 of the Tariff (price) Council of the Republic of Azerbaijan dated July 21, 2015.
- Annex No. 2 to "Instructions on the methods of calculation of medicine prices" approved by Decision No. 4 of the Tariff (price) Council of the Republic of Azerbaijan dated July 21, 2015.

⑤ **Statistic Data**

−Please answer the following questions (if the number is not applicable, please give an answer to the best of your knowledge).

−Put the year of the presented data as well if it's available.

| | | |
|---|---|---|
| 1. | Number of pharmacists | 5250 (2019 year) |
| 2. | Number of GMP inspector (National & Local) | 7 (2019 year) |
| 3. | Number of pharmaceutical manufacturers / manufacturing sites | 4 (2019 year) |
| 4. | Number of traditional medicine manufacturers / manufacturing sites | 0 (2019 year) |
| 5. | Number of pharmaceutical importers | 45 (2019 year) |
| 6. | Number of pharmaceutical wholesalers | 101 (2019 year) |

⑥ **Education and License of Pharmacists in your country**

（1） Number of years in primary, secondary and high school education

| | |
|---|---|
| Primary | 4 years |
| Secondary | 5 years |
| High school | 2 years |

（2） Number of years / weeks in the following categories during university or college

| | |
|---|---|
| University / college: | 4/3 years |
| Professional education: | NA years |
| Practical training: | NA years |
| Duration of training by each facility: | NA years |

Hospital pharmacy: 4 weeks
Community pharmacy: 4 weeks
Pharmaceutical company: 4 weeks
Others: NA weeks
Age at graduation: 22 years old

In Azerbaijan, there is a strategic plan for pharmaceutical human resource development in place. This strategic plan, "Guidelines to certification of persons carrying out medical and pharmaceutical activities", was approved by Ministry of Health in 2010. There are two key points in the document. Firstly, pharmacists that have not continuously carried out activity within their specialty for over 5 years may be involved in pharmaceutical activity after having passed training in corresponding educational facilities. Secondly pharmacists who work in drugstores are obliged to undergo training within capacity building facilities at least once in five years.

（3） Are there any national examinations for pharmacists in your country?
No

（4） Which of the followings must you fulfill to obtain a pharmacist's license?
* If practical training is mandatory, give the subjects and training period.
Practical training is mandatory to obtain a pharmacist's license
The training period is one (1) month. Practical training consists of the training at the designated sites by which supervisors will sing a log book that is issued to intern pharmacists at the beginning of the training and provide a report whether or not the intern pharmacist completed the training satisfactorily.

（5） Number of pharmaceutical university or college graduates:
University graduates 72-78 / per year approx.
College graduates 30-36 / per year approx.

The alumni's placement rate (%)
a. Hospital: 26 %
b. Community Pharmacy: 54 %
c. Government Organization: 8 %
d. Enterprise: 10 %
e. Others: 2 %

⑦ **Side effect report**

All healthcare professional, MAH`s and the patients are enjoined to report the details of adverse drug reactions (ADR) to the National PV center. In AEC website there is downloadable ADR form which any healthcare professional or patient can accomplish and submit the ADR form to the office of the agency via post office or fax. Beside of that, right now we are on process to design a user-friendly application for online reporting ADRs. All adverse drug reaction reports collecting, evaluating, analyzing and submitting WHO global ICSR database

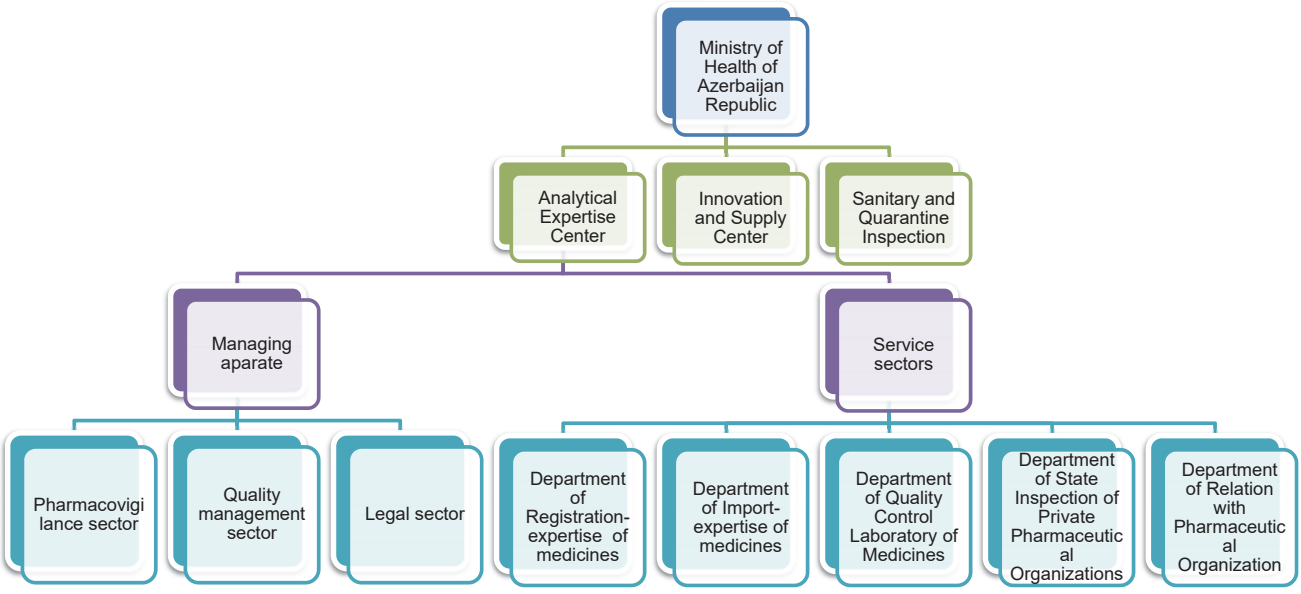
(VigiBase) by pharmacovigilance experts at national PV center. When a severe side effect case is occurred in a medical institution, healthcare professional who is in charge for reporting, must report and inform national PV within 24 hours about ADR. After evaluation procedure if there is any issues according serious adverse drug reaction, AEC is establishing contacts between the parties and taking the necessary measures to minimize the damage caused by drugs. Also at national PV center pharmacovigilance specialist sends report via web based program (VigiFlow) to WHO-UMC global ICSR database (VigiBase).

# Azerbaijan Republic

## Analytical Expertise Center of the Ministry of Health


独立行政法人 国際協力機構

## Structure of state system of pharmaceutical regulation in Azerbaijan Republic




1

独立行政法人 国際協力機構

# Analytical Expertise Center


- In Azerbaijan, the Pharmacovigilance Department of the Analytical Expertise Center of the Ministry of Health is responsible for the safety of drugs. Analytical Expertise Center is a National Medicines Regulatory Authority in the field of pharmacy established in 2006 and subordinates to MoH
- The Pharmacovigilance activities started in 2007, by the establishment of Analytical Expertise Center of the Ministry of Health. Three years later, in 2010, AEC was approved as national PV and joined the Uppsala Monitoring Centre (UMC) of the World Health Organization and since has been reporting adverse drug reactions (ADRs) to the UMC database.
- In 2017, the Pharmacovigilance Department was established. At the present time, Azerbaijan provides changes in the Law on Medicines and will approve new national regulations for pharmacovigilance activities which will be harmonized to European Union (EU) system.




# Pharmacovigilance sector

I have been working as a pharmacovigilance specialist since June, 2016 and involved in below mentioned activities :

- formulation of sector legislation
- tracing, recording, evaluating, archiving adverse drug reactions, transmitting information to the UMC of the WHO;
- examining the official websites of World Health Centers
- minimizing the risk by monitoring the warnings on pharmaceutical safety
- investigating security-related applications by registering owners
- taking the necessary measures, by investigating Risk Management Plans (RMP) and Periodic Safety Update Reports (PSUR);
- preparation of a list of medicines under additional monitoring;
- delivering of information to healthcare professionals;
- taking the necessary measures to promote the spontaneous data transmission by healthcare professionals for the best application of pharmacovigilance system.

# Legislation for Pharmacovigilance

- Law
- **LAW of the Azerbaijan Republic on "Medicinal Products"** December 22, 2006, **No.** 208-IIIQ
- **LAW of the Azerbaijan Republic on "Protection of Population Health"** June26, 1997, **No.** 360-IQ
- Regulation
- **"Regulation of State Registration and Register Compilation of Medical Products" approved by decree of Cabinet of Ministers, on** July 13, 2007, **No.** 108
- Others
- **Temporary guideline on vigilance on side effects (adverse reactions) of medicines allowed for medicinal use, on** February 22, 2006




# Roles and Position of Pharmacists in the Azerbaijan Republic

- **Prepare, obtain , store, secure, distribute, administer, dispense, and dispose of medical products**
- **Provide effective medication therapy management**
- **Maintain and improve professional performance**
- **Contribute to improve effectiveness of the healthcare system and public health**
  - **Counsel patients**
  - **Ensure patients' safety**
  - **Educate health provider colleagues**

# Roles and Position of Pharmacists in the Azerbaijan Republic

**Generally, pharmacists working in these areas:**

- Pharmaceutical companies (distributors)
- Warehouses
- National Regulatory Authority
- Public and private hospital pharmacies
- Private and state pharmacies



# Good Practices

- In Azerbaijan Republic established national framework of quality standards and guidelines (GMP,GSP,GPP and GDP)
- Minimum national standards established for these activities.
- Developed guidelines and Standard Operating Procedures (SOPs) has prove to be a good practice to achieve uniformity of the performance of a specific function
- State pharmacy where all procedure operated under (GSP and GPP) guidelines and SOP`s developed according these standards
- Azerbaijan provides changes in the Law on Medicines and going to approve of new national regulations for pharmacovigilance activities which will be harmonized to European Union (EU) system. After approval we are going to develop national GVP guidelines .

# Difficulties/Lessons Learned from Past Experience

- Unavailability of effective pharmacovigilance regulatory framework
- Challenges to set up a national database system for pharmacovigilance in Analytical Expertise Center
- Human resource capacity constraints
- Education – need to increase the professional skills of existing staff as well as experience exchange with other countries for a new successful collaborations.
- Medical Dictionary for Regulatory Activities (MedDRA) should be translated in to the native language for improvement of ADR (Adverse drug reaction) reporting culture.



# My interests

- **Post-marketing Safety Measures for Drugs (MHLW)**
- **Evaluation of Safety Information ・Safety Measure and Risk Management Plan (RMP)**
- **Pharmaceutical approval system in Japan**

# Thank you!

khalisaakperova@gmail.com
www.pharma.az

*Regulatory Systems*
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# GEORGIA

**Part I: INFORMATION SHEET**

***Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2019）***

Name: Eteri Shurghaia

Country: Georgia

Organization/Department/Division: LEPL Drug Agency/Inspection Division

## ① Organizational Chart

−Please attach the organizational chart of pharmaceutical administration at national/state & local levels about pharmaceutical administration in your country.

−Please briefly describe each role and responsibility on pharmaceutical administration.

Drug Agency ensures execution of legislation in the field of pharmaceutical product circulation and implementation of corresponding State Policy which aims to ensure the availability of effective, safe and quality pharmaceutical product on the Georgian market.

The functions of Drug Agency are:

- Admission of pharmaceutical product to the Georgian market (Marketing Authorization)
- Issuing of permission for:
- manufacturing of pharmaceutical product (except for narcotics)
- import or export of pharmaceutical product subjected to special control (narcotic, psychotropic, precursor)
- authorized pharmacy
- clinical trial
- Register the Wholesalers and Retail sellers (pharmacies) of pharmaceutical product which are subject of notification
- Selective control of pharmaceutical products
- Supervision over the pharmaceutical market

## ② Legislation on pharmaceutical administration

−Please briefly bulletined major laws/acts

- Law of Georgia on “Drugs and Pharmaceutical Activities”
- Government Decree on “Permission conditions of and procedure for issuing of permission for and of clinical trial study of investigational product, manufacture, authorized pharmacy, import and export of pharmaceutical product subject to special control
- Government Decree on “Approval of conditions for wholesale of pharmaceutical product”
- Government Decree on “Technical Regulation – approval of sanitary/hygienic/technical conditions of pharmacies (specialized drugstore) and retail shops”
- Government Decree on “Ensuring activities on traceability of pharmaceutical product”

◆National Level ・ Drug Agency

◆Local Level ・ N/A

◆PIC/S No

## ③ Regulatory Services

−Please describe pharmaceutical regulatory services of your country in response to each topic described below.

−It is recommended to add supplemental information such as systems, regulations, responsible administrators, since you are expected to explain them to other participants.

◆Pharmaceutical Manufacturing

Manufacturing of pharmaceutical product is subject to permission.

・Systems, Regulations, etc.

According to the latest changes made in Government Decree European Commission – EC GMP was recognized as National Standard of Good Manufacturing Practice. From 1st of July 2019 it can be implemented by the manufacturer on the voluntary basis, but from the 1st of January 2022 it will be mandatory to manufacture pharmaceutical product in accordance with National Standard of GMP. In order to assess compliance with GMP requirements 5 GMP Inspectors were trained in Danish pharmaceutical college "Pharmakon".

・administered by Drug Agency, GMP Inspectors

※Example: Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice

◆Drug Import/Export

- Importation and Exportation of pharmaceutical product by wholesalers (with exemption of controlled substances/medicines) is free of charge and does not require any permission or license.
- Importation and Exportation of controlled substances/medicines are subject to permission.

・Systems, Regulations, etc.

Pharmaceutical product which is intended to be imported goes through the first inspection at the point of customs office based on the risk management principles. In case of discrepancy in packaging or labeling holder of the pharmaceutical product can be fined and cargo is withheld until it is aligned with approved product.

administered by Drug Agency, Inspection Division, Permission Unit, Narcotic Legal Turnover Unit

◆Marketing Authorization

**Pharmaceutical product can be admitted on the Georgian market through two different types of procedures: National procedure of State registration and Recognition procedure of State registration:**

・Systems, Regulations, etc.

**National procedure of State registration of pharmaceutical product**

During the National procedure Agency performs administrative and scientific-technical expertise of registration dossier. Based on positive results of the administrative expertise the documents further undergo scientific-technical expertise to define product`s standardization, quality, safety and therapeutic efficiency

**Recognition procedure of State registration of pharmaceutical product**

The basis of application of recognition procedure of State registration of pharmaceutical product is the differentiation of other country or interstate regulatory authority by stringency and ability to admit to the own market only high quality pharmaceutical product.

The Georgian government defines the list of other countries or interstate regulatory authorities in order to recognize the pharmaceutical products authorized by them.

The first importation of pharmaceutical product already admitted to Georgian market with different packaging-labeling doesn't require newly registration. Such pharmaceutical product is admitted to the Georgian market on the basis of notification.

・ administered by Drug Agency, Registration Division

※Example: Good Quality Practice

◆Drug Distribution (including drug selection, procurement, sale)

The beginning and end of pharmaceutical product wholesale and retail sale is subject to obligatory notification to the Agency.・Systems, Regulations, etc.

The principle of regulation of sale of pharmaceutical product lays in ensuring of product storage and transportation/dispensing conditions and adequate administration of documentation to ensure product traceability.

・ administered by Drug Agency: Permission Division, Inspection Division

◆Medicine Safety (post-marketing)

Stakeholders involved in handling and using of medicines are obliged to inform Agency about any adverse reaction related to medicines which was not indicated in leaflet.・Systems, Regulations, etc.

Drug Agency, Registration Division

※Example: Good Pharmacovigilance Practice

◆Relief System for Adverse Drug Reactions

・Systems, Regulations, etc.

In 2018 Georgia became a full member of the WHO Program for International Drug Monitoring. Agency has been reporting and receiving data related to the ADR. PV system is implemented and needs further improvement.

・ administered by Drug Agency, Registration Division

④ **Drug Pricing**

⑤ There is no price control and pharmaceutical product price making system is free in competitive segments. Nevertheless, there are number of state programs providing by the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia which ensure patients accessibility to medicines free of charge or on the basis of a small copayment: State Program for Elimination of Hepatitis C; Universal Health Care (UHC) Program; HIV / AIDS State Program; State Program of Drug Addiction; Mental Diseases; Providing special medicines; Medications for Early Breast Cancer; TB Management; Dialysis and Renal Transplantation.

−Please describe about price control and drug price mechanism at public sector in your country.

⑥ **Statistic Data**

−Please answer the following questions (if the number is not applicable, please give an answer to the best of your knowledge).

−Put the year of the presented data as well if it's available.

| | | |
|---|---|---|
| 1. | Number of pharmacists | not available |
| 2. | Number of GMP inspector (National & Local) | 5 (2019) |
| 3. | Number of pharmaceutical manufacturers / manufacturing sites | 52 (2019) |
| 4. | Number of traditional medicine manufacturers / manufacturing sites | 25 (2019) |
| 5. | Number of pharmaceutical importers | 254 (2019) |
| 6. | Number of pharmaceutical wholesalers | 652 (2019) |

※All participants. Please describe the following general information as much as you know.

## ⑦ Education and License of Pharmacists in your country

（1） Number of years in primary, secondary and high school education

| | |
|---|---|
| Primary | 6 years |
| Secondary | 3 years |
| High school | 3 years |

（2） Number of years / weeks in the following categories during university or college

| | |
|---|---|
| University: | Bachelor Degree 4 years |
| | Master Degree 2 years |
| College | 2 or 3 years |

| | |
|---|---|
| Professional education: | years |
| Practical training: | years |
| Duration of training by each facility: | years |
| Hospital pharmacy: | weeks |
| Community pharmacy: | weeks |
| Pharmaceutical company: | weeks |
| Others: | weeks |
| Age at graduation: | years old |

3） Are there any national examinations for pharmacists in your country?

Yes

- Bachelor Degree

Computerized test exam “Module in specialized subjects and practical skills”

- Master Degree

Professional project

（4） Which of the followings must you fulfill to obtain a pharmacist's license?

* If practical training is mandatory, give the subjects and training period.

N/A

* If practical training is optional, give the reasons.

(i.e. Training is necessary to prepare for the national examination)

N/A

（5） Number of pharmaceutical university or college graduates:

not available people / per year

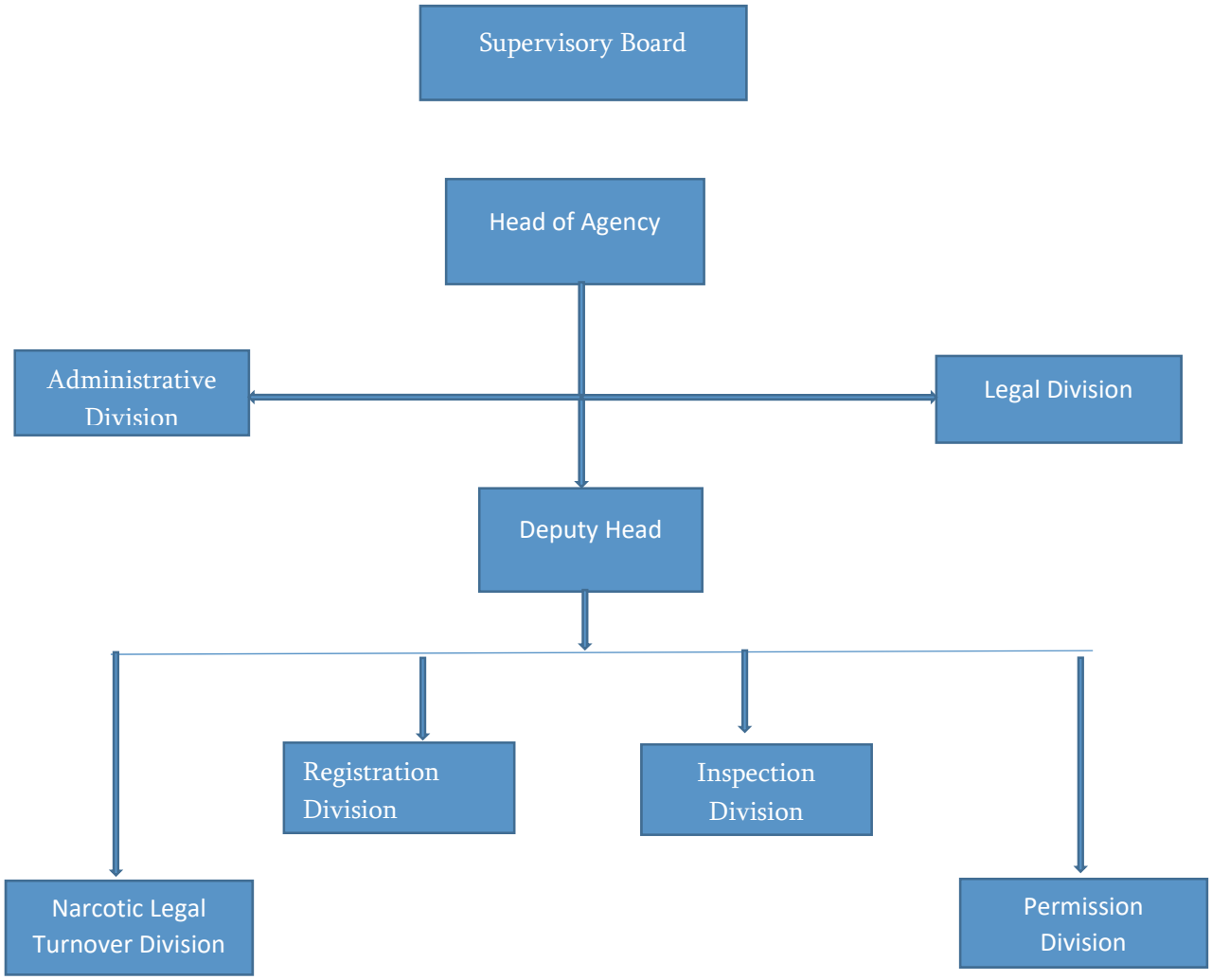
The alumni's placement rate (%) No data

a. Hospital: %
b. Community Pharmacy: %
c. Government Organization: %
d. Enterprise: %
e. Others: %

⑧ **Side effect report**

Please describe the flow of reporting system (from a medical institution to an administrative agency), when a severe side effect case is occurred in a medical institution. Describe specifically the rule and responsibility of each organization (an administrative agency / a medical institution), and their collaboration/cooperation.

Head of hospital should appoint a coordination group or person to collect information related with medicines adverse reaction. Physicians should collect data about ADR, fill the form and within 10 days transmit it to the coordination group or dedicated person. Coordination group or dedicated person once per month should provide Agency with all collected and assessed data. Agency should assess all data and submit it to the Uppsala Monitoring Centre. Within the program of treatment of patients with resistant TB form any SAE should be reported to the National Center for Tuberculosis and Lung Diseases by the end of the next working day.


Supervisory Board
Head of Agency
Administrative Division
Legal Division
Deputy Head
Registration Division
Inspection Division
Narcotic Legal Turnover Division
Permission Division

# DRUG AGENCY OF GEORGIA

MINISTRY OF INTERNALLY DISPLACED PERSONS FROM THE OCCUPIED TERRITORIES, LABOUR, HEALTH AND SOCIAL AFFAIRS

ETERI SHURGHAIA

## GMP INSPECTOR, INSPECTION DIVISION

- 14 years of supervision of pharmaceutical activities
- Participation in the policy making activities
- Focal points in the WHO Global Surveillance and Monitoring System for SF medical products

- Since October, 2018 – GMP Inspector (with reference to EU-GMP legislation):
  - Inspection of manufacturers of pharmaceutical product
  - Implementation of Quality Management System

## ROLES AND POSITION OF PHARMACISTS IN GEORGIA

### Public Sectors:

- ✓Assessment of product registration dossier
- ✓Inspection of pharmaceutical activities
- ✓Sampling of medicinal product
- ✓Issuing permission for authorized pharmacies, manufacturers, clinical trials, import/export of controlled medicinal product
- ✓Registration of retail pharmacies/wholesalers

## ROLES AND POSITION OF PHARMACISTS IN GEORGIA

### Private Sectors:

In private sectors pharmacists occupy position of responsible persons or other position.

- ✓Pharmacies (retail) - dispensing of medicines
- ✓Authorized Pharmacies - procurement, holding, supply, compounding and dispensing of medicines (including controlled medicines)
- ✓ Wholesalers - procurement, holding and supply of medicines
- ✓Manufactures - production, quality control, quality assurance, holding and supply of medicines
- ✓Pharmacists can also be involved in the different activities related to the marketing of medicines

## GOOD PRACTICE

### Achievements

- ✓ Implementation of national standard of Good Manufacturing Practice (European Commission - EC GMP)
- ✓ Establishment of GMP Inspectorate
- ✓ Full membership of the WHO Program for International Drug Monitoring

### On-going projects

- ✓ Implementation of Quality Management System
- ✓ Establishment of national standard of Good Distribution Practice (EC GDP)
- ✓ Establishment of medicines control laboratory
- ✓ Improvement of PV system
- ✓ Harmonization of legislation with EU regulations

## DIFFICULTIES/MAJOR CHALLENGES

- Insufficient organizational capacities
- Lack of opportunities for continuous trainings

## INTERESTS

- Harmonization of GMP inspection procedures through the close cooperation with Japanese GMP Inspectorate
- Sharing Japanese best practices and standards in the fields of Good Regulatory Practice and QMS
- Learn from experience of experts in the area of regulatory services.

THANK YOU

ありがとう

მადლობა

*Regulatory Systems*
*on Ensuring Access to Quality Medicines*

# INDONESIA

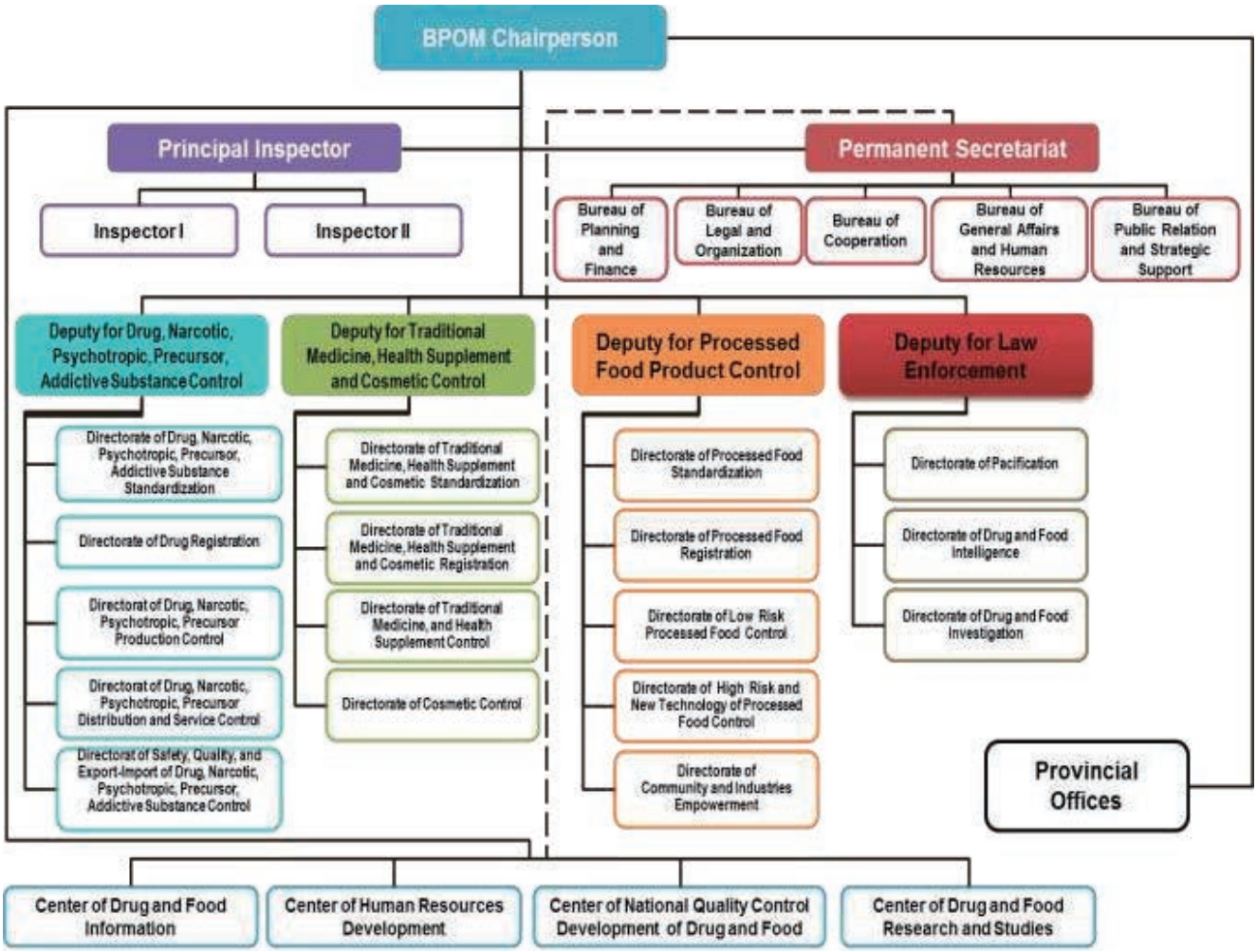
**Part I: INFORMATION SHEET**

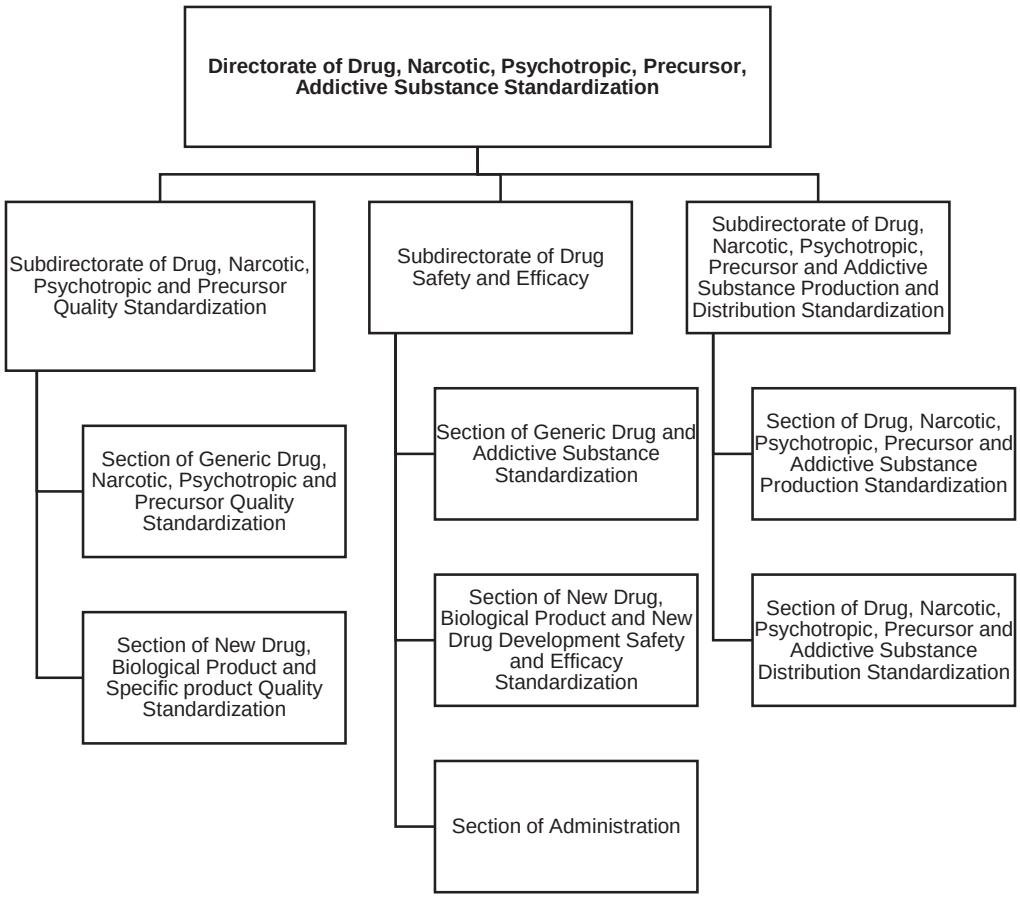
***Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2019）***

Name: Nita Widhatiningsih
Country: Indonesia
Organization/Department/Division:
Badan Pengawas Obat dan Makanan (BPOM/NADFC)/ Directorate of Drug, Narcotic, Psychotropic, Precursor, Addictive Substance Standardization/ SubDirectorate of Efficacy and Safety Standardization of Drug

## ① Organizational Chart

−Please attach the organizational chart of pharmaceutical administration at national/state & local levels about pharmaceutical administration in your country.






**The description of each role and responsibility on pharmaceutical administration.**

**The National Agency of Drug and Food Control (NA-DFC)**

- NA-DFC is a non-departmental government institution based on Presidential Decree Number 166 in the year 2000 which is responsible directly to the President for its operation and build policy coordination with the Ministry of Health. https://www.pom.go.id/new/view/direct/solid
- NA-DFC is assigned and functioned as national regulatory authority on pharmaceutical administration in Indonesia

**Deputy of Therapeutic Products and Narcotics, Psychotropic and Addictive Substance Control**

- Responsible for pre-market evaluation on efficacy, safety and quality of drugs, biological products and medical devices in Indonesia as well as operates a clinical trial scheme followed by post-market control of therapeutic products, narcotics, psychotropic and addictive substance.
- It is also responsible for inspection on good manufacturing practices, production and distribution units, sampling, recalls, public warning and enforcement of regulation.
- The organization is supported by, among others, National Committee on Drug Evaluation, National Committee on Medical Devices Evaluation and Evaluation Committee on Promotion of Over the Counter Drugs, Traditional Medicines and Food Supplement. https://www.pom.go.id/new/view/direct/solid

**Directorate of Drug, Narcotic, Psychotropic, Precursor, Addictive Substance Standardization**

- Responsible for preparing standards, regulations, and policies related to the supervision of drugs, narcotic, psychotropic, precursor, addictive substance.

– Standardization is carried out centrally, to avoid differences in standards that might occur due to each province setting its own standards. https://www.pom.go.id/new/view/direct/strategic

## ② Legislation on pharmaceutical administration

−Please briefly bulletined major laws/acts

- ◆ In national level, legislation on pharmaceutical administration is conducted by Indonesia NADFC, under The Deputy of Drug, Narcotic, Psychotropic, Precursor, and Addictive Substance Control.
- ◆ The technical implementation of drug control locally is conducted by NADFC regional offices in 33 provinces
- ◆ Indonesia has become a PIC/S member No.41, effective since 1st July 2012.

## ③ Regulatory Services

−Please describe pharmaceutical regulatory services of your country in response to each topic described below.

−It is recommended to add supplemental information such as systems, regulations, responsible administrators, since you are expected to explain them to other participants.

– The regulation is provided only in bahasa on http://jdih.pom.go.id/

– Regulatory services for pharmaceutical product are conducted by NADFC, under the Deputy of Drug, Narcotic, Psychotropic, Precursor, and Addictive Substance Control, which responsible for the administration of:

◆ Pharmaceutical Manufacturing

- Administered by : Directorate of Drug, Narcotic, Psychotropic, and Precursor Production Control
- Systems, Regulations :
  1. Regulation of NA-DFC No. 13 year 2018 on amendment of regulation of NA-DFC No. HK.03.1.22.12.12.8195 year 2012 on implementation of Good Manufacturing Practice (GMP).
  2. Regulation of NE-DFC No. 04.1.33.12.11.09937 year 2011 on Certification Procedure of Good Manufacturing Practice

◆ Drug Import/Export

- Administered by : Directorate of Safety, Quality, and Export-Import Control of Drug, Narcotic, Psychotropic, Precursor and Addictive Substance (Sub-Directorate of Export-Import Control of Drug, Narcotic, Psychotropic, and Precursor)
- Systems, Regulations : Regulation of Head of NADFC
  1. No. 27 year 2016 on Recommendation Procedure of Export and Import of drug, traditional medicines, medical supplements, and/or cosmetics as complementary goods.
  2. No. 5 year 2017 on importation control of drug and food materials into the territory of Indonesia
  3. No 4 year 2017 on importation control of drug and food into the territory of Indonesia

◆ Marketing Authorization

- Administered by : Directorate of Drug Registration
- Systems, Regulations :
  1. Regulation of the Minister of Health No. 1010/Menkes/Per/XI/2008 amended by regulation no. 1120/Menkes/Per/XII/2008 on Drug Registration,
  2. Head of NADFC Regulation No. 24 year 2017 on Criteria and Procedure of Drug Registration

◆ Drug Distribution (including drug selection, procurement, sale)
- Administered by : Directorate of Drug, Narcotic, Psychotropic, and Precursor Distribution Control
- Systems, Regulations :
  1. Regulation of NADFC Indonesia No. 9 year 2019 on Technical Guideline on Good Distribution Practice,
  2. Regulation of the Head of NADFC No. 25 year 2017 on the Procedure of Good Distribution Practice licensing

◆ Medicine Safety (post-marketing)
- Administered by : Directorate of Safety, Quality, and Export-Import Control of Drug, Narcotic, Psychotropic, Precursor, and Addictive Substance (Sub-Directorate of Safety Control of Drug, Narcotic, Psychotropic, and Precursor)
- Systems, Regulations :
  1. Regulation of the Minister of Health No. 16 year 2013 on Pharmaceutical Industries,
  2. Regulation of the Head of NADFC No. HK.03.1.23.12.11.10690 year 2011 on Regulation of the Implementation of Pharmacovigilance for Pharmaceutical Industry

※Example: Good Pharmacovigilance Practice

◆ Relief System for Adverse Drug Reactions
- None

## ④ Drug Pricing

−Please describe about price control and drug price mechanism at public sector in your country.

– Drug pricing policy is regulated and controlled by Ministry of Health
– Regulation of Minister of Health no. 98 year 2015 on concerning the Provision of Information on the Highest Retail Price of Drugs

## ⑤ Statistic Data

−Please answer the following questions (if the number is not applicable, please give an answer to the best of your knowledge).

−Put the year of the presented data as well if it's available.

1. Number of pharmacists: ± 73.047 (2019)
   Source (Association of Pharnacist of Indonesia)
2. Number of GMP inspector (National & Local): 111 personal (2018)
   https://www.pom.go.id/new/view/direct/industri-farmasi
3. Number of pharmaceutical manufacturers / manufacturing sites: 220 (2019)
   https://www.pom.go.id/new/view/direct/industri-farmasi
4. Number of traditional medicine manufacturers / manufacturing sites: ± 80 (2017)
5. Number of pharmaceutical importers: ± 185 (2017)
6. Number of pharmaceutical wholesalers: ± 2200 (2018)

※All participants. Please the following general information as much as you know.

**⑥ Education and License of Pharmacists in your country**

（1） Number of years in primary, secondary and high school education

Primary 6 years

Secondary 3 years

High school 3 years

（2） Number of years / weeks in the following categories during university or college

University / college: 3.5-4 years

Professional education: 1 year (including practical training in hospital pharmacy, community pharmacy, and/or national regulatory agency and/or pharmaceutical company)

Practical training: 3 – 4 month

Duration of training by each facility: 2 weeks – 2 month

Hospital pharmacy: 2 weeks – 2 month

Community pharmacy: 2 weeks – 2 month

Pharmaceutical company: 2 weeks – 2 month

Others: weeks

Age at graduation: 23-24 years old

（3） Are there any national examinations for pharmacists in your country?

Yes

Academic Exams 1 days

~~Clinical~~ Practical Exams 1 days

~~No~~

（4） Which of the followings must you fulfill to obtain a pharmacist's license?

* If practical training is mandatory, give the subjects and training period.

It is mandatory to take Community Pharmacy practice (at pharmacy) and government (eg. public health, Badan POM). While at the hospital and pharmaceutical companies, the training is carried out based on the chosen study. The practical training period at pharmacies is vary from 3 weeks to 2

months (depend on university regulation) and the others are the same as already mentioned on number (2) above.

* If practical training is optional, give the reasons.
(i.e. Training is necessary to prepare for the national examination)

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（５） Number of pharmaceutical university or college graduates: No official data available

The alumni's placement rate (%)

a. Hospital and Community Pharmacy (government and private): 32%
http://www.depkes.go.id/development/site/tenaga-kesehatan/
b. Government Organization: N/A_____%
c. Enterprise: N/A_____%
d. Others: N/A_____%

## ⑦ Side effect report

The monitoring system of side effect report conducted by NADFC consists of :

1. Spontaneous reporting from health care professionals using Yellow Form (post mail to NADFC), email to pv-center@pom.go.id or online reporting (http://e-meso.pom.go.id)
2. Report from pharmaceutical industries in the form of:
   - spontaneous reporting/CIOMS Form (using post mail to NADFC, email to pv-center@pom.go.id or online reporting (http://e-meso.pom.go.id),
   - PSUR/PBRER , scientific publication and study reports (RMP), regulatory action in other country, and Marketing Authorization Holder action in other country (using post mail to NADFC or email to pv-center@pom.go.id).

The rule and responsibility for side effect report as follows:

1. Regulatory and pharmaceutical industy are collaborating in managing risk in term of risk-benefit ratio for population
2. Healthcare professionals and healthcare facilities manage risk in term of risk-benefit ratio for patients
3. Patients manage risk in term of personal values

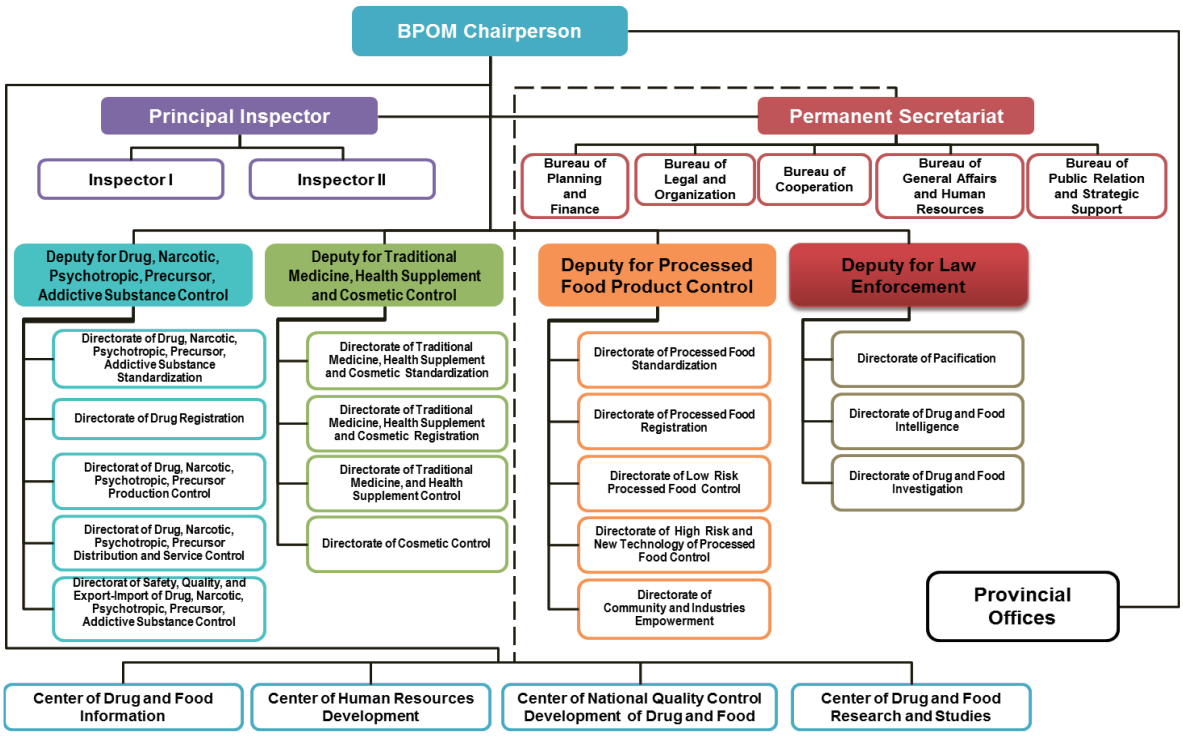
# Indonesia

Badan Pengawas Obat dan Makanan (BPOM)/
The National Agency of Drug and Food Control (NA-DFC)

## Nita Widhatiningsih



# Badan Pengawas Obat dan Makanan (BPOM/NA-DFC)



# Scope of Drug and Food Control






# Background

- BPOM is a non-ministerial government institution led by Chairperson, which directly responsible to the President of Republic of Indonesia.
- BPOM has 33 regional offices which supported by accreditated laboratories in each office (ISO/IEC 17025: 2005)

# 1. Introduction of the work

(2) Job tenure

As part of the team which develops the regulation on drug safety and efficacy

Eg. Guideline on bioequivalence studies

(3) The role and position of pharmacist in Indonesia briefly described as follows:

a. In pharmaceutical industries: manufacturing of drug as well as drug development, including quality control of Pharmaceutical Preparations, security, procurement, storage and distribution or distribution of drugs,
b. Health care facilities: Management medicine, procurement, storage and distribution or distribution of drugs, medical services for prescription, services drug information,
c. Government/regulator: development and implementation of national regulation relate to drug, including development of guideline/standard, drug control, technical guidance relate to drug, coordination with central and regional government agencies for drug control; enforcement of violations of the provisions of laws and regulations with regard of drug, etc.



# 2. Good Practice

## Achievements

- 2011-2018
  - Part of the team in developing regulation related to bioequivalence studies.
  - Evaluation of bioequivalence study protocol and report of generic medicinal product
  - Part of the bio-equivalence study inspection team
- 2018-present: as a part of the team which develops the regulation on drug safety and efficacy, such as draft Guideline on Evaluation of Safety and Efficacy of Anticancer Drug, and draft Guideline on Risk Management Plan.

## 3. Difficulties/Lessons Learned from Past Experience

- Difficulties on implementing risk impact assessment during regulation development.
- Method/analysis for measuring policy effectiveness



## 4. Your interests

- Pharmaceutical regulatory system and its problems in Japan and other countries
- Regulatory systems in Japan to facilitate the development of new drugs through the SAKIGAKE Designation system and Scheme to rapid authorization of unapproved drug.
- Having other perspectives regarding management for access to quality medicines that may be applicable to be implemented in Indonesian drug regulatory system

*Regulatory Systems*
*on Ensuring Access to Quality Medicines*

# IRAQ

**Part I: INFORMATION SHEET**

***Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2019）***

Name: Noor Najim Abdulla Al-Wiswasi

Country: IRAQ

Organization/Department/Division: Ministry of Health/pharmacy department/clinical pharmacy division

① **Organizational Chart**

| The organizational chart of pharmaceutical administartion at national level: | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Syndicate of Iraqi pharmacist** | **Ministry of Health** | | | | | | | |
| | **Technical Deputy of the Ministry** | | | | | | | |
| | **Directorate oF Technical Affair** | | | | | | **The state Company for Marketing Drugs and Medical Aplliances (KIMADIA)** | **High Committee for Drug Policy** |
| 1. Licensing of pharmacist<br>2. Licensing of private pharmacy wholesalers & scientific bureaus<br>3. Regulation regarding pharmaceutical products in private sectors in cooperation with MOH | **Quality Control Lab.** | **Registration Department** | **Pharmacy Department** | **2 National Committees for Selection of pharmaceutical and herbal products** | **Need Estimation** | **Herbal products department** | Procurement & Distribution of medicines and medical appliances in the public sector | Had the Higher Authority for administering regulations over other levels for private and public sectors |
| | ✓ Testing the domestically, nationally & privately imported pharmaceutical products according to the standards<br>✓ Research and development studies | Registering pharmaceutical companies& products | ✓ Availability of medicine<br>✓ Regulation for medicines use for in- &out-patient<br>✓ Drug & therapeutic committee<br>✓ Inventory system<br>✓ Quality of drug<br>✓ Rational use | Selection of products to be used in private and public sectors | Estimation of country needing from medicines and medical appliances in public sectors | Licensing & regulations regarding marketing of herbals & herbal products | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | regarding the bioequivalence. | | ✓ Pharmacy Residency& Sub-specialty<br>✓ Patient care<br>✓ License for import in private sector<br>✓ Pharmacovigilance<br>✓ License for national manufactures<br>✓ Monitor cGMP<br>✓ Internal & external inspection<br>✓ License for import<br>✓ Regulation for use<br>✓ Management of narcotic & controlled substances | | | | | |

| The organizational chart of pharmaceutical administartion at local level: | | | |
|---|---|---|---|
| Health Directorate | | | |
| Pharmacy department | | | |
| **Estimated Need** | **Pharmaceutical Services in public sectors** | **Clinical pharmacy** | **Storage and distribution** |
| Responsible for estimating the needs of health institutes for pharmaceutical products according to the national list | ✓ Availability of pharmaceutical products<br>✓ Regulation regarding pharmaceutical products use for medical outlets and out-patient<br>✓ Herbals and herbal products use regulations unit<br>✓ Therapeutic and drug committee unit | ✓ Regulation for quality of drugs<br>✓ Tracking ,monitoring & documenting adverse drug reaction<br>✓ Rational drug use<br>✓ Pharmacist residency | ✓ Inventory system for pharmaceutical products storage<br>✓ Distributing of pharmaceutical products to health institutes |

② **Legislation on pharmaceutical administration**

–Please briefly bulletined major laws/acts

◆National Level

- Narcotics law administered by Iraqi parliament
- Pharmacy Syndicate law administered by Iraqi parliament
- Practicing the Pharmacy Profession law administered by Iraqi parliament
- General Health law administered by Iraqi parliament
- The State Company for marketing Drugs & Medical Appliances law administered by Iraqi parliament

◆Local Level

- Import, production or sale of chemicals and medical preparations instructions administered by MOH
- Sale of herbal medicines instructions administered by MOH
- Sale of herbal medicines instructions administered by MOH
- Health condition for drug store instructions administered by MOH
- Licensing for establishment of a factory or a company for the manufacture of medicines, medical preparations and cosmetics instructions administered by MOH

- Pharmacist gradient instructions administered by MOH

◆PIC/S

No

③ **Regulatory Services**

−Please describe pharmaceutical regulatory services of your country in response to each topic described below.

−It is recommended to add supplemental information such as systems, regulations, responsible administrators, since you are expected to explain them to other participants.

◆Pharmaceutical Manufacturing (Systems, Regulations, etc.)

・Licensing for public and private administered by MOH

・The regulation, inspections administered by MOH (GMP, GLP) and MOI

◆Drug Import/Export (Systems, Regulations, etc.)

・The regulations and systems for import for public sector administered by MOH (registration, pharmacy, laboratory control departments and KIMADIA

・The regulations and systems for import for private sector administered by MOH (registration, pharmacy, laboratory control departments and pharmacy syndicate

・There are no systems for export

◆Marketing Authorization (Systems, Regulations, etc.)

・The systems is administered by MOH (Pharmacy departments +KIMADIA) for public sector

・The systems is administered by MOH (Quality control laboratory) for public sector

◆Drug Distribution (including drug selection, procurement, sale) (Systems, Regulations, etc.)

・The systems is administered by MOH (Need Estimation, registration, pharmacy departments and KIMADIA in addition to the national committee for drug selection) for public sector

・The systems is administered by MOH (Need Estimation, registration, pharmacy departments in addition to the national committee for drug selection) for private sector

◆Medicine Safety (post-marketing) Systems, Regulations, etc.

・The systems is administered by MOH (pharmacy department – Pharmacovigilance and clinical pharmacy) for public sector

・The systems is administered by MOH (pharmacy department – Pharmacovigilance) for private sector

◆Relief System for Adverse Drug Reactions (Systems, Regulations, etc.)

No system

④ **Drug Pricing**

–Please describe about price control and drug price mechanism at public sector in your country.

- For public sector there is no pricing system because the medicines are given to the patients free of charge, and the procurement depends on the lowest presented price comparing to the registered price in the registration file in MOH.
- For the public sector, the systems is administered by MOH (registration department –price documented in the registration file of the company- and the High committee of pricing + the pharmacy syndicate

⑤ **Statistic Data**

–Please answer the following questions (if the number is not applicable, please give an answer to the best of your knowledge).

–Put the year of the presented data as well if it's available.

1. Number of pharmacists 18000 (2018)
2. Number of GMP inspector (National & Local) 25 (2018)
3. Number of pharmaceutical manufacturers / manufacturing sites 28 (2018)
4. Number of traditional medicine manufacturers / manufacturing sites 0 (2018)
5. Number of pharmaceutical importers 400 (2018)
6. Number of pharmaceutical wholesalers 350 (year)

※All participants. Please describe the following general information as much as you know.

⑥ **Education and License of Pharmacists in your country**

（1） Number of years in primary, secondary and high school education

Primary 6 years

Secondary 3 years

High school 3 years

（2） Number of years / weeks in the following categories during university or college

University / college: 5 years
Professional education: 6 years
Practical training: 1 years
Duration of training by each facility: years
Hospital pharmacy: 12 weeks
Community pharmacy: 24 weeks
Pharmaceutical company: 0 weeks
Others: 12 weeks
Age at graduation: 23 years old

（3） Are there any national examinations for pharmacists in your country?

NO

Academic Exams days
Clinical Exams days

（4） Which of the followings must you fulfill to obtain a pharmacist's license?

* practical training is mandatory, give the subjects and training period.
3 years (2 as a hospital pharmacist+1 in health center)

（5） Number of pharmaceutical university or college graduates: 1650 / per year

The alumni's placement rate (%)

a. Hospital: 80 %
b. Community Pharmacy: %
c. Government Organization: %
d. Enterprise: %
e. Others: 20 %

⑦ **Side effect report**

Please describe the flow of reporting system (from a medical institution to an administrative agency), when a severe side effect case is occurred in a medical institution. Describe specifically the rule and responsibility of each organization (an administrative agency / a medical institution), and their collaboration/cooperation.

The report is run from the hospital, health directorate and finally to the MOH

In the medical institutions the clinical pharmacist are responsible for documenting the report and take the take the correcting actions depending on the regulations that had been administered by MOH (pharmacy department), then the report directly documented on the patient record and electronically, to be delivered to the health directorate and MOH.

# REPUBLIC OF IRAQ

## MINISTRY OF HEALTH (MOH)

NOOR N. ALWISWASI
MSc. Pharmaceutics



## Organization Hierarchy

**MOH**

Minister of Health

The Technical Deputy of the Ministry

Directorate of Technical Affairs

- Pharmacy department
- Registration department
- Department of Need Estimation
- Quality Control laboratory
- 2 National Committees for Pharmaceuticals & Herbal Selection
- Herbal products department

The State Co. for Marketing Drug and Medical Appliances

High Committee for Drug Policy

Syndicate of Iraqi Pharmacist

## Pharmacy Department Hierarchy

1. Division of Pharmacy in Public Health institute
2. Division Clinical Pharmacy
3. Division National Drug Manufacturers
4. Division Private Importing
5. Division Narcotics & Controlled Substances
6. Division Pharmacovigilance
7. Division Pharmacy and Therapeutic Committee (PTC)
8. Division Medical Appliances




- For the Clinical Pharmacy Division, which I belong to, it is responsible for

1. Issuing instructions for the rational use of medicines
2. Ensuring the good quality of medicines and medical supplies
3. Supervising the programs of clinical pharmacists residency
4. Controlling the special functions of clinical pharmacist (TDM, DIC, IV admixtures, admixtures of chemotherapy, etc.)

## Regulatory services that I engaged in

- Issuing instructions and controls for the rational and correct use of medicines, (antibiotics, analgesics, anesthetics)
- Clinical Pharmacy residency programs
- TDM
- DIC




## Roles of Pharmacists

The pharmacist roles would be in:

- Selection of pharmaceutical products
- Registration
- Procurement and Distribution
- Importing
- Quality control
- Manufacturing
- Marketing Authorization
- Patient care
- Post marketing monitoring
- Pricing

## Position of Pharmacists

- Technical
- Educational
- Training
- Administrative
- political




## Our Experiences About Good Practices

We have many achievements to improve our good practice like:

- Developing new regional QC labs to decrease the time required for release patches (on going)
- Developing PhV center for post marketing monitoring
- Developing sub-specialty in clinical pharmacy to ensure rational use of medicine (on going)
- Using the new technologies like electronic records to save time, efforts and money. (on going)

- On site visit for registered manufacturer to ensure the quality of the imported medicines
- Updating the GMP for our manufacturers according to the global criteria (on going)
- Treatment protocols and guidelines (on going).




## Difficulties and Struggles

- Lack of physician commitment to the national list and protocols
- Shortage of medicines and appliances because of the procurement system
- Lack of patient adherence
- Political and favoritism issues

*Regulatory Systems*
*on Ensuring Access to Quality Medicines*

# LAOS

# COUNTRY REPORT

FOR

## Regulatory Systems on Ensuring Access to Quality Medicine

**(JFY 2019)**

**(June 30 – August 02, 2019)**

**Tokyo, JAPAN**


**Mrs. Vongsy PHANTHAVONG**

**Technical officer**

Ministry of Health – Lao P.D.R

Pharmacy Hospital Management Division, Food and Drug Department

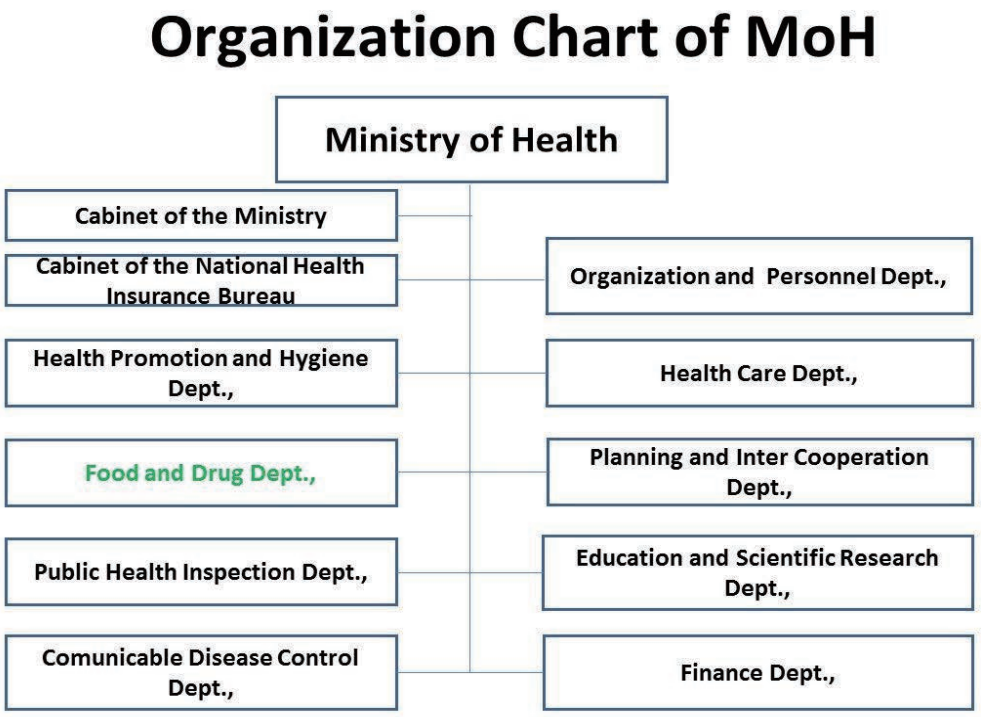
Tel: (+ 856 -21) 214014; (+856-21) 226079

Fax: (+ 856 -21) 213495

E-mail: vongsy.phanthavong@yahoo.com

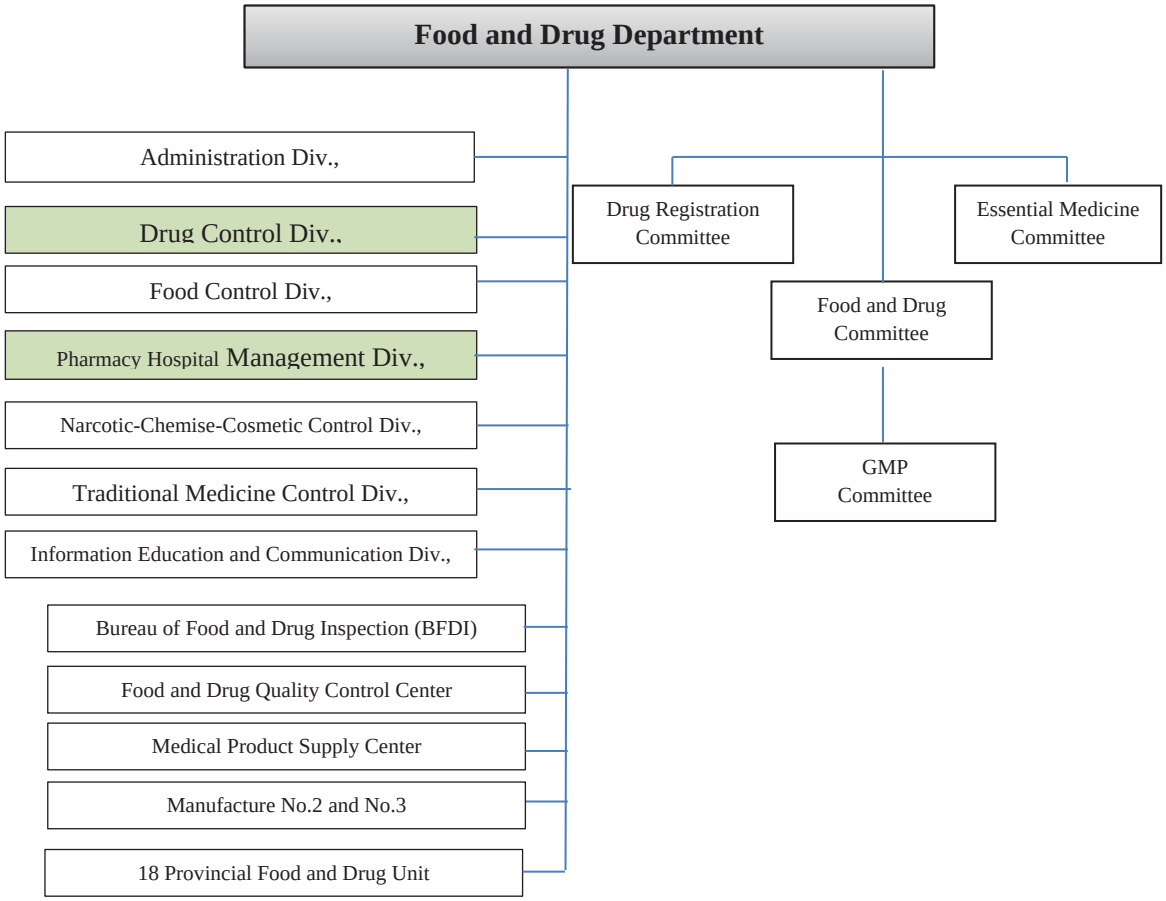
Website: www.fdd.gov.la

## 1. Organizational Chart




The Ministry of Health is a central management authority, which collaborates with the Food and Drug Department to regulate implementation of the inspection and removal of drug from the market, the Food and Drug Administrative Committee, according to the decree No. 49 of the Council of Ministers, has the role to assure quality of Food and Drug, when problem on quality of food and Drug occurs, the Food and Drug administrative Committee should coordinate with the Ministers (Prime Minister's Office).

## Food and Drug Organization Chart




◆ **Vision:**

- To ensure good quality, safety and efficacy of drug and Food for Lao people

◆ **Mission:**

- Develop and implementing strategy and Policy
- Develop, implementing and enforcement of law and regulation governing Food, Drug and Medical Product
- Pre-marketing and Post marketing surveillances activities
- Strengthening of quality assurance system including quality control for Food, Drug and Medical Product
- Continue education for both public and private providers
- Promotion of rational use of drug amongst health worker as well as communities

The Food and Drug has responsibility for consumer protection on food and drug based on the Forth MoH's action plan, In the Organizational structure of the food and drug Department there are seven divisions in the organization chart, for the Drug Control Division is a one in Charge of the Pharmaceutical Regulatory Systems on Ensuring Access

to Quality Medicine and for the Pharmacy Hospital Management Division Ensuring access the Essential medicines, Rational use of medicines and Pharmacovigillance in Health facility.

## 2. Legislation on Pharmaceutical administration

The Legislation establishment is one of the thirteen elements (priorities) in the National Policy to assure that the successful implantation of the Drug policy through using the related, updates 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. Revised Drug and Medical Product law issued in 21 December 2011
3. Degree for National Health Insurance No. 470/Gov., dated 17 Oct 2012
4. Degree for Traditional Medicine No. 155, dated 30 Sep 2003
5. Regulation for Drug registration No. 1441, dated 13 Aug 2003
6. Regulation Establish Factory and Company No. 1820, dated 25 Aug 2017
7. Regulation for Pharmacy No. 2922, dated 21 Sep 2016
8. Regulation for good manufacturing practice and quality control of drugs No. 1021, dated 11 Aug 1999
9. Regulation on Good Manufacturing Practice No. 937/MOH, 12/07/2004
10. Regulation for disposal of medicines including vaccines No. 1862, dated 05 Aug 2016
11. Decision/Approval based on National medicine policy main goal and related components
12. Regulation of Donation of Drugs and Medical Product No.2579/MoH dated 12$^{th}$ Nov 2003 concerning Drug and Medical Equipment Donation.
13. Regulation on the banned drug in Lao No.1018/MOH in 2003
14. Regulation on specific controlled medicine and uncontrolled and OTC Drug No.2580/MOH, on 25/11/2002
15. Regulation on concerning Food, Drug and Medical Equipment Advertisement No. 2581/MOH in 2003
16. Revolving Drug Fund Guideline
17. Lao Pharmacovigillance Guideline

18. Good Manufacturing Practice Guideline
19. The ASEAN common technical dossier (ACTD) for the registration of the pharmaceuticals for the human use.
20. Draft SOP for recall Drug and medical Product
21. Draft SOP for fast track registration
22. Draft SOP for Causality assessment
23. Draft for filling ADR Form and reporting ADR Cases
24. Draft for Quality Management System (QMS) Manual
25. Draft for Good Regulatory Practice (GRP) Guideline

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 Etc….the revise law has 50 articles. The above existing regulation needs to be revised.

## 3. Regulatory Services

Drug Division in charge of the Pharmaceutical Regulatory Systems on Ensuring Access to Quality Medicine respectively:

◆ **Pharmaceutical Manufacturing**

- **Licensing of manufacturing site:**

Licensing and Registration is a pre-marketing authorization activity with belong to the responsibility of Drug 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.

- **Licensing pharmaceutical Company and pharmacy:**

The Licensing for Pharmaceutical 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.

- **Drug Registration System:**

According to the regulation No. 1441, on August 13, 2003 covering drug registration in Lao PDR, every drug before marketing must be registered. The drug selection for registration is mainly based on National Essential Medicine List and needs of hospitals.

Now the drug products has registered about 1,962 items (2019), there are the import production 1610 items (2019), the local production 352 items (2019) and traditional medicines and Health supplement registered 500 items (2019).

In registration system, after 3 years the companies have to submit application forms for renewal of registration. The procedure of registration is divided into 2 steps:

- Step 1: Application for the permission to import or manufacture drug sample intended to be registered.
- Step 2: Application for the approval of granted credential certificate

**◆Drug Import/Export**

The drug Import/Export must only be license Certificate of the pharmaceutical companies and the product must be registered, for the process the pharmaceutical companies must be submit the documentation of import to Food and drug Department as following detail:

- Letter from the company for importation request
- Purchase order
- Invoice
- Packing list.

In current, There is no any pharmaceutical product exported since the capacity of domestic pharmaceutical manufacturer still not reach the ASEAN GMP requirement.

**Remark:** For Donation of Drugs and Medical Product from Health Program not to be registered, the document that required are:

- Letter from the Health Program for importation request
- Purchase order
- Invoice
- Packing list
- Certificate of Origin
- Certificate of Analysis
- GMP
- For Vaccine there should have Certificate of lot release and Prequalified from WHO.

**◆Marketing Authorization**

The marketing authorization for import pharmaceutical products is as mentioned above, the importer must has the license Certificate and the product must be registered, for the domestic manufacturer must has the GMP certificated which is issued by Ministry of Health Lao PDR, and the pharmaceutical products must be sent to the Food and Drug Quality Control Center for analysis, the registration of the products must be after getting their Certificate of Analysis. The registration certificate is invalid in 3 years period, therefore the domestic and import products must be re-registering in every 3 years.

**◆Drug Distribution ( including drug selection, procurement, sale )**

The Ministry of Health established Procurement and Supply Committee for Medicines and Medical Products No. 0150 / SAT in January 24, 2017. This Committee has been revised o 22 March 2019, No. 0583.

This Committee consists of Food and Drug Department, Finance Department, Cabinet, Department Health Care and Rehabilitation, Department of Health Education and research, Department of Planning and Cooperation, and other related Ministry. Under Food and Drug Department, the Medical Product Supply Center is appointed as a coordination agency for facilitating procurement process of medicines and medical products.

In the past, decentralized system was use for procurement of medicines and medical products, but currently the Medical Product Supply Center has started central tendering procurement for the 5 central hospital and 3 centers, 06 southern provinces and this year expand to 09 northern provinces.

**◆ Medicine Safety ( post-marketing )**

The Food and Drug Department in cooperation with the Bureau of Food and Drug Inspection and the Food and Drug Quality Control Center play a key role in monitoring quality and safety of pharmaceutical products in the market.

For inspection in Public and private sector is conducted once year using the 10 indicators for monitoring as following:

**1.** Order in the Pharmacy
**2.** Banned drug
**3.** Availability of ED with INN + clear label
**4.** Quality of Drug + Expiry date
**5.** The correct bill

**6.** Drug dispensing

**7.** Knowledge of drugs sellers

**8.** Prescription for antibiotics drug

**9.** Essential equipment and documents

**10.** Presence of technical staff

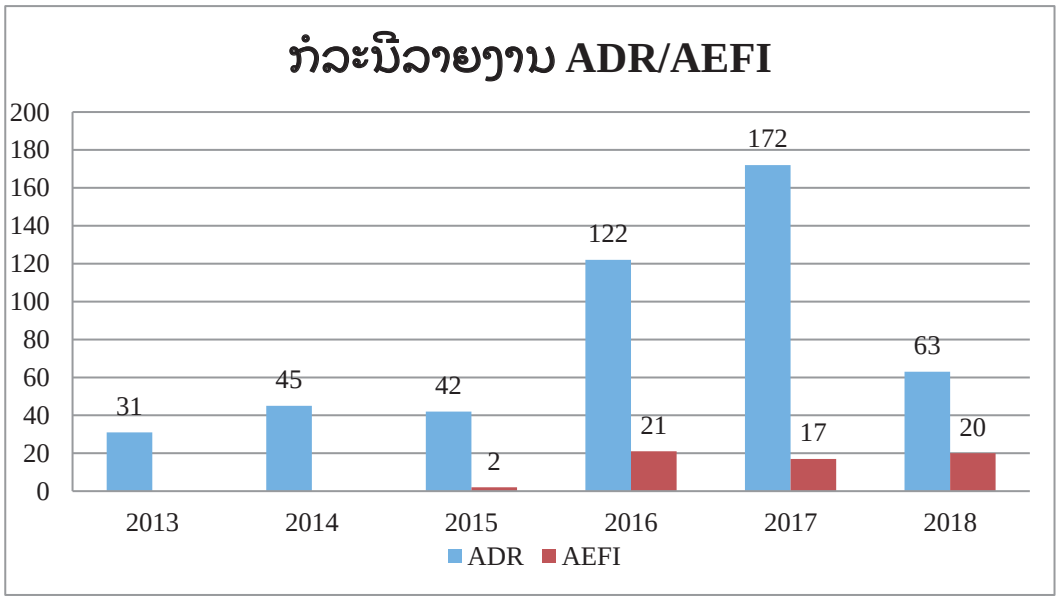
One of the requirements for drug registration is that a sample of the product should be sent for analysis. Since the company applying for registration selects the registration sample, it might not necessarily be representative of the quality of the product that will be eventually marketed. Post-marketing surveillance, i.e. analysis of sample taken from the distribution chain by the BFDI, essential to identify substandard and counterfeit products.

◆ **Relief System for Adverse Drug Reactions**

In year 2008, we organized training course for ADR to the pharmacists and Drug Therapeutic Committee of central and provincial levels whole country, and the ADR Report forms were developed and distributed to all hospital, but the reporting was not very actively. In the year 2012, the FDD is implementing the pilot project on PV focus on retroviral medicines, PV report Form has been developed and safety reports are requested to all cases. Laos became official Uppsala Monitoring Center as WHO system of ADR report as 122 member countries in May 2015.

In year 2017, we has combined training course for ADR & AEFI, the WHO support Funding to Training of Trainer for Provincial and District level: in year 2018 there are 06 Provinces and in year 2019 to expand 05 Provinces.

Case for ADR & AEFI report are following:



## 4. Drug Pricing

There is no pricing control in private sector. In Public sector the guideline on drug revolving fund has been use for pricing of medicines with 25% markup. However, currently the National Health Insurance Bureau has implemented health insurance program using capitation and case based payment.

There has been an issue of high price of medicines in the country. Therefore the Food and Drug Department conducted a survey on Medicine price and availability in Lao PDR in 2013 using WHO/HAI methodology. The results of this survey has highlighted several areas in need of attention for further in-depth study and development of new policies/regulations to increase affordability and availability of essential medicines in the country as core element of good quality health services. Also, increase procurement distribution efficiency and/or new medicine pricing policies/regulation can result in higher availability and affordability of essential medicines and improved access for all. Most importantly, access to affordable medicines can make further progress towards Universal Health Coverage (UHC) as high prices of medicines can be a burden to the patients for access to health care services particularly the poor to cover Lao population

This year in May, a scoping exercise on medicine pricing control has been conducted and there has been some recommendation for the next step in term of medicines pricing control.

## 5. Statistic Data

a/. Number of Pharmacists

(Average number of Pharmacists by category (Data year 2017-2018)

Data 2684

Years 2018

b/. Number of GMP inspection

Data 13 (GPM Committee)

Years 2019

c/. Number of Pharmaceutical manufacturers/ manufacturing sites

Data 8

Years 2019

d/. Number of traditional medicine manufacturers/ manufacturing sites

Data 4

Years 2018

e/. Number of traditional medicine household

Data 13

Years 2018

f/.Number of pharmaceutical importers

Data 77

Years 2019

g/. Number of pharmaceutical wholesalers

Data 2684

Years 2019

## 6. Information on your hospital pharmacy

◆ **Organization chart of the pharmaceutical department or the pharmacy to which you belong**

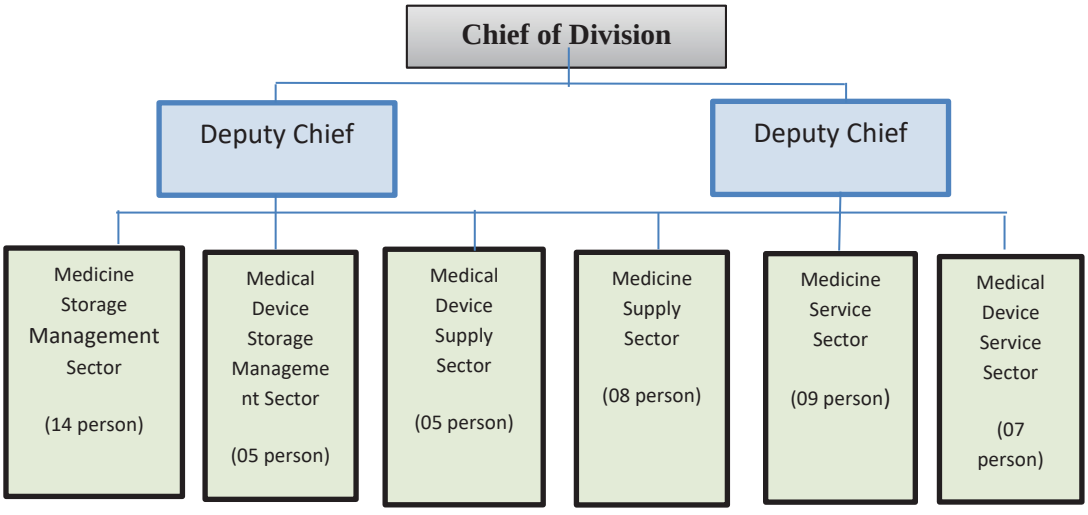
❄**Remark: This is a presentation information of only one hospital**

- **Roles, responsibilities and missions**

Drug division is a crucial and indispensable division which is responsible for seeking the source of medicines, medical devices and other chemicals to become available for demand of each division, sectors and relevant units who provide the healthcare of patients in the hospital.

Research, contact and collaboration with divisions, sectors, and health centers which belong to ministry of health for discussion on medicines- medical devices-chemicals to follow up on registered and unregistered medicines in Laos.

◆ **Organizational structure of Mahosod Hospital**



Pharmacy Hospital Division consist: 1 Chief, 2 Deputy chiefs and there has 6 Sectors.

**06 sectors:**

- Medicine Storage Management Sector
- Medical Device Storage Management Sector
- Medical Device Supply Sector
- Medicine Supply Sector
- Medicine Service Sector
- Medical Device Service Sector

**a/.** Number of section chiefs:

Data 1

Years 2019

**b/.** Number of deputy chiefs

Data 2

Years 2019

**c/.** Number of managers:

Data 6

Years 2019

◆ **Number of staff**

a/. Number of pharmacists

Data 05 peoples

Years 2019

b/. Number of clinical pharmacists

Data 01 peoples

Years 2019

c/. Number of technicians:

Data 34 peoples

Years 2019

◆ **Number of the kinds of drugs managed in your pharmacy or hospital**

| Item | Number |
|---|---|
| **Oral Medicines** | **150** |
| **Injections** | **135** |
| **Medicines for external Use** | **45** |
| **Total:** | **330** |

◆ **Number of prescriptions dealt in your pharmacy per day**

| Item | Number |
|---|---|
| **inpatients** | **650** |
| **Outpatients** | **450** |

◆ Equipment of the pharmacy in your hospital:

At the hospital have a dispensary room and the room area about 80 $m^2$, in side of the room there are rules and facilities available such as cabinet for general medicine, cabinet for psychotherapy medicine, cold storage for cold medicine, medication tray and so on..., there are also have computer and use excel sheet system for the control and recode of medicine information, there are also have the Therapeutic Drug Monitoring in Hospital, there can use internet at the pharmacy for sending report of medicine to its related and connect for m-supply program in Drug Storage.

## 7. Education and License of Pharmacists in your country

**( 1 ) Number of years in primary, secondary and high school education**

| Items | Number |
|---|---|
| Primary | **5 years** |
| Secondary | **4 years** |
| High school | **3 Years** |

**( 2 ) Number of years / weeks in the following categories during university or college Sample for Pharmacist Education:**

| Items | Number |
|---|---|
| University / college: | 5 years |
| Professional education: | 2 years |

| | |
|---|---|
| Practical training: | 2 years |
| Duration of training by each facility: | 1year |
| Hospital pharmacy: | 4 weeks |
| Community pharmacy: | 4 weeks |
| Pharmaceutical company: | 4 weeks |
| Others: | 4 weeks |
| Age at graduation: | 25 years old |

**( 3 ) Are there any national examinations for pharmacists in your country?**

| Items | Number |
|---|---|
| Academic Exams | 5 days |
| Clinical Exams | Based on a completion of the practical training |

**（４）Which of the followings must you fulfill to obtain a pharmacist's license?**

1 To be a university or college graduate

2 Pass the national examination

3 Conclude practical training after graduation

**（５）Number of pharmaceutical university or college graduates:**

- Approximate 70-80 person per year

**The alumni's placement rate (as of: 100 %)**

| | |
|---|---|
| Hospital | 30 % |
| Community Pharmacy | 15 % |
| Government Organization | 30 % |
| Enterprise | 20 % |
| Others | 5 % |

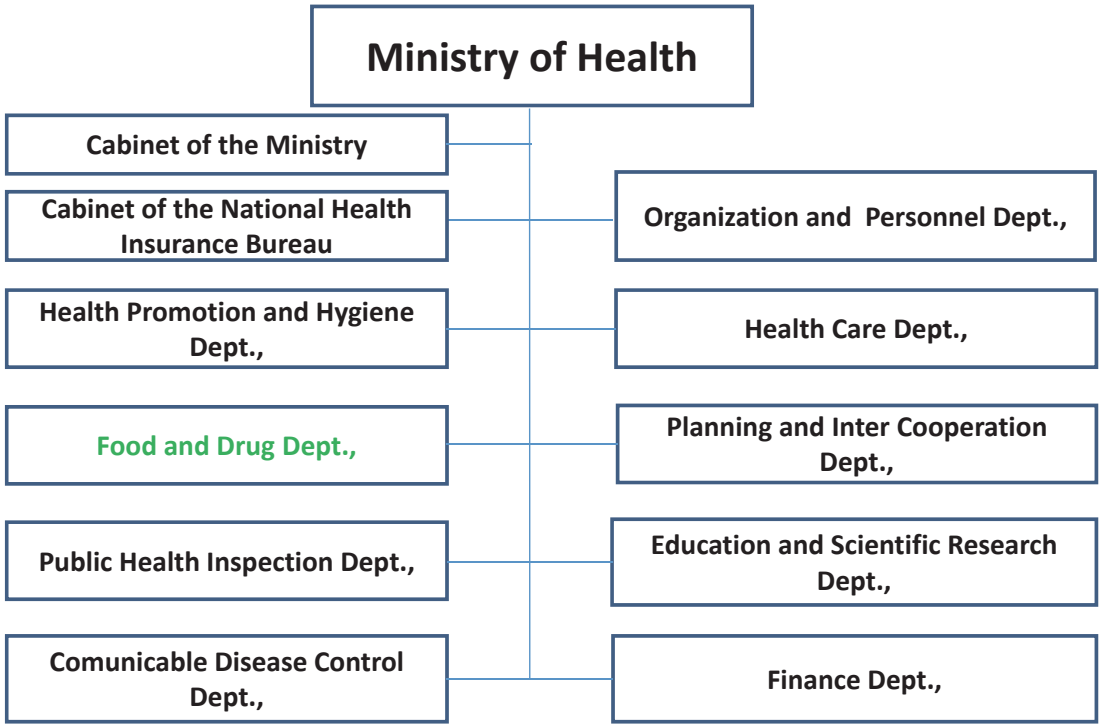
**References:**

- Drug Control Division, Food and Drug Department (MoH)
- Pharmacy Hospital Management Division, Food and Drug Department (MoH)
- Medical Statistic Division, Budgeting and Planning Department (MOH).
- Administration and Statistic Division of Mahosod Hospital
- Administration and Statistic Division of University of Health Science.

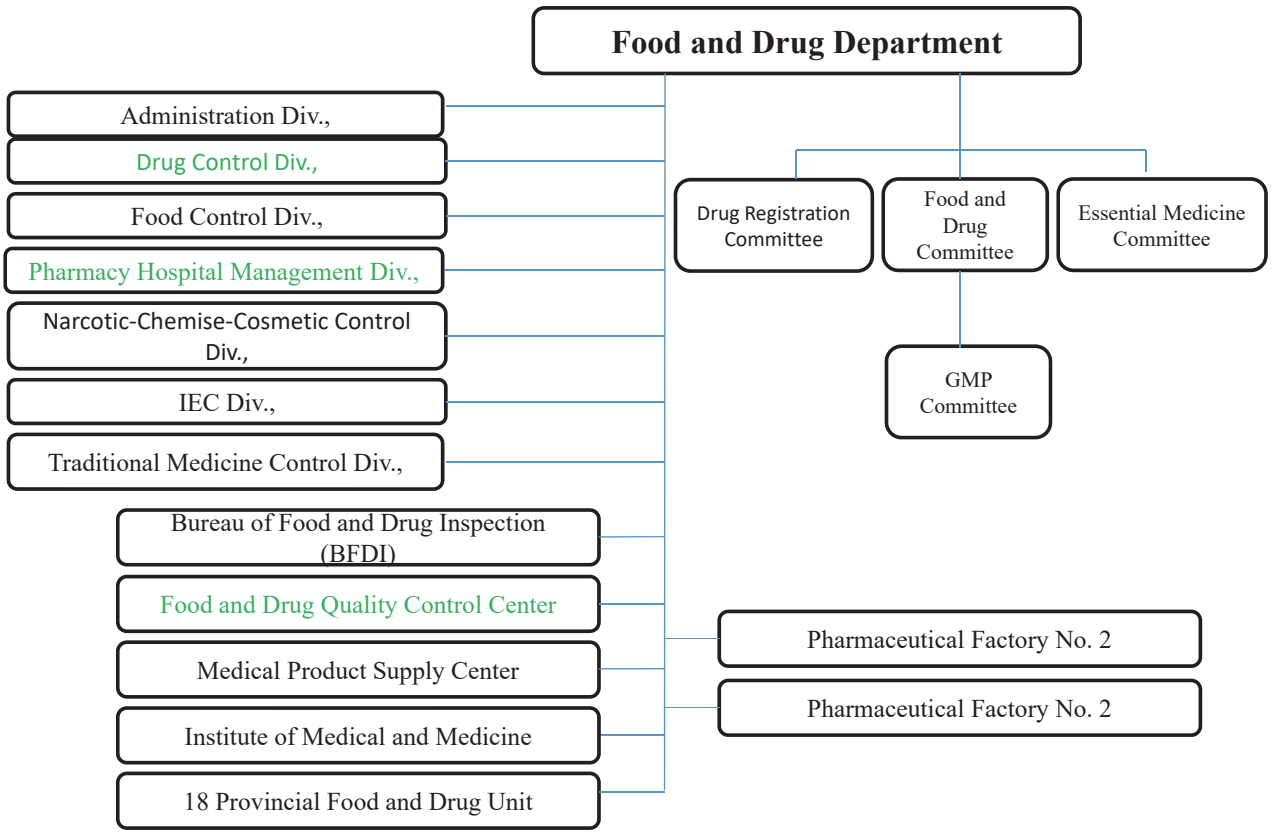
# Regulatory System
## (Regulation of Drug Law to Medicine)

By: Ms. Vongsy Phanthavong
Pharmacy Hospital Management Division
Food and Drug Department, MoH
Lao PDR.

# Organization Chart of MoH



# Food and Drug Organization Chart




# Vision & Mission

**Vision:** To ensure good quality, Safety and Efficacy of Drugs and Medical product as well as their rational use for Lao people.

**Mission:**

•Develop and implement strategy, Policy, Law and Regulation.

•Enforcement of law and regulation governing drug and medical devices.

•Pre-marketing and Post-marketing surveillance of drugs, medical devices and cosmetic products.

•Strengthening of drugs and medical product quality assurance system including quality control.

•Provide education and information on the use of drugs and medical products for both public and private sector.

•Promote rational use of drugs.

# Policy, Law, Regulation, SOP and Guideline

- National Drug Policies, dated on 13/8/2003
- Law on Drug and Medical Products No: 07/NA , date: 21 December 2011.
- Degree for National Health Insurance No. 470/Gov., dated 17 Oct 2012
- Degree for Traditional Medicine No. 155, dated 30 Sep 2003
- Regulation for Drug registration No. 1441, dated 13 Aug 2003.
- Regulation for Pharmacy No. 2922, dated 21 Sep 2016.
- Regulation Establish Factory and Company No.1820, date 25 Aug 2017.
- Regulation for good manufacturing practice and quality control of drugs No. 1021, dated 11 Aug 1999.
- Regulation on Good Manufacturing Practice No.937/MoH dated 12/07/2004.
- Regulation for disposal of medicines including vaccines No.1862, dated 05 Aug 2016.

# Law, regulation, SOP and Guideline Cont…

- Regulation on the banned drug in Lao No.1018/MoH in 2003.
- Regulation of Donation of Drugs and Medical Product No.2579/MoH dated 12th Nov 2003.
- Regulation on specific controlled medicine and uncontrolled and OTC Drug No.2580/MOH, on 25/11/2002
- Regulation on concerning Food, Drug and Medical Equipment Advertisement No. 2581/MOH in 2003
- Revolving Drug Fund Guideline
- Lao Pharmacovigillance Guideline
- Good Manufacturing Practice Guideline

# Law, regulation, SOP and Guideline Con't….

**In 2019, some SOPs and Guidelines have been drafted as following:**

- Draft SOP for recall Drug and medical Product
- Draft SOP for fast track registration
- Draft SOP for Causality assessment
- Draft for filling ADR Form and reporting ADR Cases
- Draft for Quality Management System (QMS) Manual
- Draft for Good Regulatory Practice (GRP) Guideline

# Good Practices

**Implementation of National Regulatory Authority (NRA) Strengthening:**

- In year 2017, WHO rapid benchmarking of the NAR in Lao PDR, In currently The NRA was improved.

| NRA Function assessed | Sub Indicators MET/Expected to be MET | Indicators MET/Expected to be MET | Sub Indicators % MET | Maturity level |
|---|---|---|---|---|
| 01-NATIONAL REGULATORY SYSTEM (NRS) | 22.5 out of 51 | 3 out of 10 | **44** | **1** |
| 02-REGISTRATION AND MARKETING AUTHORIZATION (RMA) | 23 out of 27 | 4 out of 6 | **85** | **1** |
| 03-VIGILANCE (PVL) | 17 out of 20 | 4 out of 6 | **85** | **1** |
| 04-MARKET SURVEILLANCE AND CONTROL (MSC) | 5 out of 5 | 6 out of 6 | **100** | **2** |
| 05-LICENSING PREMISES (LIC) | 12.5 out of 16 | 5 out of 6 | **78** | **2** |
| 06-REGULATORY INSPECTION (RI) | 13.5 out of 20 | 3 out of 6 | **68** | **2** |
| 07-LABORATORY ACCESS AND TESTING (LAT) | 24.5 out of 31 | 6 out of 10 | **79** | **1** |
| 08-CLINICAL TRIAL'S OVERSIGHT (CTO) | 5 out of 27 | 3 out of 6 | **19** | **1** |

# Good Practices

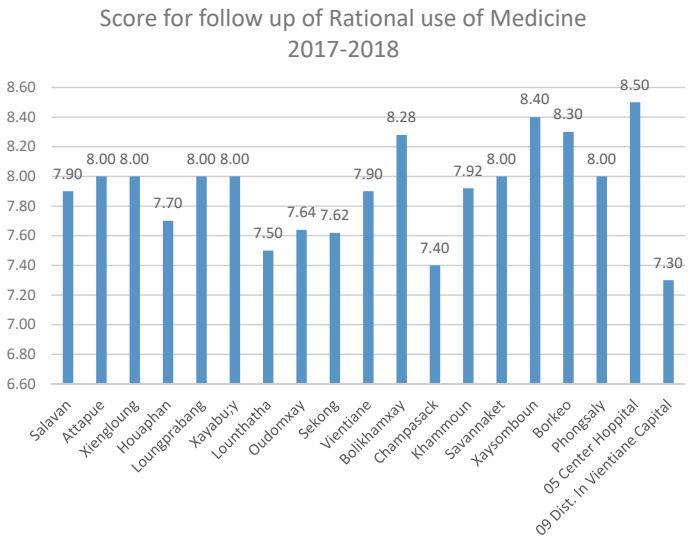
## Implementation of drug procurement:

- Strengthening the procurement work together with the hospitals, centers and Provinces.
- In the past, decentralized system was used for procurement of medicines and medical products, but currently central tendering procurement have been initiated for the 5 central hospitals and 3 centers, and then expanded to 06 southern provinces and this year to 09 northern provinces.

# Good Practices(Con't)

**Rational use of Medicine**

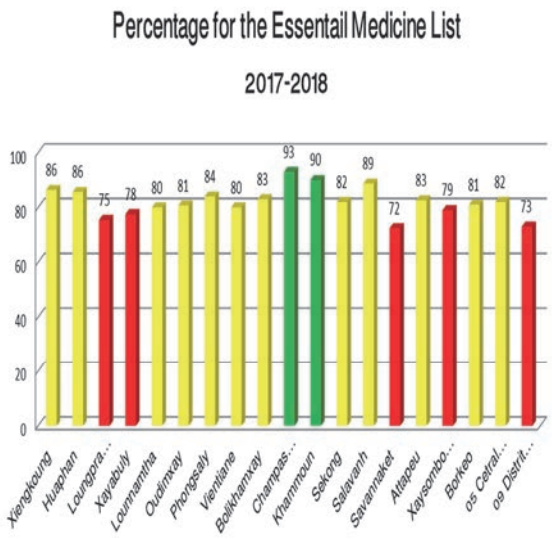
- Review Standard Treatment Guideline and Drug Therapeutic Committee;
- Promote Rational use of Medicine;
- Conduct training and follow up for Rational use of Medicine in central, provincial, and district hospitals and health centers based on 10 indicators and 25 chronic diseases in the standard treatment guideline.



# Good Practices(Con't)

**Availability of Essential Medicines**

- Promote the use of Essential Medicines List (EML) in Health facilities;
- Ensure the availability of good quality essential medicines in order to improve access to essential medicines in health facilities, and to contribute to achieving Universal Health Coverage (UHC); and
- Follow up on the use of EML in central, provincial and district hospitals and health centers.




# Good Practices(Con't)

**Traditional Medicine and CM**

- There has been a policy on promoting traditional medicine in the health system.
- Promote traditional medicine at all levels of public health services.
- The use of Traditional Complementary Medicine Services is an increase expanding in the public health services.
- Promote traditional medicinal products are of good quality for domestic use and export.
- 119 Medicinal plants have been protected and belong to MoH (2018).
- In 2018 by Guangxi Botanical Garden of Medicinal Plants supported development of Lao Herbal Pharmacopoeia Volume 1 which included standard of 160 medicinal plants.
- There are 7 factories producing allopathic medicines and 3 factories producing traditional medicines in Laos.
- In May 2019; number of registered traditional medicine, Health Supplement, Food Supplement & Dietary Supplement are following:

- TM 124 items (domestic products); 194 items (imported products)
- Health Supplement 30 items (domestic products); 78 items (imported products)
- Food Supplement 31 items (imported products); Dietary Supplement 43 items (imported products);

# Good Practices(Con't)

**Registration**

- The procedure of registration is divided into 2 steps:
- Step 1: Application for the permission to import or manufacture drug sample intended to be registered
- Step 2: Application for the Product Registration approval

➢ To renew the certificate after its expire 03 year

- 1,972 items of pharmaceutical products have been registered
- Almost all registered products are Generics
- The registered drug products in Laos are from: Australia, Bangladesh, Belgium, China, France, Germany, India, Indonesia, Japan, Korea, Malaysia, Pakistan, Philippines, Switzerland, Thailand, UK, USA, Vietnam….

# Good Practices(Con't)

**Dispensing and Drug Storage**

- Excel sheet is used in the dispensing room of health facility to record on medicines use.
- M-Supply program have been used for inventory management of medicines and medical products in health facilities and warehouses. Currently, M-supply program have been installed in 156 units, and will be expanded to 29 units this year.
- The drug storages in health facilities have been monitored using good storage practice guideline.

# Good Practices(Con't)

**Medicine including vaccine safety surveillance**

- In 2008, FDD established ADR Committee
- In 2012, FDD implemented the pilot project on Target Spontaneous Report of 2 ARV drugs at 05 HIV treatment centers and expanded to 09 centers
- In 2013 FDD established PV unit
- FDD became an associate member in 2013 and a full member of Uppsala Monitoring Center as 122nd member countries in May 2015
- Since 2017, FDD in cooperation with NIP has conducted training of trainer (TOT) course for ADR & AEFI reporting and monitoring for health staff at provincial and district levels in eight provinces and this year this TOT course will be conducted in 05 Provinces.

# Good Practices(Con't)

**National Health Insurance:**

- The National Health Insurance in Lao PDR started in 2015 with the pilot project in Sekong Province, and expanded to each Province in 2016 and there will has cover on 2025 in Lao PDR.
- Currently, costing of essential health service packages have been conducted

# Difficulties/Lessons learned

- Management of Procurement, supply and distribution of drugs at all levels from central to local levels is not uniform.
- There have been unregistered medicines in public and private sectors
- Sale Prices of drugs are different in the whole country.
- There have been a policy to promote the use of traditional medicines with modern medicines, but its implementation is still weak.
- Availability Essential Medicine in some health facility is under 85%
- ADR/AEFI monitoring and reporting has focused recently only in public sector and not private sector,

# The priority topic in this workshop

## We are interested in all topics from the course

•We would like to learn from Japanese experience and other participating countries how they manage the implementation of pharmaceutical Law and related regulations.

•The lessons gained from the course can help improve my work related to pharmaceutical supply chain management especially hospital pharmacy management which can further improve access to good quality and affordable medicines with the ultimate goal of reaching UHC.

## Challenges

- No guideline for procurement of medicines and medical products.
- No regulation for Medicine Price Control
- Limited knowledge and experience in dossier review/assessment for registration of new medicines.
- Limited knowledge and experience in causality assessment for Pharmacovigilance (PV) and we have only PV unit, not yet PV Center.
- Insufficient English knowledge and skills

# Thank you
# Arigato gozaimasu

*Regulatory Systems*
*on Ensuring Access to Quality Medicines*

# LIBERIA

# REPUBLIC OF LIBERIA

# LIBERIA PHARMACY BOARD

## REGULATORY AGENCY MINISTRY OF HEALTH

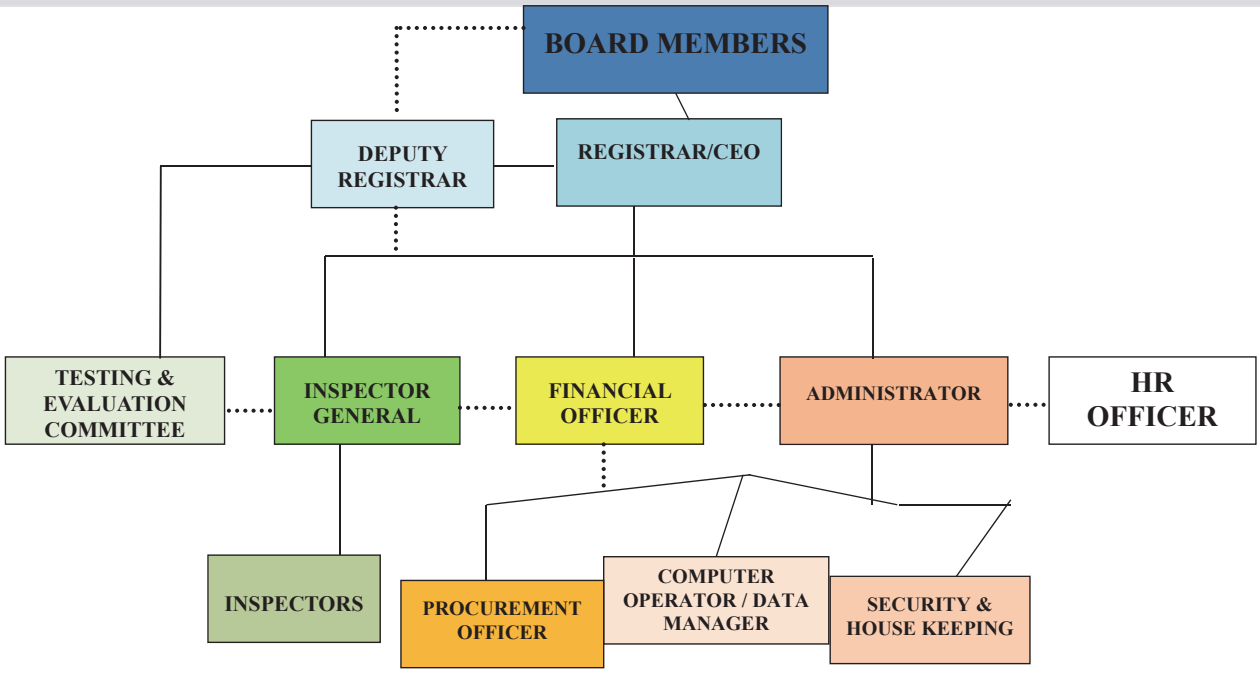




## Cont…

- the Liberian Pharmacy Board (commonly called Pharmacy Board of Liberia or PBL), is a regulatory authority that was established by an ACT of Pharmacy in 1967 to regulate the practice of pharmacy in Liberia (L. 1966-1967.
- An act to amend the Public Health and Safety Law to create a pharmacy board within the Department of Health).
- Headquarters Montserrado County
- Seven (7) Board Members
- The Board is headed by a registrar

# ORGANOGRAM








**Mandate** :

The primary objective of the Liberian Pharmacy Board are as follow:

- promote,
- preserve,
- protect the public health,
- safety, and welfare,
- and advise the minister of health on pharmaceutical matters.

## REGULATORY FUNCTIONS

- Maintains a registry of pharmaceutical outlets that sells and distribute drugs, medications, and other materials used to diagnose and prevent illness and disease, and treat injury
- Regulate the practice of pharmacy in Liberia
- Conduct state board exams for pharmacists and pharmacy technicians for licensure
- Develops standards/ guidelines for professional competency
- Promulgates rules and regulations
- Adjudicates complaints against professionals and, when necessary, imposes disciplinary sanctions.




## PHARMACEUTICAL REGULATORY AGENCIES

There are three pharmaceutical regulatory agencies:

1. Pharmacy Division at the Ministry of Health,
2. Liberia Pharmacy Board (LPB)
3. And most recent in 2010 established the Liberia Medicines and Health Products Regulatory Authority (LMHRA)

**Pharmacy Division**:
- Policy making,
- deployment of pharmacists throughout the country
- formulation of the therapeutic guidelines for Liberia

**Liberia Pharmacy Board:**
- Revert to slide 5

**Liberia Medicine and Health Products Regulatory Authority:**
- Quality control of pharmaceutical products (revision of GMP Guidelines and regulation)
- Whole sale and Importation



# Pharmacist's in the Healthcare system

All pharmacists practicing in Liberia must have obtained an under-graduate degree and enrolled at the school of pharmacy for 4 years, with the following roles and positions:

- Provide pharmaceutical healthcare services (clinical pharmacist)
- Procurement, inventory management and storage
- Pharmaceutical Regulators (dispensaries, Pharmaceutical outlets and warehouses)
- Provision of pharmaceutical information through community engagement
- Community pharmacist (supervise pharmacy shops)

# Cont…..

The pharmaceutical sector is composed of:

- Pharmacies ( all categories of pharmaceutical)
- Medicine stores (over-the-counter medication)
- Hospital, Health center and Clinic (dispensaries)

Number of licensed Pharmacists:

- 168 pharmacists

Pharmacy technician

- 69 Pharm Tech ( awaiting licensure)

Positions occupied by pharmacist

- Pharmaceutical Inspector General,
- Managing director
- Chief pharmacist (Republic of Liberia)
- Registrar
- County Pharmacist





# THANKS

# REPUBLIC OF LIBERIA
# MINISTRY OF HEALTH (MOH)

## LIBERIA PHARMACY BOARD


**JEFFERSON PIAH HARRIS**

BSc(Zoology), B-Pharm, MPCPharm, MPAL, RPh/
INSPECTOR GENERAL LIBERIA PHARMACY BOARD
ACTING PRESIDENT, PHARMACEUTICAL
ASSOCIATION OF LIBERIA
+231-886536997
Jeffharris_10@yahoo.com




## 1. Pharmaceutical Regulation, Pharmacy Board of Liberia

- Liberia Pharmacy Board (LPB) is a regulatory arm of the Ministry of Health (MOH) RL, was established in 1966-7 by an Act of Legislation.
- To regulate the practice of pharmacy in the Republic of Liberia) as a specialized body of the Liberia Health Sector serving as the directing and coordinating regulatory authority for the practice of pharmacy in Liberia.
- As a regulatory institution its organogram comprises of an Inspectorate Department
- The Department is headed by a Pharmacist, whose position is the “Inspector General” appointed by Board of Directors, no Job tenure.

# Cont…

Regulatory services provided per job description are as follow:

- Preparation of an annual inspection work plan
- Inspect Hospital, Clinic, Health Center (dispensaries) and Pharmaceutical outlets (medicine Stores and Pharmacies ) at community level
- Ensure that personnel performing pharmaceutical services are certified by the Liberia Pharmacy Board
- That all pharmaceutical outlets comply with annual registration process
- Conduct concise inspection on Premises as well as physical inspection on pharmaceutical products for drug quality and safety
- Ensure establishment of premise based on minimum standards




# ROLE & POSITION OF PHARMACISTS

**Pharmacists in Liberia play various roles as:**

- Pharmaceutical Regulators
- Clinical Pharmacist
- Community Pharmacist
- Pharmaceutical drug inspectors
- Professors
- Conduct state board exam for licensure

# Position Occupied

**And occupied such positions as:**

- A Pharmacist administrator
- Chief Pharmacist Republic of Liberia
- Deputy Minister
- County pharmacist
- Pharmaceutical Inspector General
- Managing Director




# 2. Good Pharmaceutical Practices

Good pharmaceutical Practices is cardinal for quality control, efficiency, productivity and safety

•Examples: Physical Inspection on storage, distribution of pharmaceutical Products and personnel

- ✓ Confiscation and incinerations of substandard, expired, counterfeit products
- ✓ Continual conduction of various kinds of pharmaceutical inspections, awareness and training
- ✓ Stakeholder engagement to review policy documents in the pharmaceutical sector as a possible means of addressing current public health concern like the emerging antimicrobial resistance
- ✓ Continual development of human resource capacity, community engagement and awareness

# Cont…

In our regulatory functions as a pharmacist the issue of the continual proliferation and circulation of counterfeit medicine and strategy for the control and or mitigation difficult.

Lesson learned from these challenges are:

- Inadequate education among the people in relation to the danger and the negative public health implication
- No defined policy and penalty for who be violators
- Emerging Antimicrobial resistance



# 3. Difficulties/Lessons Learned from Past Experience

As a regulator the most difficult and challenge encounters on a frequent basis is the enforcement of regulatory guidelines especially:

- Inspection for regulatory compliance
- Illegal opening of retail pharmaceutical outlets in rural community
- Confiscation of pharmaceutical products from retail outlets which are considered unsafe for public consumption
- Proliferation of counterfeit, substandard and fake pharmaceutical products

# 4. Your interests

My interest as a pharmacist is Drug quality and Safety, with this in mind I hope to strengthen my capacity in three specific area as:

(1) Countermeasures against counterfeit medicines

(2) Acquisition of new knowledge for improvement of quality assurance

(3) To ensure access to quality medicine by acquiring additional knowledge



THANKS FOR YOUR ATTENTION

*Regulatory Systems*
*on Ensuring Access to Quality Medicines*

# MYANMAR

**Part I: INFORMATION SHEET**

***Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2019）***

Name: Mr Zay Yar Moe

Country: Myanmar

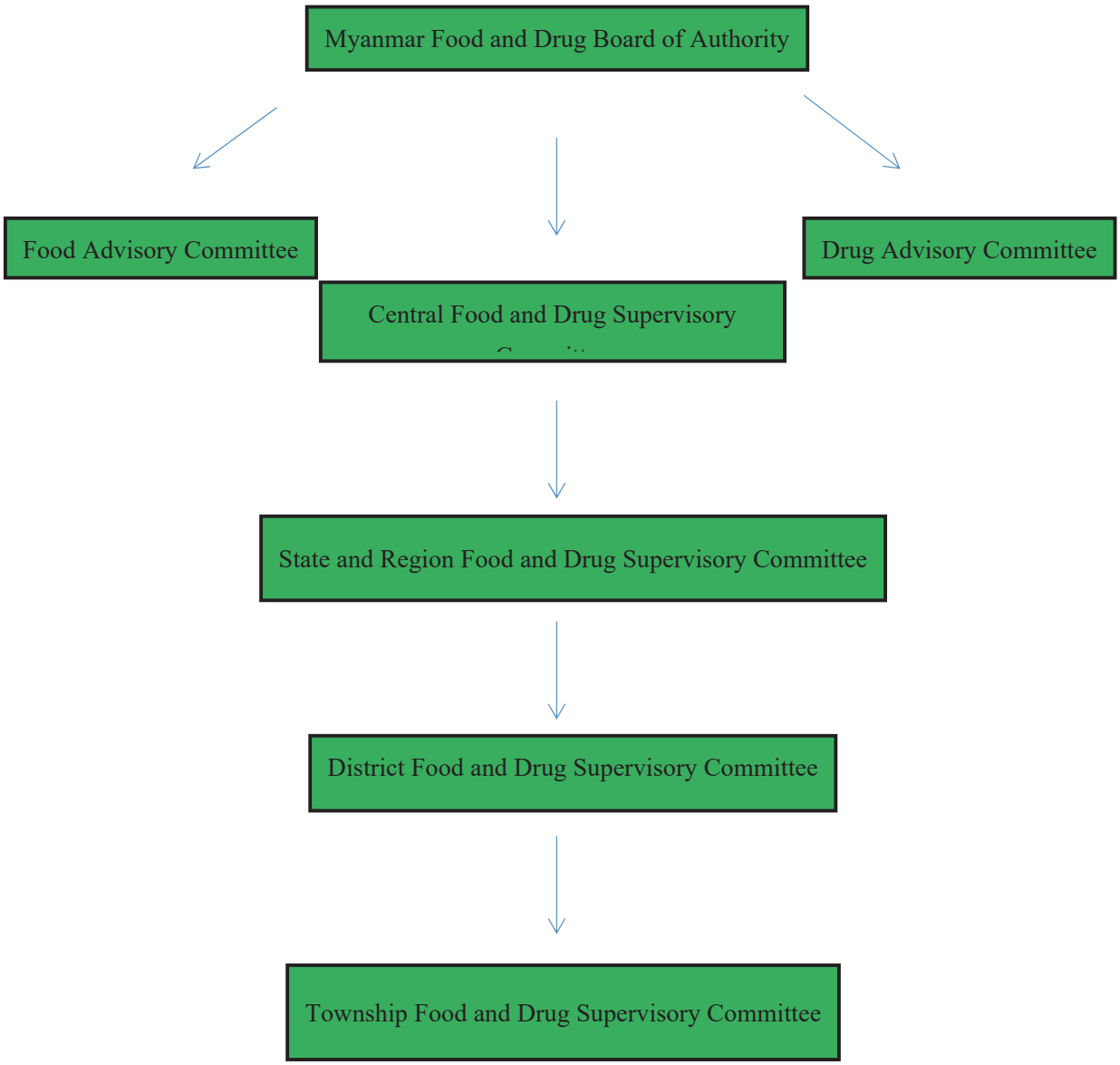
Organization/Department/Division: Ministry of Health and Sports

## ① Organizational Chart

−Please attach the organizational chart of pharmaceutical administration at national/state & local levels about pharmaceutical administration in your country.

−Please briefly describe each role and responsibility on pharmaceutical administration.

## ② Organizational Chart of Pharmaceutical Administration at National/state & local levels



**Role and responsibility on pharmaceutical administration**

Myanmar food and drug board of authority was formed according to the national drug law amending in 2014. The union minister of health and sports is the chairman of Myanmar food and drug board of authority. Director General of department of food and drug administration is the secretary of that board of authority and also chairman of Central food and drug supervisory committee while Drug control director of department of food and drug administration is the secretary of that committee. Heads of states/regions and districts health department are chairmen while heads of department of food and drug administration in states/regions and districts are also secretaries of respective States/ regions and districts food and drug supervisory committees. There is no office of department of food and drug administration in township level where the head of health department is the chairman.

Drug advisory committee provides technical support relating to drugs.

**Role and responsibility of Myanmar food and drug board of authority (National level)**

1. Laying down the policy relating to registration of drugs
2. Laying down the policy relating to determination of an essential drugs
3. Laying down the policy relating to the utilization of drugs
4. Determining the qualifications of persons entitled to apply for license and the terms and conditions thereof for the manufacture, storage, distribution and sale of pharmaceutical raw material or registered drug
5. Stipulating terms and conditions for the manufacture, import, export, storage, distribution and sale of pharmaceutical raw material or registered drug
6. Determining good practices for assurance of quality in respect of manufacture, clinical tests and laboratory analyses of the pharmaceutical raw material or registered drug and all matters relating to drugs
7. Permitting, refusing, temporary revocation and cancelation of registration of drug
8. Granting, refusing, temporary revocation and cancelation of a license
9. Stipulating terms and conditions relating to labeling of drugs, and advertising
10. Determining and cancelling any type of substance as a drug
11. Forming committees in respect of matters relating to expertise and determining the functions and duties of such committees
12. Forming Food and Drug Supervisory Committees in the states, divisions, districts and townships in order to supervise matters relating to food and drugs; determining the functions and duties of such committees
13. Prescribing primary laboratories and appellate laboratories
14. Stipulating terms and conditions relating to food

The Board of Authority may delegate any organization or any person to carry out its functions and duties.

**Role and responsibility of central food and drug supervisory committee (Central level)**

The Board of Authority delegated the central food and drug supervisory committee to carry out its Functions and duties.

**Role and responsibility of state/region food and drug supervisory committee (State/Region level)**

1. Supervising district and township food and drug supervisory committees relating to permitting of pharmacy license
2. Supervising the manufacture, storage, distribution and sale of pharmaceutical enterprises and food manufacturing businesses within the state/region
3. Carrying out the duties and functions of district and township food and drug supervisory committees by itself if necessary
4. Following the order and directive issued by the central food and drug supervisory committee

**Role and responsibility of district food and drug supervisory committee (District level)**

1. Confirmation, postponing and cancelation of the pharmacy license from township food and drug supervisory committees
2. Supervising the manufacture, storage, distribution and sale of pharmaceutical enterprises and food manufacturing businesses within the district
3. Carrying out the duties and functions of township food and drug supervisory committees by itself if necessary
4. Confirmation, postponing and cancelation and directing the punishments of township food and drug supervisory committees relating to food and drug
5. Following the order and directive issued by the superior food and drug supervisory committee

**Role and responsibility of township food and drug supervisory committee (Township level)**

1. Issuing, postponing and cancelation of pharmacy license
2. Supervising, inspection and punishing the offences relating to all matters of food and drug
3. Following the order and directive issued by the superior food and drug supervisory committee

※Hospital pharmacy only

−Please briefly describe the role of pharmacist in medical care system in your country. If possible, focus on the position of the pharmacist in medical institutions.

③ **Legislation on pharmaceutical administration**

−Please briefly bulletined major laws/acts

◆National Level

・National Drug Law (2014 Amendment) administered by Myanmar Food and Drug Board of Authority

・ Narcotic Drugs and Psychotropic Substance (1993) administered by Myanmar Food and Drug Board of Authority and Myanmar Police Force

◆Local Level

・ National Drug Law (2014 Amendment) administered by State and Region Food and Drug Supervisory Committee

・ Narcotic Drugs and Psychotropic Substance (1993) administered by State and Region Food and Drug Supervisory Committee

◆PIC/S

Yes OR No

If yes, joined when

## ④ Regulatory Services

−Please describe pharmaceutical regulatory services of your country in response to each topic described below.

−It is recommended to add supplemental information such as systems, regulations, responsible administrators, since you are expected to explain them to other participants.

◆Pharmaceutical Manufacturing

・Systems, Regulations, etc.

・Good Manufacturing Practice administered by Myanmar Food and Drug Board of Authority

※Example: Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice

◆Drug Import/Export

・Systems, Regulations, etc.

・Good Storage Practice administered by Myanmar Food and Drug Board of Authority

・Good Distribution Practice administered by Myanmar Food and Drug Board of Authority

◆Marketing Authorization

・Systems, Regulations, etc.

・ ASEAN CTD administered by Myanmar Food and Drug Board of Authority

※Example: Good Quality Practice

◆Drug Distribution (including drug selection, procurement, sale)

・Systems, Regulations, etc.

・Good Clinical Practice administered by Department of Medical Services

◆Medicine Safety (post-marketing)

・Systems, Regulations, etc.

・ Good Pharmacy Practice administered by Department of Food and Drug Administration and Township Food and Drug Supervisory Committee

・Good Pharmacovigilance Practice administered by Department of Food and Drug Administration and Township Food and Drug Supervisory Committee

※Example: Good Pharmacovigilance Practice

◆Relief System for Adverse Drug Reactions

・Systems, Regulations, etc.

・Adverse Drug Reaction Monitoring System administered by Department of Medical Services and Department of Food and Drug Administration

## ⑤ Drug Pricing

−Please describe about price control and drug price mechanism at public sector in your country.

Our country have no price control and drug price mechanism. But Myanmar Pharmaceutical and Medical Equipment Entrepreneur Association in association with Ministry of Commerce are working drug pricing especially for imported drugs.

## ⑥ Statistic Data

−Please answer the following questions (if the number is not applicable, please give an answer to the best of your knowledge).

−Put the year of the presented data as well if it's available.

| | | |
|---|---|---|
| 1. | Number of pharmacists | 3900 (2018year) |
| 2. | Number of GMP inspector (National & Local) | 15 (2018 year) |
| 3. | Number of pharmaceutical manufacturers / manufacturing sites | 10 (2018year) |
| 4. | Number of traditional medicine manufacturers / manufacturing sites | (year) |
| 5. | Number of pharmaceutical importers | 220 (2018year) |
| 6. | Number of pharmaceutical wholesalers | 16000 (2018 year) |

※Hospital pharmacy only

## ⑦ Information on your hospital pharmacy

（1） Organization chart of the pharmaceutical department or the pharmacy to which you belong

a. Number of section chiefs:

b. Number of deputy chiefs:

c. Number of managers:

（2） Number of staff

a. Number of pharmacists:

b. Number of clinical pharmacists:

c. Number of technicians:

（3） Number of the kinds of drugs managed in your pharmacy or hospital

a. Oral medicine:

b. Injections:

c. Medicines for external use:

（4） Number of prescriptions dealt in your pharmacy per day

a. For inpatients:

b. For outpatients:

（5） Equipment of the pharmacy in your hospital

a. Does your hospital have a dispensary room?

If "Yes", how large is it?

Yes _____ $m^2$ No

b. Does the pharmacy have a clean room or laminar flow hood?

Yes / No

If "Yes", please describe it in detail

Detail: _____

c. Does the pharmacy have computers?

Yes / No

If "Yes", what is the purpose of using them.

Purpose: _____

d. Do you implement Therapeutic Drug Monitoring (TDM : Therapeutic Drug Monitoring) in your Hospital?

Yes / No

e. Do you prepare TPN (Total Parental Nutrition)

Yes / No

f. Can you use Internet at the pharmacy?

If "Yes", what is the purpose of using it.

Yes / No

Purpose: _____

※All participants. Please describe the following general information as much as you know.

**⑧ Education and License of Pharmacists in your country**

（1） Number of years in primary, secondary and high school education

| | |
|---|---|
| Primary | 5 years |
| Secondary | 4 years |
| High school | 2 years |

（2） Number of years / weeks in the following categories during university or college

| | |
|---|---|
| University / college: | 4 years |
| Professional education: | 3 years |
| Practical training: | 4 years |
| Duration of training by each facility: | 3 years |
| Hospital pharmacy: | 12 weeks |
| Community pharmacy: | weeks |
| Pharmaceutical company: | weeks |
| Others: | weeks |
| Age at graduation: | 22 years old |

（３）Are there any national examinations for pharmacists in your country?

Yes

Academic Exams 2 days

Clinical Exams ____ days

No

（４）Which of the followings must you fulfill to obtain a pharmacist's license?

* If practical training is mandatory, give the subjects and training period.

There is no rule and regulation upon Pharmacist License. Pharmacist license are still under planning and consideration to give SaWa (as a Pharmacist Lisense).

* If practical training is optional, give the reasons.

(i.e. Training is necessary to prepare for the national examination)

（５）Number of pharmaceutical university or college graduates:

250 people / per year

The alumni's placement rate (%)

a. Hospital: 10 %
b. Community Pharmacy: 30 %
c. Government Organization: 5 %
d. Enterprise: 20 %
e. Others: 35 %

⑨ **Side effect report**

Please describe the flow of reporting system (from a medical institution to an administrative agency), when a severe side effect case is occurred in a medical institution. Describe specifically the rule and responsibility of each organization (an administrative agency / a medical institution), and their collaboration/cooperation.

When a severe side effect case is occurred in a medical institution, they are reported to Department of Medical Services and Department of Food and Drug Administration. There is Adverse Drug Reaction Review committee in Department of Medical Services in association with Department of Food and Drug Administration. The Department of FDA launches adverse drug reaction form in software application for both iOS and android version. The ADR review committee make an inspection team for inspecting signs and symptoms of side effects, nature of underlying diseases, medical staff’s use of medicine, store of medicine and quality and safety of medicine. According to their findings, conclude the cause of side effect and take action.

# Republic of the Union of Myanmar

## Ministry of Health and Sports

**Mr Zay Yar Moe**
**Medical Officer (Supply Chain)**

独立行政法人 国際協力機構

## Introduction

**Organization**

Ministry of Health and Sports

Department of Medical Services

**Job Teneure**

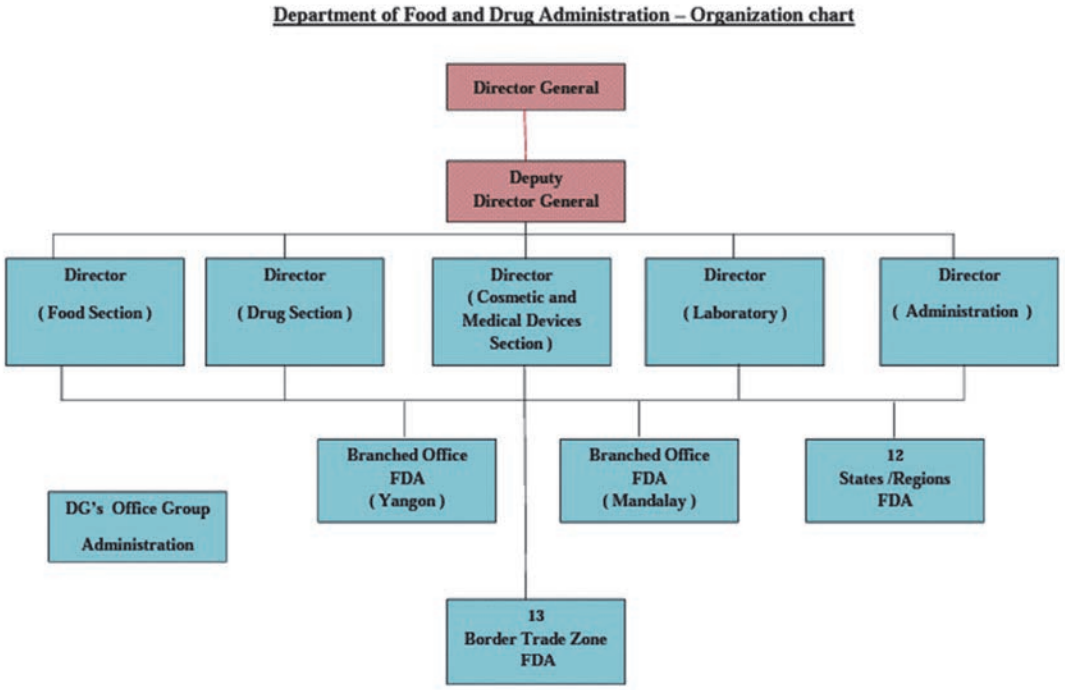
Medical Officer(Supply Chain)

**Regulatory services of my work**

- Procurement of Qualified Drugs and Medical Equipment
- Distribution of these drugs and equipment to hospital and State/Regional health Departments

独立行政法人 国際協力機構

# Organization Setup of Food and Drug Administration Department




幾構

# Roles and Position of Pharmacists in Myanmar

1. Clinical Pharmacists (in hospitals)
   -Manage the supply chain of drug store
2. Pharmacists in Research
   -Carrying out in analytical research of drugs and clinical trial
3. QC managers and Production managers in pharmaceutical factories
4. Academic pharmacists (in universities of pharmacy)
5. Sale managers (in pharmaceutical companies)
6. In-charge in private pharmacies
   -Manage GPP and GSP of pharmacies
7. Regulators in food and drug administration



独立行政法人 国際協力機構

# Good Practice

1. Most of pharmacies came to notice GPP and abide the national drug law
   - No selling of unregistered drugs, expired drugs and multi-combined drugs packs
   - Can differentiate and sell POM and OTC
   - Obtain information about falsified drugs
   - Proper storage condition of drugs (+)
2. More skillful inspectors
3. Quality Lab services in local
4. Increased public awareness




# 2. Good Practice

Solutions for past problems

1. Strengthen GPP training
2. Enforce law and regulation
3. Public awareness programs
4. Increased sampling and quality Lab testing
5. Regular inspection on pharmacies

## On-going projects to deal with current problems

1. Training on members of township food and drug supervisory committees about GPP
2. Risk-based PMS activities
3. Detecting and taking action drugs selling shops without license
4. More participation of township food and drug supervisory committee
5. Similar penalties for same offences all over the country




## Successful countermeasures against problems

1. Regular Inspection on pharmacies (GPP & GSP)
2. Quality Mini-laboratory services
3. Notify the public and pharmacies
4. Training the inspectors, wholesalers and retailers
5. Public awareness programs

## Challenges

- Use of un-registered medical products
- Organization and function of the Drug Inspectorate need to be strengthened through appropriate legislation
- Shortage of human resources at DFDA
- Awareness campaign for health practitioners and the general public regarding the importance of use of registered medical products



## My Interest

(1) Proper supply chain system

(2) Administrative management in pharmaceutical regulatory system


ありがとう(ございます)
Arigatō (gozaimasu).
Thank you.

*Regulatory Systems*
*on Ensuring Access to Quality Medicines*

# THAILAND

**Part I: INFORMATION SHEET**

***Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2019）***

Name: Phrueg Apilardmongkol
Country: Thailand
Organization/Department/Division:
Planning and Regulatory Affairs Division,
Quality Assurance Department
The Government Pharmaceutical Organization

## ① Organizational Chart

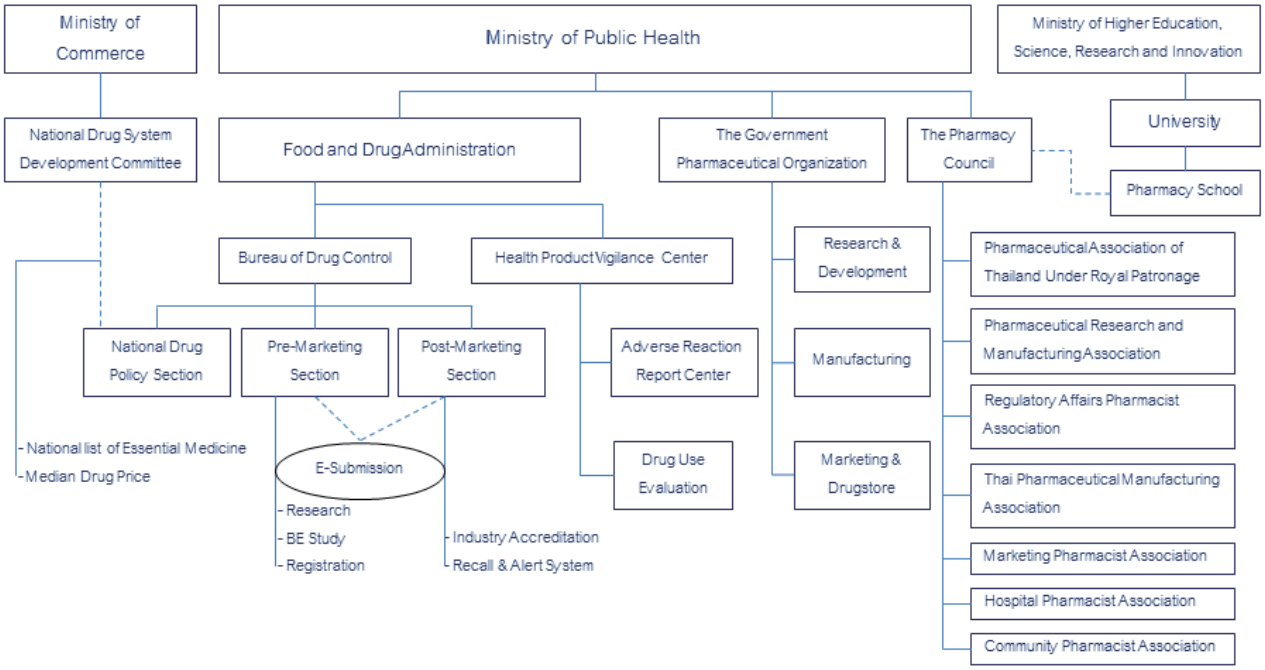



*Chart: Thailand's National Drug system*

**Pharmaceutical Administration**

Food and Drug Administration (FDA) responsibilities including of;

• Pre-marketing Control: This includes control of manufacturing facilities, product quality and advertising before product-launch to the market.

• Post-marketing Control: To maintain compliance with approved products and with legislation and regulations.

• Surveillance Program for Consumers' Safety Operational centers, e.g. Adverse Product Reaction Monitoring Center (APRMC), exchanged with other agencies at local and international level to detect any adverse effects or unexpected outcomes from consumer use of products.

• Consumer Education: To provide health products' information.

• Technical Support and Cooperation with other Agencies: Conduct seminars and workshops, with participants from both public and private sectors.

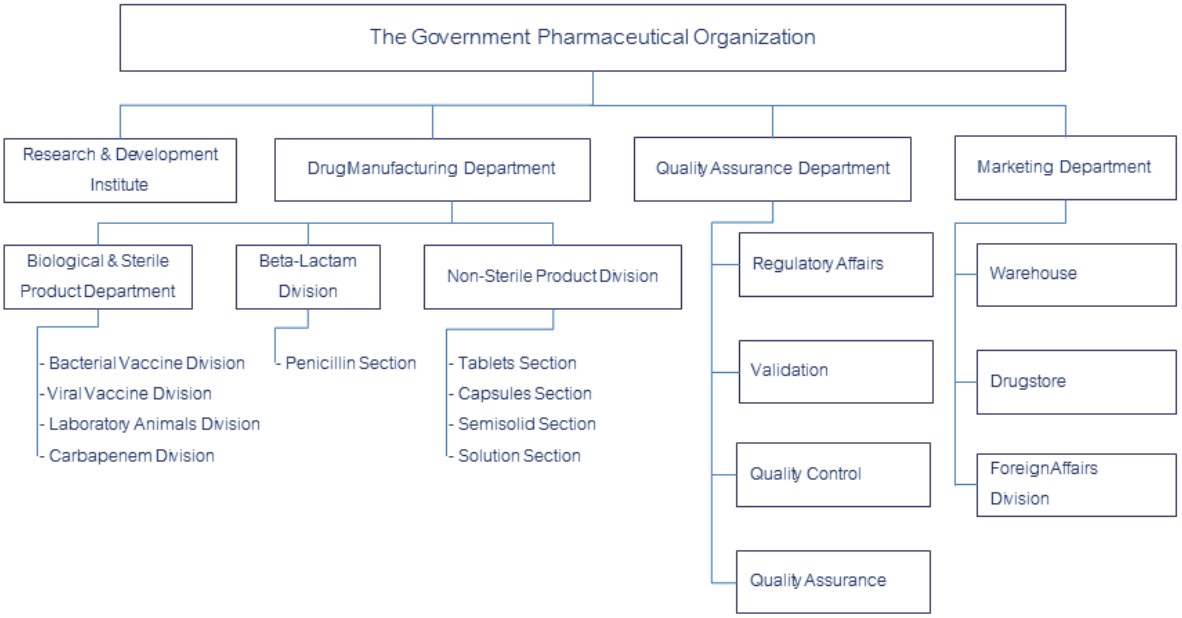



*Chart: The Government Pharmaceutical Organization*

**Pharmaceutical Research, Manufacturing and Marketing**

The Government Pharmaceutical Organization (GPO)

• To manufacture, sell, and supply drug products and medical supplies.

• To maintain necessary price level of drugs and medical supplies for the Thai society to ensure people's accessibility.

• To research and develop new pharmaceutical products and medical supplies to respond to the need of the Thai society.

**② Legislation on pharmaceutical administration**

◆ National Level

・Drug Act, 1967 (B.E.2510) revised 2019 administered by Bureau of Drug Control

・The Narcotics Act 1979 (B.E.2522) revised 2019 administered by Narcotics Control Division

・Psychotropic Substances Act 2017 (B.E.2559) administered by Narcotics Control Division

◆ Local Level

・Ministerial Regulation by Ministry of Public Health administered by FDA & Public Health Office

・Ministry Announcement administered by FDA & Public Health Office

◆ PIC/S

・Yes since August 1st, 2016

③ **Regulatory Services**

◆ Pharmaceutical Manufacturing

| | |
|---|---|
| ・Good manufacturing practice | administered by FDA, TIPA, TPMA |
| ・Good laboratory practice | administered by FDA, TIPA, TPMA |
| ・Good clinical practice | administered by FDA, TIPA, TPMA |
| ・Drug registration | administered by FDA, RAPAT |

◆ Drug Import/Export

| | |
|---|---|
| ・Drug registration | administered by FDA |
| ・Knowledge sharing from FDA | administered by PREMA, RAPAT |

◆ Marketing Authorization

| | |
|---|---|
| ・National Median Drug Price | administered by National Drug System Development Committee |
| ・Drug advertisement control | administered by FDA, MPAT, PREMA |

◆ Drug Distribution (including drug selection, procurement, sale)

| | |
|---|---|
| ・Drug procurement | administered by National Drug System Development Committee , FDA |
| ・Good distribution practice | administered by FDA |
| ・Good storage practice | administered by FDA |

◆ Medicine Safety (post-marketing)

| | |
|---|---|
| ・National List of Essential Medicines | administered by National Drug System Development Committee |
| ・Hospital Accreditation | administered by FDA, HP |
| ・Safety Monitoring Program | administered by FDA, Drug manufacturer |
| ・Post-Market surveillance | administered by FDA, HPVC |

◆ Relief System for Adverse Drug Reactions

| | |
|---|---|
| ・Safety Monitoring Program | administered by Drug manufacturer, Hospital |
| ・Spontaneous ADR report | administered by Drug manufacturer, CPA |
| ・Post-Market surveillance | administered by FDA, HPVC |

**Abbreviation and Acronyms**

| | |
|---|---|
| MoPH | Ministry of Public Health |
| NDI | National Drug System Development Institute |
| FDA | Food and Drug Administration |
| GPO | The Government Pharmaceutical Organization |
| RA | Regulatory Affairs / Regulatory Authorities |
| PAT | Pharmaceutical Association of Thailand under Royal Patronage |
| RAPAT | Regulatory Affairs Pharmacist Association |
| PReMA | Pharmaceutical Research and Manufacturing Association |
| TPMA | Thai Pharmaceutical Manufacturing Association |
| MPAT | Marketing Pharmacist Association |
| HP | Hospital Pharmacist Association |
| CPA | Community Pharmacist Association |

④ **Drug Pricing** Please describe about price control and drug price mechanism at public sector in your country.

National Drug System Development Committee is the coordination group between Ministry of Public Health, Ministry of Commerce, and Ministry of Finance; aim to support patients to access the medicines, rational drug use and reduce the rate of drug resistance. The Committee announced The National list of Essential Medicines (NLEM) since 2013 and has been annually revised. NLEM can be divided into 6 groups including of

A: First line drug complied with medical guideline

B: Second line drug, after the first line drug was ineffective or ADR occurred

C: Drugs with multiple indications, must have been prescribed by medical specialist

D: Drugs with multiple indications, higher price than A and B lists. The drug may have chance of improper drug use. This drug group must have been prescribed by medical specialist

E1: The drug is in clinical researching, all patients must be monitored

E2: Patients need a special management to access the drug.

In 2018, the committee announced the National Drug Median Price to maximize cost-effectiveness for the hospital. The drug median price and NLEM works together to reduce the drug price for better access.

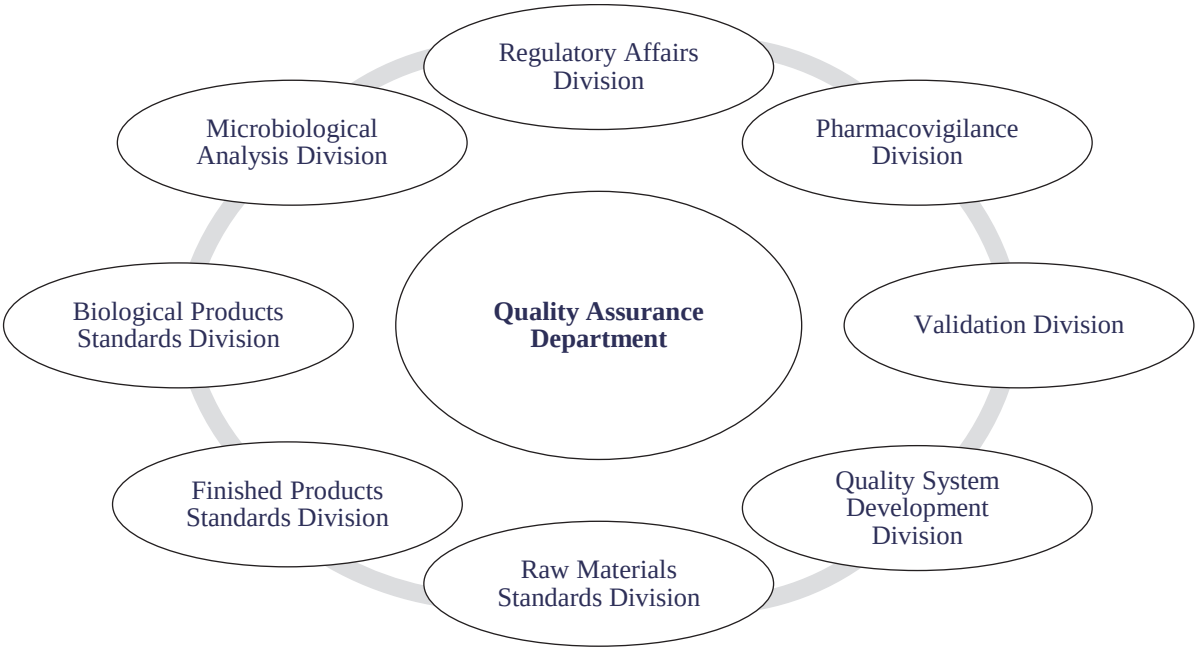
National Drug Median Price affected only at the government hospital. For private sectors, the median price or ceiling is not set. But the drugs' price must have been announced to the patients, including of purchased price and selling price.

The drug median price list will be revised annually in the same way as NLEM. Latest announcement of target drug groups including of H2RA / PPI, NSAIDS, Antilipidemia, ACEI, ARB, Antiplatelet, Glucosamine, Drug affecting bone metabolism, and Anticancer.

⑤ **Statistic Data**

| | | | |
|---|---|---|---|
| 1. Number of pharmacists | | 40,152 | (2019) |
| 2. Number of GMP inspector (National & Local) | National | 38 | (2019) |
| 3. Number of pharmaceutical manufacturers / manufacturing sites | | 160 | (2018) |
| 4. Number of traditional medicine manufacturers / manufacturing sites | | 879 | (2017) |
| | GMP accredited | 36 | (2018) |
| 5. Number of pharmaceutical importers | | 811 | (2018) |
| 6. Number of pharmaceutical wholesalers | | 194 | (2018) |

**⑥ Information on your industrial pharmacy**




(1) Organization chart of the pharmaceutical department or the pharmacy to which you belong.

a. Number of department director: 14
b. Number of division manager: 14
c. Number of section header: 60

(2) Number of staff

a. Number of pharmacists: 374
b. Number of R&D pharmacists: 85
c. Number of PD pharmacists: 118
d. Number of QA & QC pharmacists: 95
e. Number of Marketing Pharmacists: 18

(3) Number of the kinds of drug products

a. Oral medicine: 139
b. Injections: 10
c. Medicines for external use: 14

## ⑦ Education and License of Pharmacists in your country

(1) Number of years in primary, secondary and high school education

| | |
|---|---|
| Primary | 6 years |
| Secondary | 3 years |
| High school | 3 years |

(2) Number of years / weeks in the following categories during university or college

| | |
|---|---|
| University / college: | 6 years |
| Professional education | 4 years |
| Practical training: | 1 year |
| Duration of training by each facility: | 6 - 12 weeks |
| Hospital pharmacy: | At least 6 weeks |
| Community pharmacy: | At least 6 weeks |
| Pharmaceutical company: | 24 - 42 weeks |
| Others: | 6 - 18 weeks |
| Age at graduation: | 23 - 25 years old |

(3) Are there any national examinations for pharmacists in your country?

| | | | |
|---|---|---|---|
| Yes | Academic Exams | (MCQ) | 2 days |
| | Clinical Exams | (Practical) | 1 day |

(4) Which of the followings must you fulfill to obtain a pharmacist's license?

| | |
|---|---|
| • Every pharmacy students: | At least 6 weeks on hospital clerkship |
| | At least 6 weeks in drugstore clerkship |
| • Clinical pharmacy students: | At least 6 weeks inpatient care clerkship |
| | At least 6 weeks outpatient care clerkship |
| • Industrial pharmacy students: | At least 6 weeks quality assurance clerkship |
| | At least 6 weeks manufacturing clerkship |

(5) Number of pharmaceutical university or college graduates: (approx.) 2,000 people / per year

The alumni's placement rate (%)

| | | |
|---|---|---|
| a. | Hospital | 35 % |
| b. | Community Pharmacy | 15 % |
| c. | Government Organization | 20 % |
| d. | Enterprise | 25 % |
| e. | Others | 5 % |

## ⑧ Side effect report

Health Product Vigilance Center (HPVC), under supervision of Ministry of Public Health responsible for collecting ADR report from other local and international sections. Health products surveillance program are including drugs, medical devices, herbal medicine, vaccines and biologics drugs.

ADR data has been collected from hospitals, clinics, drugstores, manufacturers, and international organization. After collecting of report, HPVC collaborates with FDA to monitor safety of health products, including recall and alert system. Classification of ADRs can be divided into Non-serious ADR, and Serious ADR including; Death, Life threatening, Comorbidity, Teratogenicity.

Surveillance system including of;

1. Spontaneous reporting of ADRs (passive surveillance) received from hospitals, manufacturers, drugstores or international organization.
2. Stimulated passive surveillance
   - Safety Drug Monitoring Program conducted by drug manufacturer
3. Active surveillance
   - Intensive Drug Monitoring (Drug Event Monitoring) in high alert drugs. Patients should be monitored in hospital during the medicine course.

# THAILAND

## THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## Ministry of Public Health

Phrueg Apilardmongkol

Pharmacist, Regulatory Affairs



## Introduction of the work

### Roles and Positions of Pharmacist in Thailand

**Research pharmacist**

- Drug formulation development
- Clinical research
- Drug import / registration

**Industrial pharmacist**

- Drug manufacturing control
- Quality assurance and quality control

**Marketing pharmacist**

- Medical representative

**Education pharmacist**

**Drugstore pharmacist**

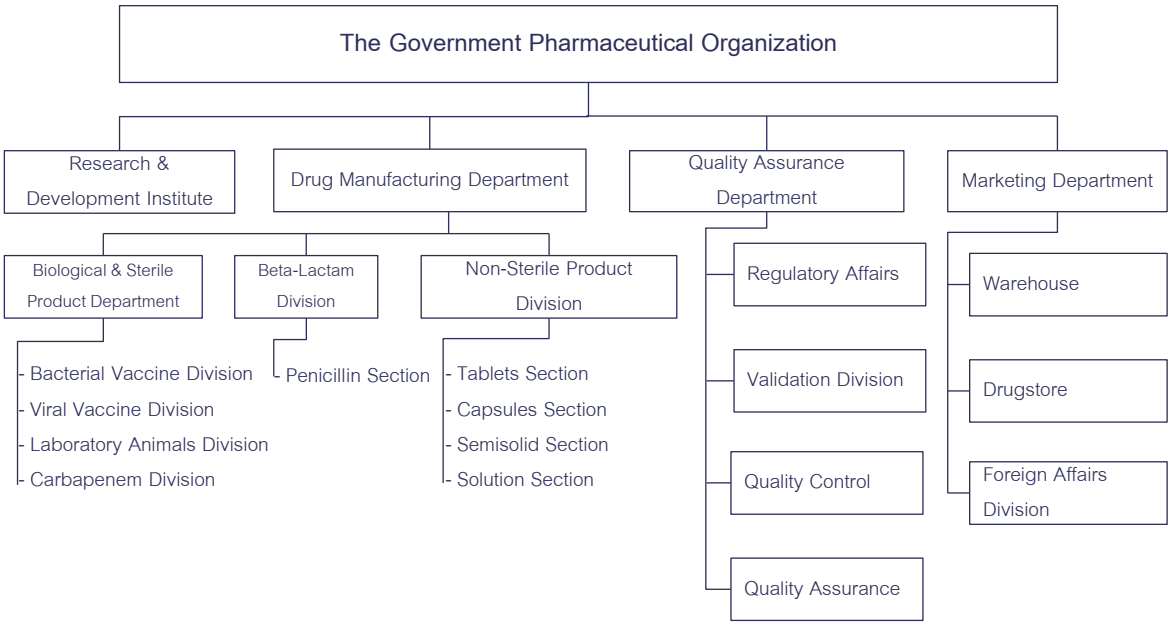
- Drug distribution and dispensing
- Follow up and patients visit

**Hospital pharmacist**

- Drug warehouse
- Extemporaneous preparation
- Therapeutic drug monitoring
- Drug dispensing

# Introduction of the work

## Organization and Department








# Introduction of the work

## My Roles and Positions

**Organization and Department**

- Regulatory Affairs Division

**Job Tenure**

- Drug registration, technical dossier preparation

**Engaging Regulatory Service**

- Pre-Marketing Registration
- Post-Marketing Monitoring
- Export / Import Products

# Good practice

## Experiences About Good Practice

**Regulatory Affairs**

- Technical drug dossier (CTD / ACTD) preparation and submission
- Variation of drug dossier
- Preparation of import and export products
- Developing dossier for electronics drug submission system

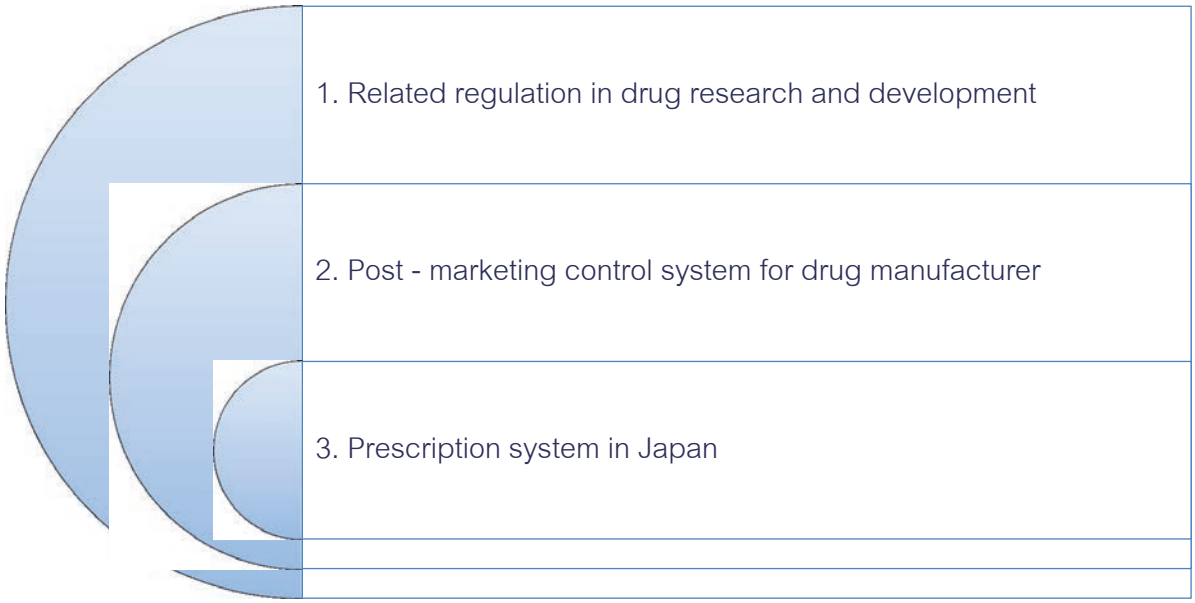




# Difficulties/Lessons learned from past experiences

- Utilization of drug database
- Harmonization of drug registration data between Thailand and overseas
- Data storage and management of registered data
- Handling post-marketing control

# Interests


1. Related regulation in drug research and development
2. Post - marketing control system for drug manufacturer
3. Prescription system in Japan

*Regulatory Systems*
*on Ensuring Access to Quality Medicines*

# TIMOR-LESTE

Japan International Cooperation Agency

***REGULATORY SYSTEMS ON ENSURING ACCESS TO QUALITY MEDICINES***

***(JFY 2019)***

**Inception Report**

Name : Lubiensca Encarnação Dias

Country : Timor-Leste

Organization/Department/Division : Serviços Autonomos de Medicamentos e equipamentos da Saude (SAMES)/Werehouse Department/Senior Officer of Pharmacist

**PART I: INFORMATION SHEET**

**Why? To clarify and share the basic information on each country and yourself among all participants**

The best "***Regulatory Systems On Ensuring Access To Quality Medicines"*** for countries like Timor-Leste is prequalification. For the other country they can consider a drug registration systems. As we know that Timor-Leste does not have any manufacture, and the all medical products are import from the outside country.

**Introduction**

**TIMOR-LESTE MAP**


Timor-Leste or east Timor, a southest Asian nation occupying half the island of Timor, is ringed by coral reefs teeming with marine life.

Landmarks in the capital, Dili, speak to country's stuggles for independence from Portugal in 1975 and then Indonesia in 2002. The iconic 27m-tall Cristo Rei de Dili statue sits on a hilltop high over the city, with sweeping views of the surrounding bay.

Capital : Dili

Population: 1.296 milliom (2017)

Points of Interest : Atauro Island, Jaco Island, Tatamailau, Cristo Rei of Dili, Nino Konis Santana National Park and more

Official language: Portuguese and Tetun

**The vision of Ministry of Health of Timor-Leste**

The Government is committed to a vision of ensuring safe, effective, reliable quality, essential medicines to be avalaible at affordable cost at all times to the entire population of Timor-Leste. The national drug Policy there for recognizes that priorities must be made in terms of selecting drug of supply, to meet the most important needs of the healthcare system, solving the most important heath problems of the population.

**Mission**

Consistent the vision statements, the mission of ministry of health is strive to ensure the avalaibility and affordability of health services to all the people of Timor-leste, to regulate the health sector and to promote community and stakeholders' participation (including other sector).

1. **Organizational Chart (Attach)**
2. **Legislation on Pharmaceuticals Administration**
   a. ***The Medicine Law; (Parmaceutical Law, Drug Law).***

      Amn updated Drug Law of the Republic of Timor-Leste shall form the legal basis and framework for regulatory control, matching objectives of the National Drug Policy. It shall incorporate elements of existing rules and regulations which are in line with this policy Following enactment of the Lawby the relevant bodies, detailed regulations governing the standards and procedures for carrying out the provisions of the law shall be formulated.

      *Scope of the Law, decrees and duidelines, forming a regulatory framework for the pharmaceutical sector.*

      The Legal and regulatory framework shall include the following:

      *Specifics; National Drug Regulatory Authority (synonyme: National Drug Administration)*

1. The law shall pave the way for the establishment of a National Drug Administration syn. National Drug Regulatory Authority, in the organization of the Ministry of Health

2. Its duties and powers regarding the enforcement of the Drug Law, with technical regulations for authority and authority, clearly defined in the Drug Law.
3. The National Drug Administration shall be thefocal point for implementation of the National Drug Policy.
4. The National Drug Administration shall be advised by a advisory body. (hereinafter called Advisory Board)

*Access To Medicines And Pharmaceutical Supply*

*b.* A centralized procurement and supply system has been established, the SAMES with the aim to ensure availability and supply of medicines to all levels of health care in a predictable manner. The Public Health objectives of the SAMES system shall be defined in the new Drug Law of Timor Leste.

*c.* There is no local level legislation for pharmaceuticals, but Timor-Leste is currently implementing a decentralization plan which will implement responsibilities for the municipalities. At the National level, DNFM and SAMES have different responsibilities for the pharmaceuticals supply chain.

**3. Regulatory Services**

Pharmaceutical Manufacturing- NA drug import-Department of Pharmacy oversee registrations for local imports. SAMES can procure and import medicines for use in the public system without registration. Marketing authorization-NA Drug Distribution- SAMES have a five years plan ,procurement manual- SAMES also have a separate procurement law to facilitate procurement of medicines. Adverse drug reactions- reporting at the department of pharmacy

**A. Licensing of Importers, Wholesalers and Pharmacies**

The Ministry of Trade and Development is responsible for issuing a general trade license for any corporation, before it can apply to the Drug Administration for license to operate as medicine importer, wholesaler or retail pharmacy.
Legislation shall require that importers, wholesalers, pharmacies and other retail outlets:

Be licensed by the National Drug Administration, and Fulfill standard requirements of the Ministry of Health in providing and maintaining suitable premises and quality procedures including appropriate storage conditions for medicines to preserve their quality and efficacy (Good Distribution Practices) and that qualified personnel are available to endure good pharmacy practices Pharmaceutical personnel, and healthcare personnel with right to prescribe, shall be licensed by the National Drug Administration, and kept in updated recording database in the Drug Administration, and in updated printed records over licensed prescribers, provided to all pharmacies with 2 updates per year.

B. **Medicine / Drug Registration and Marketing Authorization**

Approval is required through Registration of a medicine for approved purpose(s) (indications) before a medicine can be imported, sold or used in Timor Leste. Only medicines with adequate documentation about its efficacy and its safety, in its use for the suggested indication(s) can be approved bt registration. In addition, import license and marketing authorization from the Drug Administration is required before any product is allowed on the market. Regulations for issuing or denying marketing authorizations shall be clearly defined and shall be based on evaluation of safety, efficacy, quality and need. approved bt registration. In addition, importlicense and marketing authorization from the Drug Administration is required before any product is allowed on the market. Regulations for issuing or denying marketing authorizations shall be clearly defined and shall be based on evaluation of safety,

efficacy, quality and need. approved bt registration. In addition, importlicense and marketing authorization from the DrugAdministration is required before any product is allowed on the market. Regulations for issuing or denying marketing authorizations shall be clearly defined and shall be based on evaluation of safety, efficacy, quality and need.

Marketing Authorization shall be valid for a specified period of time and a review shall be required for renewal of registration. A registration fee shall be charged for pharmaceutical and other products as determined by Ministry of Health. A database for registration and monitoring imports of pharmaceutical products shall be developed.

**Post Marketing Surveillance.**

All marketed medicines shall be under vigilance to ensure constant conformity with the conditions and terms of the marketing authorization and safety

4. **Drug Pricing**

   Medicines are provided free of charge in all public health facilities. SAMES Procure medicines at internationally competitive prices.

5. **NA**

6. **NA**

7. **Education and License of pharmacist in Timor-Leste**

   1. Number of years in primary, secondary and high school education

      Primary 6 years

      Secondary 3 years

   2. Category during university

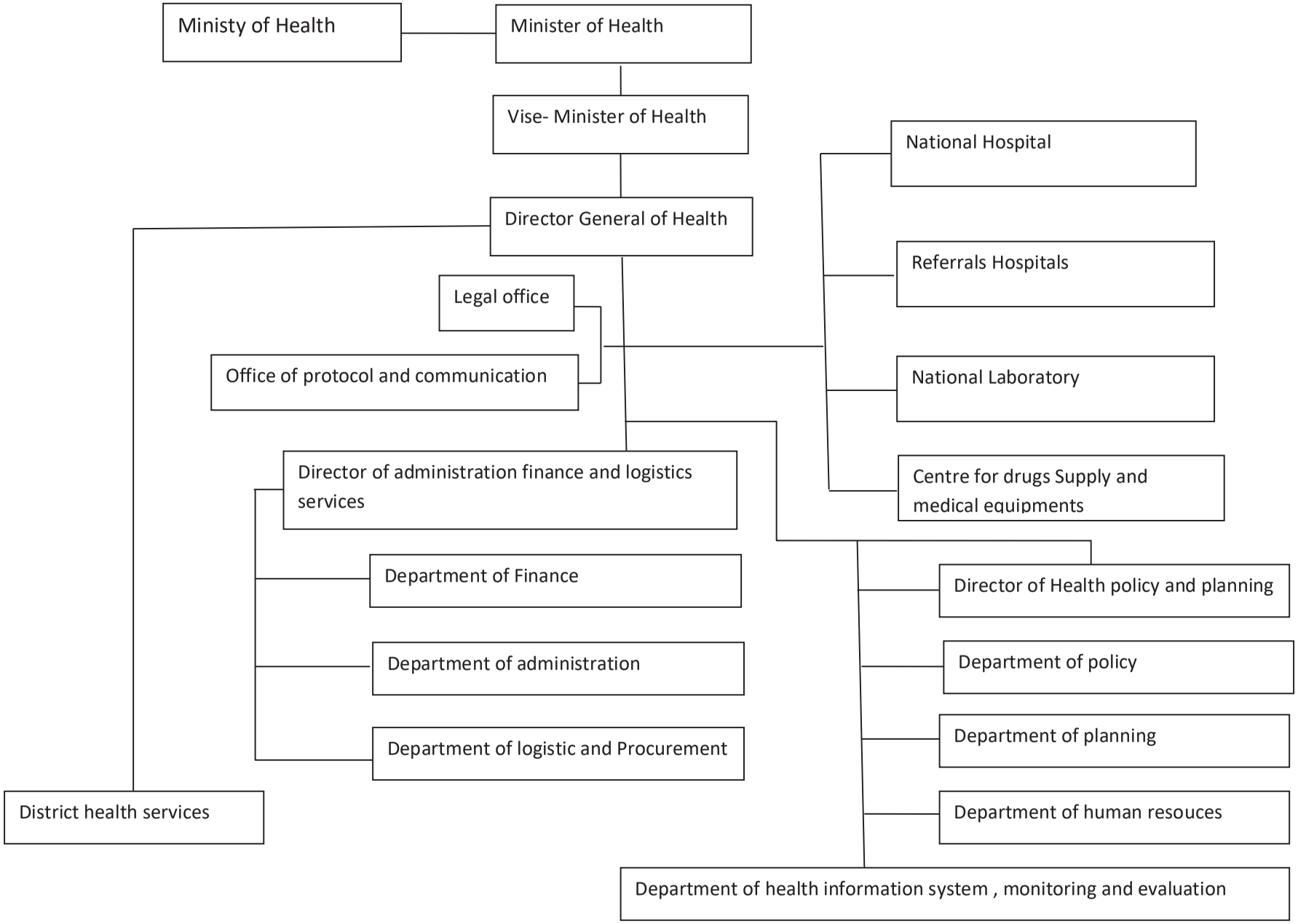
      University : 4 years

      Professional education : 2 years

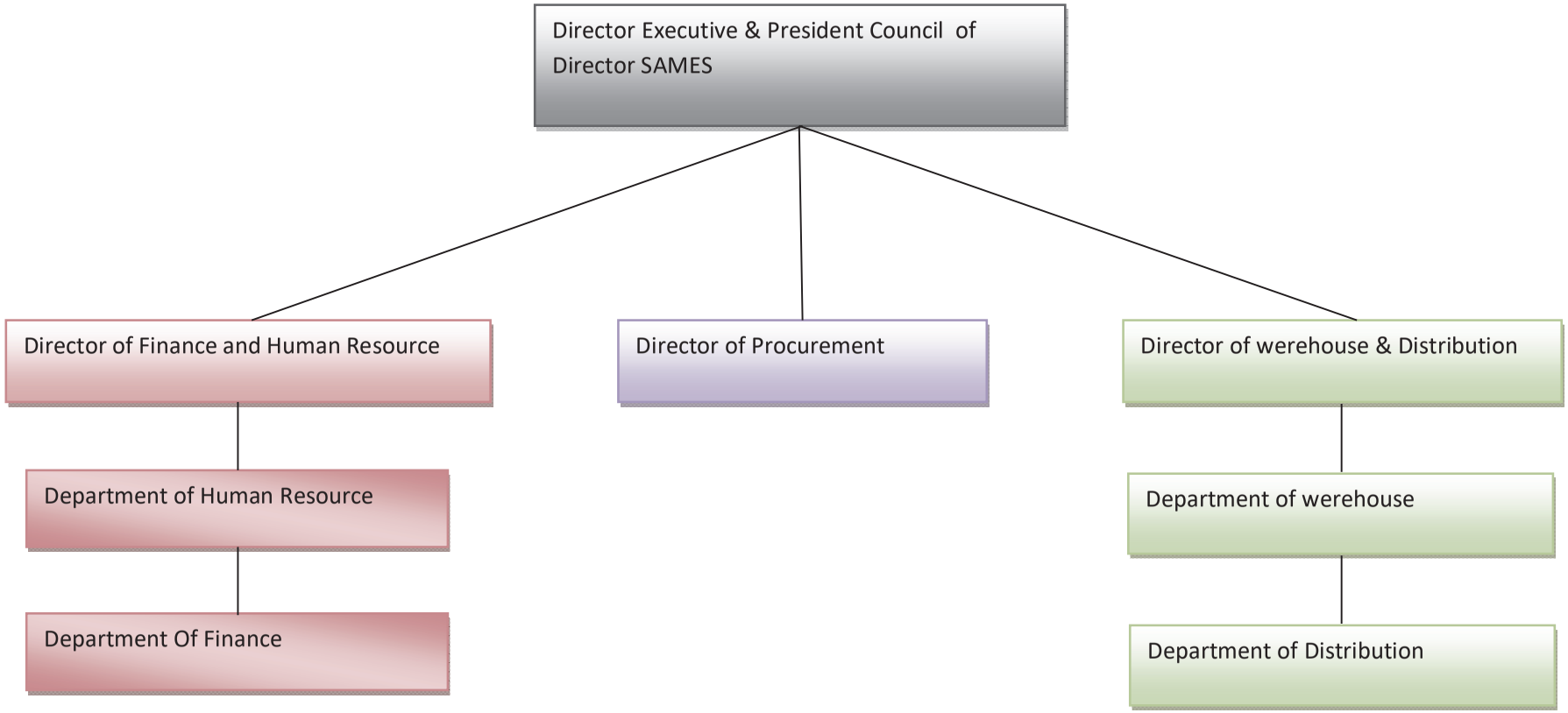
      Practical training 2 or 4months ( one month in werehouse, hospitals, private clinics and the community)

   3. In Timor- Leste at the moment there is no any examination for pharmacist

1. Oganizational chart of ministry of health in Timor-Leste



2. Organizational Chart of Serviços Autonomos de Medicamentos e equipamentos da Saude (SAMES)



Japan International Cooperation Agency

# Inception report presentation

Name : Lubiensca Encarnação Dias
Country : Timor-Leste
Organization/Department/Division : Serviços Autonomos de Medicamentos e equipamentos da Saude (SAMES)/Werehouse Department/Senior Officer of Pharmacist

# SAMES Werehouse (National Pharmacy of Timor-Leste)

# Introduction about SAMES Werehouse of Timor-Leste

- Serviços Autonomos de Medicamentos e equipamentos da Saude (SAMES) is a national werehouse in Timor-Leste only.
- SAMES have a three (3) function important are: Procurement, storage( before storage SAMES have one team that call it R&I, they do the reception and inspection for all medical product that from the supplier and then give it to werehouse and then do distribution to the all health facility around Timor-Leste including National Hospital (HNGV), 5 referrals hospital

# Introduction of the work

1. Organization/Department/Division : Serviços Autonomos de Medicamentos e equipamentos da Saude (SAMES)/Werehouse Department/Senior Officer of Pharmacist
2. Job Tenure:

   senior officer of pharmacist

## Continuation……

- As a Senior Officer in SAMES I am responsible for the warehouse, distribution and reporting activities for the tuberculosis (TB) program and malaria program.

- I am responsible for the distribution of TB Medicines to 13 districts including HNGV (Hospital National Guido Valadares) and five (5) referral hospitals every month. I am also responsible for checking the temperature of the room so that the temperature is always maintained.

## Continuation……

- Cold chain maintenance is important because the temperature is also very influential on the quality of the drug, not only that which affects the quality of medicine, but storage of structuring funds also greatly affect quality.

# GOOD Practices

Achievements & solution to the past problems

Good storage practice, good Pharmacy practices

- Avarege monthly consumption (AMC)-2017
- Inventory system (Stock cards to Msuppy)
- Space for medicines

# GOOD Practices

- Ongoing projects to deal with current problems, maintain:
- Data entry into Msupply
- Stock takes
- Two regional warehouse for medicines, consumables and reagents

# GOOD Practices

- Successful counter measures against problems
- Maintaning data entry into Msupply
- Using 5S kaizen to find the more space for medicines,consumables and reagents
- Regional Warehouse are to use very soon

# My interest

- Pharmaceutical regulatory system in japan, good manufacturing practices (GMP), drug licensing and approvalin Japan and functions and roles of pharmacy in Japan.

# Obrigada

# Thank you

*Regulatory Systems*
*on Ensuring Access to Quality Medicines*

# UGANDA

**Part I: INFORMATION SHEET**

***Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2019）***

Name: *Paul Okware Ikwaras*

Country: *Uganda*

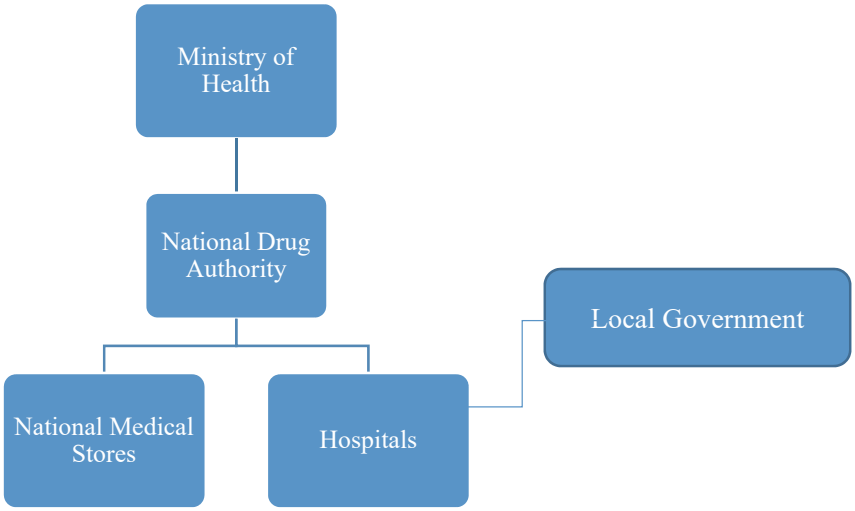
Organization/Department/Division: *National Medical Stores*

## ① Organizational Chart

−Please attach the organizational chart of pharmaceutical administration at national/state & local levels about pharmaceutical administration in your country.

−Please briefly describe each role and responsibility on pharmaceutical administration.

**Medicine regulation in the public sector in Uganda**




*The Role of the Pharmacist in Medical Care*

- *Quantification of Hospital medicine needs*
- *Ensuring the proper use and rational use of medicines in the hospital*
- *Ensuing that the medicines being used are of the required quality and specification and are safe to the patients receiving them.*
- *Research and development in the efficacy of new treatment regimes*
- *As the regulator NDA employee pharmacists in drug inspection and pharmacovigilance*
- *Hospital pharmacists are a vital part of the healthcare term. Working in either the pubic health care or private hospitals. Pharmacist are a part of the team health care team in any hospital.*
- *Ensuring proposer disposal of unused, expired and other non-viable stock*

## ② Legislation on pharmaceutical administration

−Please briefly bulletined major laws/acts

◆National Level

・ *National Drug Policy and Authority Act 1993* *administered by* *National Drug Authority*

・ *Public Health Act* *administered by* *Ministry of Health*

◆Local Level

・ *The Local Governments Act* *administered by* *Ministry of Local Government*

・ *administered by*

◆PIC/S [Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme]

_____ OR No

If yes, joined when

## ③ Regulatory Services

−Please describe pharmaceutical regulatory services of your country in response to each topic described below.

−It is recommended to add supplemental information such as systems, regulations, responsible administrators, since you are expected to explain them to other participants.

◆Pharmaceutical Manufacturing

・ *The National Drug Policy And Authority (Importation And Exportation of Drugs) Regulations, 2014* administered by *NDA*

・ administered by

◆Drug Import/Export

・Systems, Regulations, etc.

・ *The National Drug Policy And Authority (Importation And Exportation of Drugs) Regulations, 2014* administered by *NDA*

・ administered by

◆Marketing Authorization

・Systems, Regulations, etc.

・ *The National Drug Policy And Authority (Importation And Exportation of Drugs) Regulations, 2014* administered by *NDA*

・ administered by

◆Drug Distribution (including drug selection, procurement, sale)

・Systems, Regulations, etc.

・ *The National Drug Policy And Authority (Importation And Exportation of Drugs) Regulations, 2014* administered by *NDA*

・ administered by

◆Medicine Safety (post-marketing)

・Systems, Regulations, etc.

・ *The National Drug Policy And Authority (Importation*

*And Exportation of Drugs) Regulations, 2014* administered by *NDA*

・ administered by

※Example: Good Pharmacovigilance Practice

・ *The National Drug Policy And Authority (Importation*

*And Exportation of Drugs) Regulations, 2014* administered by *NDA*

・ administered by

## ④ Drug Pricing

−Please describe about price control and drug price mechanism at public sector in your country.

*There is no drug pricing regulation mechanism in Uganda.*

*A free market economy is expected to provide true market value of commodities*

## ⑤ Statistic Data

−Please answer the following questions (if the number is not applicable, please give an answer to the best of your knowledge).

−Put the year of the presented data as well if it's available.

1. Number of pharmacists *6 (2019)*
2. Number of GMP inspector (National & Local) *0 (2019)*
3. Number of pharmaceutical manufacturers / manufacturing sites *10 (2019)*
4. Number of traditional medicine manufacturers / manufacturing sites *Several but Unregistered (2019)*
5. Number of pharmaceutical importers *N/A (year)*
6. Number of pharmaceutical wholesalers *503 (year)*

※Hospital pharmacy only

## ⑥ Information on your hospital pharmacy

（1） Organization chart of the pharmaceutical department or the pharmacy to which you belong

a. Number of section chiefs:
b. Number of deputy chiefs:
c. Number of managers:

（2） Number of staff

a. Number of pharmacists:
b. Number of clinical pharmacists:
c. Number of technicians:

（3） Number of the kinds of drugs managed in your pharmacy or hospital

a. Oral medicine:
b. Injections:
c. Medicines for external use:

（4） Number of prescriptions dealt in your pharmacy per day

a. For inpatients:
b. For outpatients:

（５） Equipment of the pharmacy in your hospital

a. Does your hospital have a dispensary room?

If "Yes", how large is it?

Yes _____ ㎡ No

b. Does the pharmacy have a clean room or laminar flow hood?

Yes / No

If "Yes", please describe it in detail

Detail: _____

c. Does the pharmacy have computers?

Yes / No

If "Yes", what is the purpose of using them.

Purpose: _____

d. Do you implement Therapeutic Drug Monitoring (TDM : Therapeutic Drug Monitoring) in your Hospital?

Yes / No

e. Do you prepare TPN (Total Parental Nutrition)

Yes / No

f. Can you use Internet at the pharmacy?

If "Yes", what is the purpose of using it.

Yes / No

Purpose: _____

※All participants. Please describe the following general information as much as you know.

**⑦ Education and License of Pharmacists in your country**

（１） Number of years in primary, secondary and high school education

Primary *7 years*

Secondary *4 years*

High school *2 years*

（２） Number of years / weeks in the following categories during university or college

University / college: *5* years

Professional education: *4* years

Practical training: *10 years*

Duration of training by each facility: *years*

Hospital pharmacy: *1* weeks

Community pharmacy: *0* weeks

Pharmaceutical company: *5* weeks

Others: weeks

Age at graduation: *28 years* old

（3） Are there any national examinations for pharmacists in your country?

Yes

Academic Exams *2* days

Clinical Exams *2* days

No

（4） Which of the followings must you fulfill to obtain a pharmacist's license?

* If practical training is mandatory, give the subjects and training period.

*YES*

* If practical training is optional, give the reasons.

(i.e. Training is necessary to prepare for the national examination)

（5） Number of pharmaceutical university or college graduates:

people / per year

The alumni's placement rate (%)

a. Hospital: 3 %

b. Community Pharmacy: 90 %

c. Government Organization: 3 %

d. Enterprise: 3 %

e. Others: 1 %

⑧ **Side effect report**

Please describe the flow of reporting system (from a medical institution to an administrative agency), when a severe side effect case is occurred in a medical institution. Describe specifically the rule and responsibility of each organization (an administrative agency / a medical institution), and their collaboration/cooperation.

Reports on adverse drug reaction can be raised by any health work to the regulator using the prescribed form attached below. This information does not cascade from to the regulator but is meant to be received directly from the claimant.

ADR reporting Form New.pdf

CONFIDENTIAL

REPUBLIC OF UGANDA
MINISTRY OF HEALTH

# SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

## A. PATIENT DETAILS

| | | |
|---|---|---|
| Patient name | Patient Number | Sex: M/F* |
| Age at time of onset(yrs)* | Health Facility | Last Menstrual Period |
| Weight (kg) | District | Trimester (if pregnant) |

## B. SUSPECTED DRUG (S) DETAILS

| Generic Name* | Brand Name | Dose ,Route Frequency | Date* started | Date stopped | Prescribed for | Expiry date | Batch No |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |

## C. SUSPECTED REACTIONS

Please describe the reaction as observed and any treatment given to manage the reaction

**Outcome**

Recovered ☐ Recovering ☐ Continuing ☐ Death due to reaction ☐

| Date reaction started* | Date reaction stopped | Date of notification |
|---|---|---|
| | | |

## SERIOUSNESS OF THE REACTION

Patient died ☐ Prolonged inpatient Hospitalization ☐ Involved disability ☐ Life Threatening ☐
Congenital abnormality ☐

## D. CONCOMITANT DRUGS

Please give information on the drug(s) the patient has been taking together with the suspected drug including those taken for chronic diseases (include self medication and herbal preparations)

| Generic Name | Brand | Dosage | Date started | Date stopped | Indication(prescribed or OTC) |
|---|---|---|---|---|---|
| | | | | | |

| **Relevant laboratory tests including dates** | **Additional relevant information (medical history, allergies, failure of efficacy)** |
|---|---|
| | |

## E. REPORTER'S DETAILS

| Name/designation* | Telephone and Email Address | Date of reporting | Health facility |
|---|---|---|---|
| | | | |

* Mandatory field

# UGANDA
# National Medical Stores
# Paul Okware



## 1. Introduction of the work

### Establishment

NMS is set up by the National Medical Stores Act of 1993 as an autonomous body responsible for procurement, storage and distribution of essential medicines and medical supplies, primarily to Government health facilities.

### Vision

Our vision is “a population with adequate and accessible quality medicines and medical supplies”

## 1. Introduction of the work

**The Stores and Operations Department**

This is the core department in NMS and is responsible for the Receipt, Storage and Distribution of Essential Medicines and Health Supplies to all the accredited Health Facilities in Uganda.

Time at current position of Chief Stores and Operations Officer is 5 years




## 1. Introduction of the work

**Regulatory Services**

The vision of the NMS requires that we distribute quality medicines to the population. To achive this the Stores and operations department must ensure that all medicines ordered from suppliers dully registered by regulator.

Shipments are also checked to ensure that the regulatory has cleared each of the batches being delivered.

## 2. Good Practice

**1. Procurement**

Recentralization of funds for procurement of EMHS for facilities under MoH and Local Governments [2009] and all uniformed services (Army, Police, Prisons).

Centralized procurements ensure better monitoring of quality of EMHS. This eliminated the procurement by all Health Facilities from the black market.

Pooled procurement also made it easier to source rare and orphan drugs



## 2. Good Practice

**2. Embossment of EMHS**

A clear distinction of EMHS meant for GoU facilities and are not for sale.

This meant that GoU procured medicines are easy to identify and those been stolen can be easily identified. Those also procured outside the National Supply chain can be identified.

This has been very important in tracing the sources of medicines that may be related to an adverse drug reaction.

## 2. Good Practice

**3. Establishment a Quality Control Lab**

NMS is constructing a new 30,000 pallet location warehouse and office complex and part of this new complex shall be a new Quality Control Laboratory.

This lab shall be able to test all the pharmaceuticals being procured, being received and post-distribution samples to ensure quality of medicines is maintained through out the entire supply chain.



## 3. Challenges

**1. Irrational prescribing by health workers.**

Prescription of medicines outside of Standard Clinical Guidelines causing artificial shortage.

Poly-pharmacy - prescribing a big number of medicines

**2. Poor Supply chain visibility**

The country lacks an integrated MIS system to track medicines batches from manufacture or import to the user. A lot of the data capture manual on hard copies.

# 3. Challenges

**3. 90% of the medicines are imported.**

This makes regular cGMP inspections a challenge. Often sites are visited once a year or fewer.

This is especially difficult for manufacturing sites that are in countries that lack strong regulatory authorities.



# Expectations

1. To learn best practice in post market surveillance in supply chain
2. To appreciate best practice in QC lab management
3. Current accreditation and lab standards being used in other countries

# Thanks


THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH


NMS
MEDICAL LOGISTICS
Passionate about your Life

出典：2019 年度 JICA 課題別研修カントリーレポート

- 2019 年度 JICA 課題別研修「水道管理行政（A）」
- 2019 年度 JICA 課題別研修「水道管理行政（B）」
- 2019 年度 JICA 課題別研修「薬事行政」

Japan International Corporation of Welfare Services (JICWELS) was established with the sanction of the Minister for Health, Labour and Welfare in July 1983 and implements international technical cooperation programmes with purpose of contributiing to the promotion of health and social welfare activities in the friendly nations.

Japan International Corporation of Welfare Services (JICWELS)
Matsuoka Ginnana BLDG. 3F
7-17-14 Ginza Chuo-ku, Tokyo 104-0061 JAPAN
Tel: +81-(0)3-6206-1137
Fax: +81-(0)3-6206-1164
https://jicwels.or.jp

公益社団法人国際厚生事業団（JICWELS）は、国際的な保健・福祉分野の国際協力に貢献することを目的として、1983 年（昭和 58 年）7 月 7 日に厚生省（現厚生労働省）から社団法人の認可を受け設立されました。開発途上国の行政官研修や WHO フェローの受入れ、調査企画や研究開発並びに情報の交換及び広報活動など、海外諸国との国際交流活動を推進しています。

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公益社団 国際厚生事業団 JICWELS
広報活動委員会

〒104-0061
東京都中央区銀座 7 丁目 17−14 松岡銀七ビル 3 階
電話 03-6206-1137（国際協力チーム）
Fax 03-6206-1164
https://jicwels.or.jp