Regulatory Systems
on Ensuring Access to Quality Medicines

Country Reports

Japan International Corporation of Welfare Services (JICWELS)

Contents

Regulatory Systems
on Ensuring Access to Quality Medicines

AZERBAIDZHAN

Azerbaijan Republic

Analytical Expertise Center of the Ministry of Health

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Structure of state system of pharmaceutical regulation in Azerbaijan Republic

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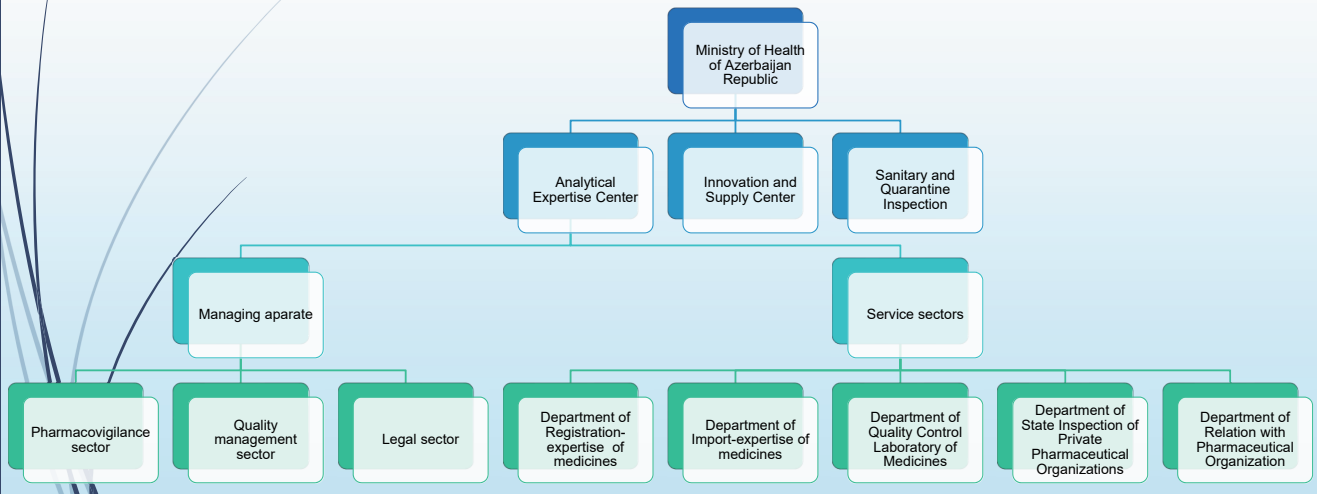

3

Analytical Expertise Center

Analytical Expertise Center is a National Medicines Regulatory Authority which is established in **2007** and subordinates to MoH. Main responsibility of the Center is to provide society with **high quality, safe and effective medicines**.

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Pharmacovigilance sector

I have been working as a pharmacovigilance specialist since January, 2017 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;

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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**

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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

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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 I was working as pharmacist 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 .

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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.

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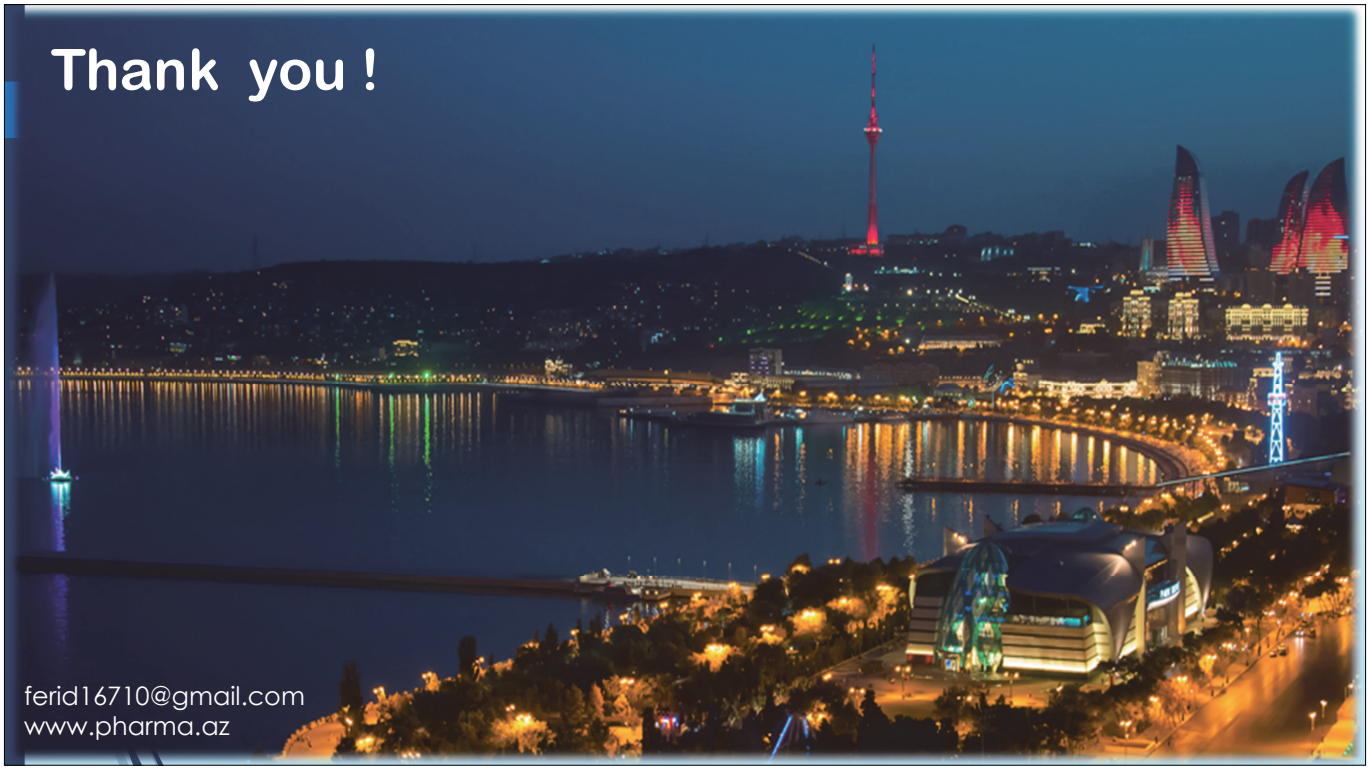
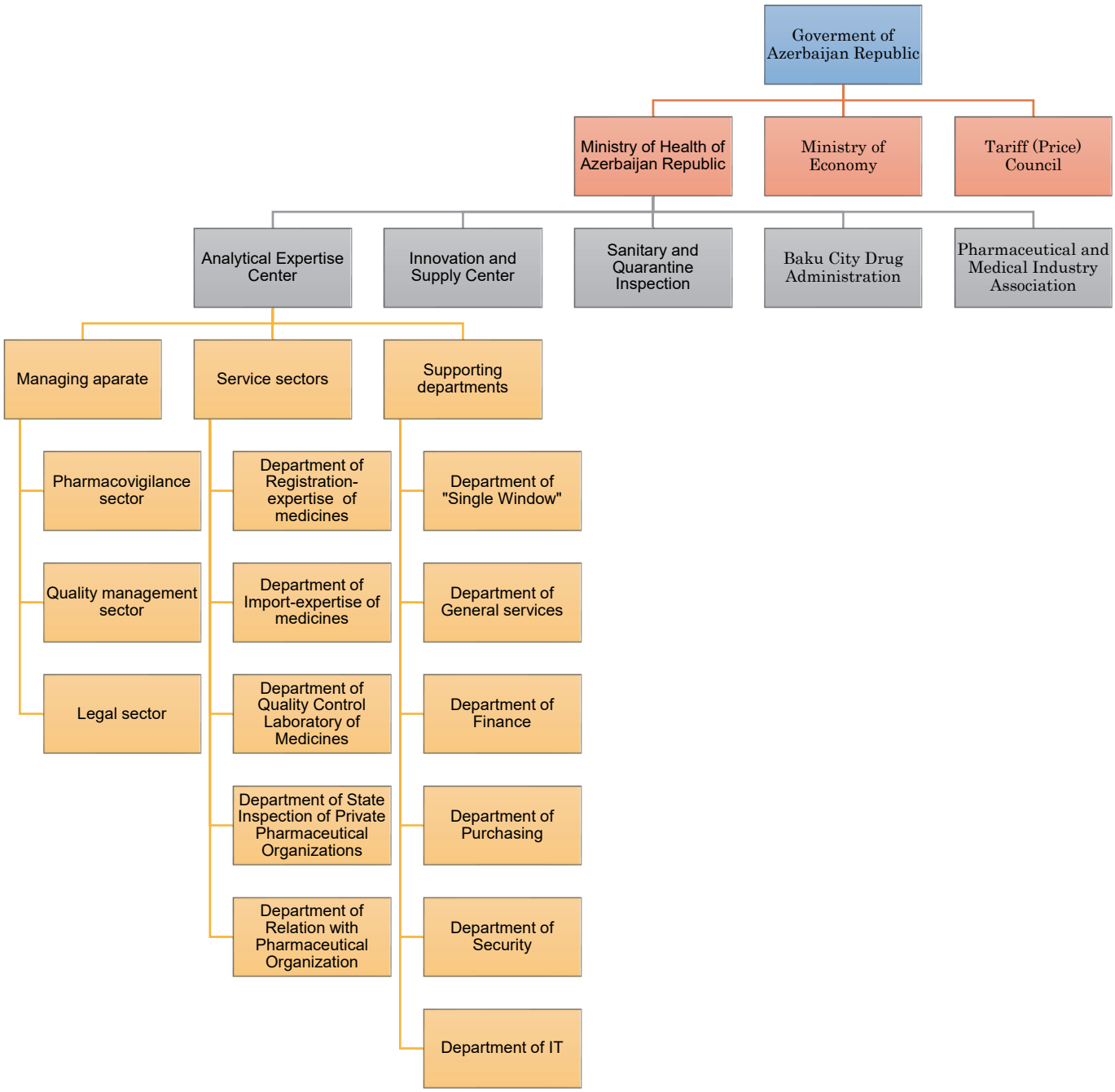
My interests

- Japanese pharmaceutical affairs and the quality risk management for post marketing. Post marketing safety measures of drugs on the market.
- Pharmaceutical approval system in Japan.
- GMP process and clearance of manufacturers .



Name: FARID HASANOV
Country: AZERBAIJAN
Organization/Department/Division: Analytical 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

◆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 3, 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 member: 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 decree 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**

1.	Number of pharmacists	5180 (2018)
2.	Number of GMP inspector (National & Local)	7 (2018)
3.	Number of pharmaceutical manufacturers / manufacturing sites	4 (2018)
4.	Number of traditional medicine manufacturers / manufacturing sites	0 (2018)
5.	Number of pharmaceutical importers and wholesalers	101 (2018)

※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	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:	23 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?

Yes

Academic Exams	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.

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).

Regulatory Systems
on Ensuring Access to Quality Medicines

BRAZIL

Brazilian Health Regulatory Agency
ANVISA

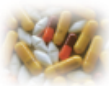
Nathalie Dias Kuwabara

- ✓ ANVISA was established by Federal Law 9.782/99.
- ✓ ANVISA's headquarter is located in Brasília, Brazilian capital.
- ✓ Currently ANVISA has approximately 2.200 employees working throughout the country, most of them located in Brasília.

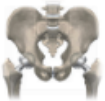
REGULATION FIELDS

ANVISA

Health Service



Medicines/API



Medical devices

Cosmetics

Pesticides

Tobacco

Sanitizing agents

Pharmacovigillance

Advertisement

Ports, airports and borders

Foods

SNVS coordination

Blood, Tissues and e organs

Official Laboratories

1. Introduction of the work

General Office of Good Manufacturing Practices Inspections
Health Regulation Specialist

Regulatory services that I´m engaged in:

- ✓ **Good Manufacturing Practices inspections in pharmaceutical companies, both national and international;**
- ✓ **Review of GMP regulations and guidelines;**
- ✓ **Activities related to monitoring the quality of medicines in the market and investigation of deviations;**
- ✓ **Revision of current regulations in Brazil in order to update them according to the best practices all over the world.**

Roles and position of pharmacists in Brazil:

In the public medical care system, pharmacists are responsible for:

- ✓ Management of the pharmacy (including storage)
- ✓ Acquisition of medicines
- ✓ Efficient distribution

Besides that, the pharmacists also have a role in the care programs, giving orientation about the use of medicines to the population, taking part in the community health education and monitoring of effectiveness of treatment.

- Recent atributions:

- ✓ Clinical attributions: pharmaceutical consultation, requisition and evaluation of laboratory tests in order to assure if the treatment is going fine, development of pharmaceutical care plan.
- ✓ Pharmaceutical prescription: only non medical prescription medicines.

Roles and position of pharmacists in Brazil:

Pharmacies:

- ✓ Formulation of medicines
- ✓ Dispensation

Pharmaceutical companies:

- ✓ pharmacists take roles in almost every department, including: production, QC, QA, engineering, marketing, R&D, etc.

2. Good Practice

Graduation: Industrial Pharmacy

Specializations: **Health Surveillance; MBA – Administration; Pharmaceutical Technology.**

7 years working for pharma companies
(QC and QA)

Anvisa since 2014

- ✓ Variations after Marketing Authorizations
- ✓ GMP Inspections

3. Difficulties/Lessons Learned from Past Experience

- ✓ Complex distribution chain of medicines in Brazil
- ✓ Harmonization of GMP knowledge over the country and with the rest of the world

4. My interests

(1)Quality during distribution of medicines

(2) Post marketing monitoring

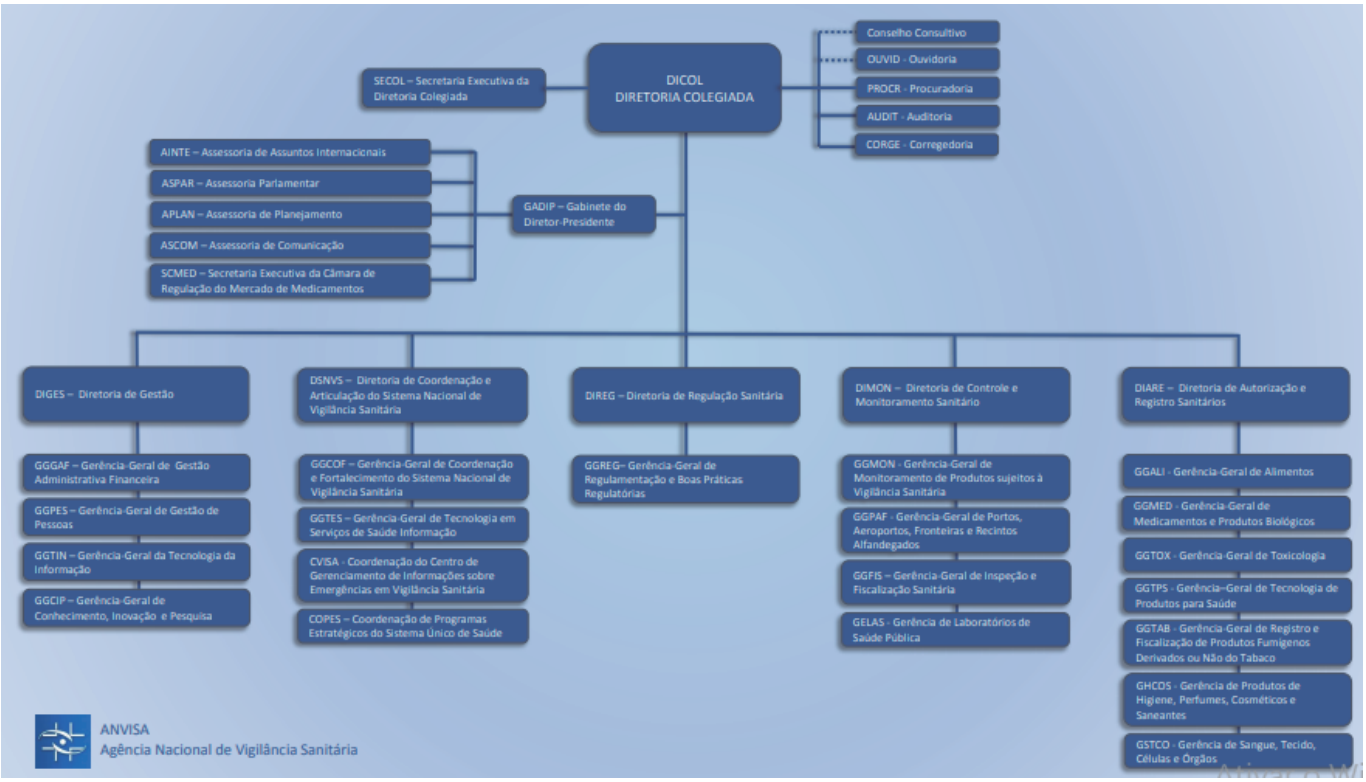
(3) Identification of substandard and falsified medicines

Name: Nathalie Dias Kuwabara
Country: Brazil
Organization/Department/Division: Anvisa/ GMP Inspection Office

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.



Created in 1999 by Law 9.782, the Brazilian Health Regulatory Agency (Anvisa) is an administrative independent and financially autonomic governmental regulatory agency, connected to the Ministry of Health.

Anvisa has its legal mandate to regulate all sectors related to products and services that may affect the health of Brazilian population. The ANVISA competence covers the health products regulation as well as the economic regulation of the market.

The General Office of Good Manufacturing Practices (GGFIS) is responsible for the inspections in pharmaceutical and medical devices industries all over the world. It's also responsible for coordinating the inspections in the industries inside Brazil. This department is also responsible for the monitoring of any kind of deviations related to medicines, Active Pharmaceutical Ingredients, medical devices, cosmetics, sanitizers and food.

Pharmacists work mostly with medicines and APIs subjects, mas there are pharmacists working in

every department inside the General Office.

② **Legislation on pharmaceutical administration**

−Please briefly bulletined major laws/acts

◆National Level

Law 6360/1976 – provides for the Health Surveillance that the medicines, drugs, and the API, cosmetics & sanitizing and other products are subjected, and gives other provisions.
Decreet 8077/2013 – regulates the activities described in the Law 6360/1976.
Law 5991/ 1973 – provides for the sanitary control for sale of medicines, drugs, API and correlates, and give other provisions.
Law 6437/1977 – define sanitary infractions to the federal law and relative penalties
Law 8080/1990 – define the Unified Health System in Brazil
Law 9782/1999 – establish the role and responsibilities of Anvisa and define the National Health Surveillance System

◆Local Level

According to the decentralized principle of the Unified Health System in Brazil, the States and Municipalities should follow the national legislation and may establish supplementary and complementary legislations.

◆PIC/S

Anvisa is not a PIC/S member yet, but in 2010 Brazil formalized the intention to become a member and it is expected in 2018/2019 an assessment by the PIC/S delegation in order to determine whether Anvisa can become a member.

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.

According Resolution RDC nº 16/2014, all companies that intend to store, distribute, pack, ship, import, export, extract, fractionate, purify, manufacture, transform and/or transport drugs and drug products for human use must require an operation permit (autorização de funcionamento - AFE), issued by Anvisa. This permit is granted upon proof of compliance to technical and administrative requirements listed in the resolution.

Another document issued by Anvisa for drug product's manufacturers is the good manufacturing practices (GMP) certificate. The minimum regulatory requirements for manufacture of drug products are described in Resolution RDC nº 17/2010, which also guides the inspections to verify compliance with the principles of GMP. The GMP inspection team is generally composed for two inspectors who evaluate

technical items throughout all the company departments, such as warehouse, utility sections (for example, HVAC, and water for pharmaceutical use), manufacturing, and quality control. An inspection can get three results: satisfactory, on-demand, and unsatisfactory. As a result of a satisfactory GMP inspection the company is granted a certificate (CBPF) valid for two years.

Within Anvisa's structure, the General-office of GMP Inspection (GGFIS), subordinated to the board of Control and Health Monitoring (DIMON), is responsible for granting or denying operation permits and GMP certificates. The performance of inspections to verify compliance with the principles of GMP within Brazilian territory is delegated to state and municipal government. National government - Anvisa - is responsible for inspecting manufacturers located outside Brazil.

Conducting inspections to verify compliance with the principles of good clinical practices is responsibility of the Clinical Research Coordenation (COPEC), subordinated to the General-office of Drugs and Biological Products (GGMED).

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

◆Drug Import/Export

All products regulated by Anvisa must obtain the agency´s consent to be imported, according to Resolution RDC nº 81/2008. The companies which intent to import those products also must be authorized. The petitions are made through an electronic system (SISCOMEX) and Anvisa's department responsible for supervise import and export activities of regulated products is the General-office of ports, airports and borders (GGPAF).

As defined by Law 6.360/1976, imported drug products must be approved at its country of origin and must be registered by Anvisa before being made available for sale. The regulatory requirements for approval of an imported drug product are the same as those for medicines manufactured in Brazil, provided by Resolution RDC 60/2014, except by the request of declaring the commitments made with another regulatory agencies about conduction of complementary studies (non clinical and clinical) for new drugs. As an exception, an individual is allowed by Resolution RDC 28/2011 to import non approved drug products, provided they are intend for personal use only, and not for sale.

Import and export of banned substances, defined in regulation Portaria 344/1998 are forbidden. Concerning drug export there is specific regulation, RDC 62/2016, only for narcotics, and psychotropic drugs export, which require an export authorization. Besides that, Anvisa issues export certificates to companies that require this document for its products registered in Brazil.

◆Marketing Authorization

For granting a marketing authorization, the holder should prove that the medicine meets the Agency requirements related to quality, safety, efficacy and administrative aspects.

Regulatory actions take place before the application submission (eg. BPF approval and approval of clinical trials design for trials conducted in Brazil), during the assessment of the application (efficacy, safety, quality and administrative reports assessments) and after marketing authorization (eg. pharmacovigilance, post approval quality changes and register cancelation).

Anvisa establish several categories of medicines, according to medicines' properties and origin, and for each category there is specific legislation and requirements. Currently, medicines are categorized as

new synthetic medicines, generic medicines, brand generic medicines, herbal medicines, biologic medicines, radiopharmaceuticals, homeopathic and dynamized medicines and specific medicines. The process described below will focus on actions related to assessment of new synthetic medicines applications for marketing authorization.

The current legislation for new marketing authorizations and register renewal of new synthetic, generic, and branded generic medicines is Resolution RDC nº 60/2014.

Several departaments of the General-office of drugs and biological products (GGMED) are involved in application assessment. Before application submission, the marketing authorization holder may request a pre submission meeting with Anvisa reviewers to discuss technical aspects of the data, especially when there is specific or unusual issues. For new synthetic medicines, application submission is made through an electronic system called Eletronic Register System.

The safety and efficacy data of the new synthetic drug is analyzed by the office of safety and efficacy assessment of new synthetic medicines (GESEF). This office is responsible for the analysis of non-clinical and clinical trials reports and also for ensuring product information compliance with critical non-clinical and clinical findings. The reviewer conduct its individual assessment of the dossier and write a detailed and conclusive report about new register, renewal and post-marketing applications of synthetic medicines. Depending on data complexity, an ad hoc expert assessement may be requested. Anvisa counts with the support of three council of experts in different therapeutical areas that work as consulters for the regulatory decision making process.

The office of assessment of pharmaceutical technology (GRMED) reviews the chemical, manufacturing, and controls documentation of the dossier. This includes the drug master file of the active pharmaceutical ingredient (API) used, the drug product production report, the quality control report, analytical method validation, stability studies, and for generic or branded generic, pharmaceutical equivalence studies. The requirements for analytical method validation are provided by resolution RE nº 166/2016; the resolution RE nº 1/2005, approved the Guideline for conducting stability studies of drug products; and the pharmaceutical equivalence studies are regulated by resolution RDC nº 31/2010. GRMED is responsible for suggesting the approval or rejection of the petition, based on its own review of quality documentation and on GESEF's reports about safety and efficacy.

Before marketing authorization, it is also required a pharmacovigilance plan, which is analyzed by Pharmacovigilance Office (GFARM). When it is identified a notable risk for the new drug, the agency requires a risk management plan with complementary actions for risk minimization.

In case of doubts or unanswered question about the dossier Anvisa may send an electronic requirement questioning the applicant about the issue. The applicant has 120 days to explain the questions, otherwise the new drug application will be rejected.

※Example: Good Quality Practice

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

In Brazil everybody citizen have the right to have access to free health services, including access to free medicines, through the Unified Health System (Sistema Único de Saúde – SUS), set up in 1988 by the Constitution. This is a decentralized system, in which the municipal and state governments have the responsibility for the management and financing of the health care. There is a budget shared by the federal,

state and municipal governments.

Medicines acquisition is not part of Anvisa legal responsibilities. Once the medicine is approved and marketed, the drug selection, procurement and distribution to population through public health service is an attribution of the Ministry of Health (MoH).

CONITEC (National Comission of Health Technology Assessment for the Unified Health System) is a collegiate permanent commission that is part of MoH structure. CONITEC objective is support the MoH on decisions related to incorporation, exclusion or change of health technologies adopted by SUS. CONITEC should follow some directives such as adopting rational criteria and efficacy, efficiency and effectiveness parameters adequate for the health necessities and incorporate health technologies relevant for the citizens and the health system, based on a cost effectiveness positive relationship. CONITEC should also review the National Relation of Essential Medicines (RENAME).

CONITEC is composed of a plenary that takes technical decisions and an executive-secretariat that handles the administrative procedures. Anvisa must designated a nominee for being part of the CONITEC plenary, among other twelve members from MoH secretaries and other public health related authorities (e.g. National Council of Medicine). Moreover, when necessary, CONITEC may request information for Anvisa about product register status, indications, caracteristics, data about market monitoring, pharmacovigilance, among other relevant information.

CONITEC must issue reports explaining the decisions basis considering at least:

- Scientific evidences about efficacy, accuracy, effectiveness and safety of the medicine, product or procedure under assessment, that where considered by the authority responsible for their register or authorization;
- Comparative economic analyses of benefits and costs in relation to the already available health technologies
- Impact of the incorporation of the health technology on SUS.

CONITEC reports and decisions are subject of a public consultation and, depending on the relevance of the theme, a public audience may be conducted to gather more contributions. After the final decision of new technology incorporation, the legal deadline to offer this in SUS is up to 180 days.

Anvisa issue Certificates of Good Distribution or Storage Practice for medicines, devices and active pharmaceutical ingredients companies in Brazil. The companies that do the transportation of medicines also must have a permit to work and follow good transport practices.

◆Medicine Safety (post-marketing)

The main national regulations in pharmacovigilance are RDC 04/2009, which regulates how the pharmacovigilance should be done by the marketing authorization holders and RDC 36/2013, which establishes rules for the patient's safety in health care system.

The post-marketing pharmacovigilance is made mainly by the voluntary reporting of adverse events (AEs) by health practitioners and by patients. A web form is available at ANVISA's website for both practitioners and patients. The adverse events' reports are also collected by the ombudsman service.

The health surveillance reporting system is called Notivisa, which is an electronic system developed by Anvisa to receive notifications of incidents, adverse events and technical complaints related to products and services under sanitary surveillance.

Some examples of adverse events that could be notified through Notivisa are: adverse event during a surgical procedure, adverse reaction to a medicine, medication error that caused harm to patient and adverse event to a cosmetic product; some examples of technical complaints that could be notified through Notivisa are: product suspected of quality deviation, product without a valid license, counterfeit product and pharmaceutical company working without an operation permit.

The notifications received through Notivisa may be used for:

- Underpin the National Health Surveillance System (SNVS) to identify adverse reactions or unpleasant product effects;
- Improve the knowledge about product effects and, as appropriate, change the recommendations of use;
- Promote actions for public health protection through regulation of marketing products in the country.

Notifications records are available for Anvisa and the sanitary authorities of states and municipalities. Notifications are assessed based on its severity, predictability (expected or unexpected event), causal relationship between the event and the product and associated risk related to the adverse event or technical complaint.

Different sanitary actions may be adopted depending on this analyses, such as, pooling notifications until receive more information or other notifications, set up an investigational process, inspect the places involved in the adverse event or technical complaint notification, collect samples for fiscal analyses, elaboration and dissemination of alerts and reports, changes in product labels, restrictions on use or marketing, prohibition of lots or cancellation of product register.

※Example: Good Pharmacovigilance Practice

◆Relief System for Adverse Drug Reactions

When important adverse drug reactions are detected, after Anvisa's evaluation, the warnings are published at Anvisa's website and the marketing authorization holders must send a letter to the health practitioners. This letter is sent to medical associations, to hospitals and institutions that are member of a sentinel network and they are also published at Anvisa's web page.

Anvisa is looking for another ways of spreading such important information in order to be closer to the patients such as using social network media, for example, facebook page.

④ **Drug Pricing**

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

In Brazil drug product manufacturers must follow the requirements established by law 10.742/2003 to set and adjust their products' prices. This law created the Drug Market Regulation Chamber (Câmara de Regulação do Mercado de Medicamentos – CMED), an inter-ministerial organ responsible for the economic regulation of Brazilian pharmaceutical market, and settled a maximum price for medicines, based on an index. The index considers inflation, market share, and raw material costs of a product.

Anvisa holds the position of Executive Secretariat in the CMED, monitor the price of drug products commercialized in Brazil, and oversees the settling of prices for new drug products. The agency publishes a list with the maximum prices allowed for drug products sold directly to the consumer by drugstores and pharmacies.

CMED also created a mandatory minimum discount (price-cap) applied for pharmaceutical distributers and manufacturers when selling medicines to public administration. Local government generally acquire drug products through electronic trading, and performs annual drug acquisition, among other strategies to promote resource optimization.

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 203.600 (2016)
2. Number of GMP inspector (National & Local) ~ 25 (2018) – local amount not available
3. Number of pharmaceutical manufacturers / manufacturing sites 1342 (2018)
4. Number of traditional medicine manufacturers / manufacturing sites not available
5. Number of pharmaceutical importers 444 (2018)
6. Number of pharmaceutical wholesalers 4761 (2018)

※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

I don't have this kind of data available.

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

Primary	5 years
Secondary	4 years
High school	3 years

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

University / college:	minimum 4000 hours
Professional education:	years
Practical training:	minimum 800 hours
Duration of training by each facility:	years
Hospital pharmacy:	weeks
Community pharmacy:	weeks
Pharmaceutical company:	weeks
Others:	weeks
Age at graduation:	years old

The time for training in each field of knowledge of Pharmacy is divided in the following way:
I - drugs, cosmetics, medicines and pharmaceutical care: minimum 60% of 800 hours;
II – clinical, genetic, toxicological and food analysis: minimum 30% of 800 hours;
III – institutional and regional specificities: minimum 10% of 800 hours.

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

Yes

Academic Exams _____ days

Clinical Exams _____ days

No. In Brazil we don't have any specific exam for pharmacists.

（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.

Described in item 2 above.

* 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:

~ 18000 people / per year (around 529 universities or colleges in Brazil)

The alumni's placement rate (%) **I don't have this data available.**

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.

The marketing authorization holder receives the AEs reporting from healthcare providers, patients and the population in general and then must send the serious adverse events (SAE) reported by healthcare providers to Anvisa (by NOTIVISA system). Serious adverse events occuring in Brazil involving case of death or risk of death, must be reported to the regulatory agency in up to seven days after the MAH acknowledged it, and in up to 15 days the others SAE (RDC nº 04/2009).

The agency will begin the analysis of the reporting of SAE in up to 15 days, and, in case of death, in up to five days. After this evaluation, Anvisa may ask for label revision, spread regulatory measures adopted, share the pharmacovigilance information with other offices in Anvisa, and search for other AEs occurred in the Sentinel Network Hospitals.

About 50% of the AE's reporting is from the Sentinel Network, a group of hospitals coordinated by ANVISA that act strongly in the reporting of AEs. In a lesser quantity, the AEs reports come from the MAH and the health care providers.

The responsibility is shared between Anvisa and the MAH in detecting and preventing AEs. The healthcare providers' reporting, on the other hand, is voluntary.

Regulatory Systems
on Ensuring Access to Quality Medicines

FIJI

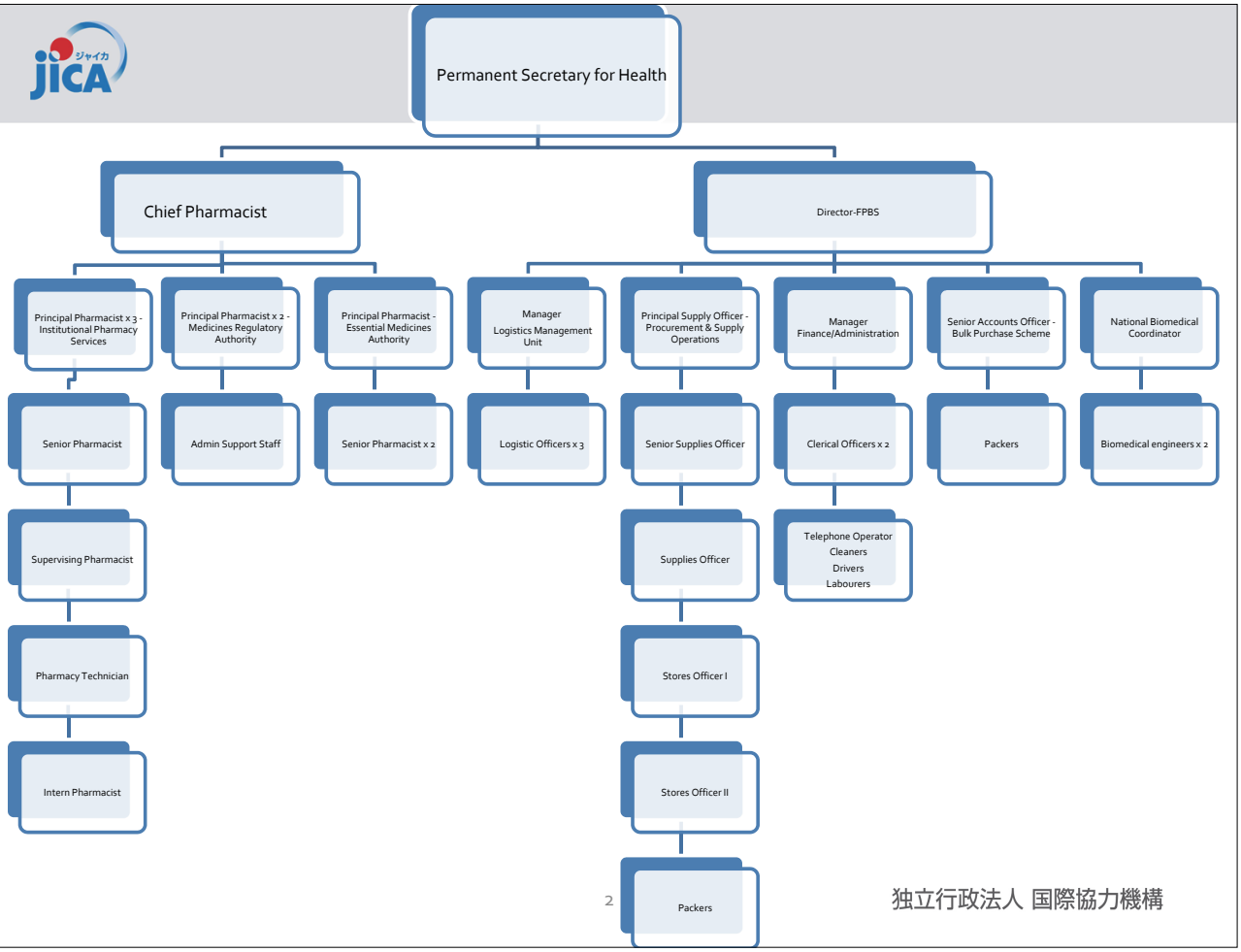
Country: Fiji

Organization: Medicines Regulatory Authority
(Ministry of Health & Medical Services)

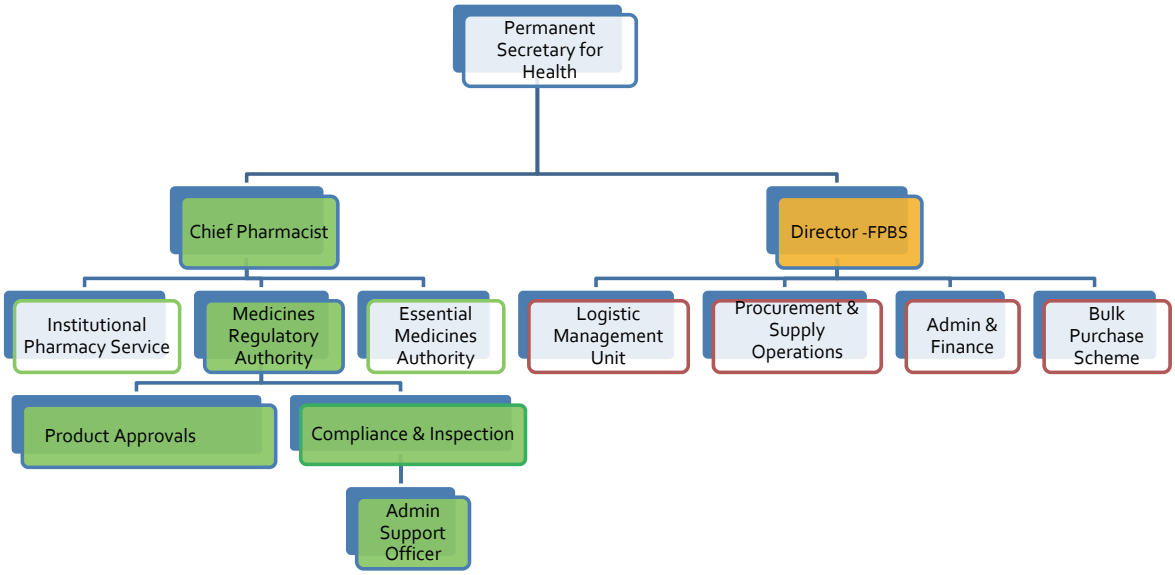
Name: Ilisabeta May Pesamino
Principal Pharmacist

Bula !!

Population: 898,760 (2016)



Pharmaceutical Division Organisational Structure



1. Regulatory Services

- Fiji imports all its medicines & medical supplies
- One manufacturer – TGA certified, export market
- Product/Manufacturer Evaluation- COPP, COA, cGMP
- Import Authorisation/Export Authorisation – permits for narcotics, psychotropic, precursor chemicals
- Licensing & Registration of Importers, wholesalers & retailers
- Inspection & Investigation – handle complaints
- Product testing – overseas test facilities
- Pharmacovigilance – ADR reporting

Roles and positions of pharmacists in Fiji

Public Health Pharmacists

- Dispensary service – Outpatient & Inpatient
- Clinical Pharmacy (Ward bed-side service)
- Medicine Information
- Inventory management

Retail Pharmacists

- Dispensary service
- Medicine Information
- Primary health care/Over-the-counter medicine prescribing & advice
- Referrals to physicians when necessary

Fiji Pharmaceutical & Biomedical Services

- Regulatory services – product assessment, licensing & registration of importers, import/export authorisation, inspection, sample testing
- Essential medicine – medicine selection & quantification, EML & treatment guidelines, promoting/awareness on rational drug use, & Anti-microbial resistance

2. Good Practice - Achievements

✓Achievements

❖ able to set a standard for the quality of medicines for the Fijian population

❖Medicines (PIC/S)

❖Vaccines (UNICEF)

❖Ongoing projects: for the same objectives

❖Drug Registration – private sector

❖Develop regulations/policies/guidelines

❖Capacity building

Solutions for past problems

❖Learn a lot from other country practices e.g. Australia, New Zealand

❖Maintain a network of mentors and professionals to assist

❖ based on existing regulations, guidelines and processes

❖Conduct research

3. Difficulties/Lessons Learned from Past Experience

Major Challenges

❖ lack of resources & necessary skills

❖ government systems & processes – contribute to delays in passing of regulations

❖ politics/funding – affect decision making when it comes to quality of medicines

❖increasing use of traditional & complementary medicines & practices in Fiji; needing a different level of skills & regulations

4. Things to take back!

(1) Learn more about how Japan conducts its regulatory services in all areas i.e. Pre-marketing evaluation, Marketing Authorisation, Post-marketing surveillance, Pharmacovigilance

(2)Identify which concepts would be applicable or can be contextualised to suit the Fiji setting

(3) Learn also from other participating countries & their practices

Part I: INFORMATION SHEET

Regulatory Systems on Ensuring Access to Quality Medicines (JFY 2018)

Name: Ilisabeta May Pesamino

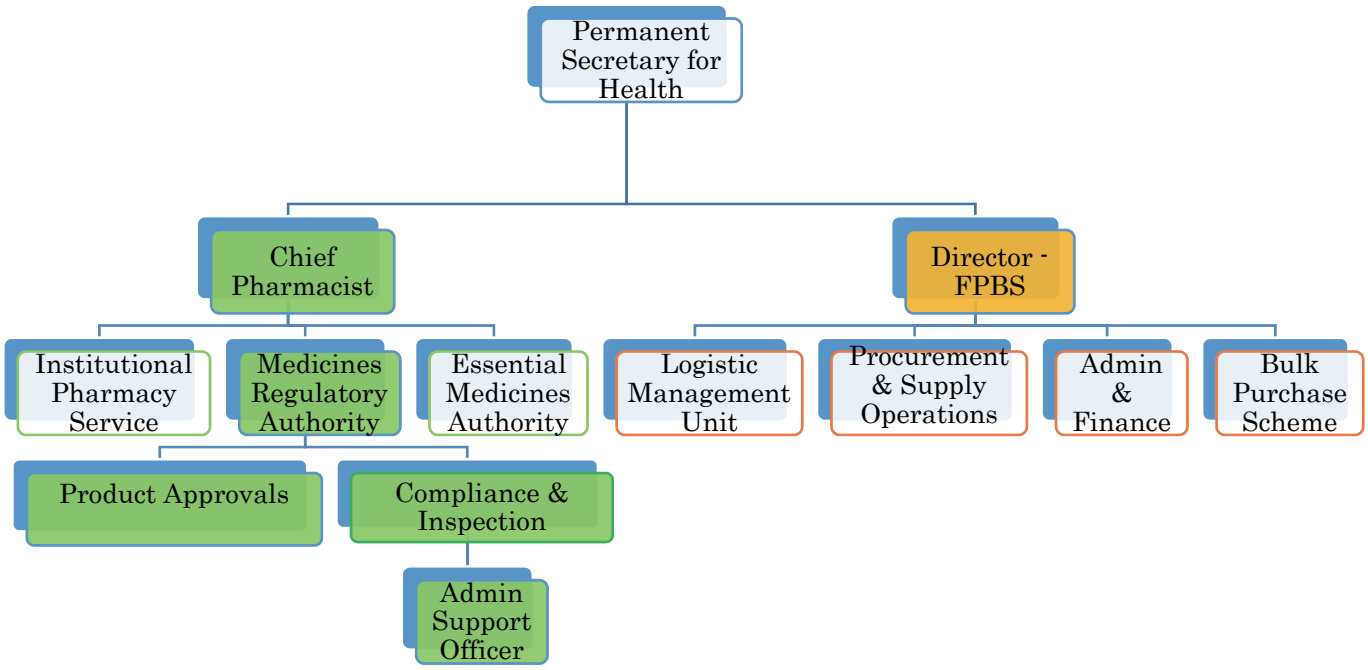
Country: Fiji

Organization/Department/Division: Ministry of Health & Medical Services

① Organizational Chart

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

Organisation Structure of the Fiji Pharmaceutical & Biomedical Services (FPBS) & the Medicines Regulatory Authority (MRA)



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

The Medicines Regulatory Authority comes under the responsibility of the Chief Pharmacist who reports directly to the Permanent Secretary, Ministry of Health & Medical Services. The unit is based at the Fiji Pharmaceutical & Biomedical Services Centre, which is under the responsibility of the Director FPBS, responsible for the Supply Chain Management System.

The Chief Pharmacist is also responsible for 2 other major services; the Institutional Pharmacy Service which is the dispensary service at all public health facilities in the country and the Essential Medicines Authority, which looks

after medicine selection & quantification, development of the Essential Medicines List & Standard Treatment Guidelines, and implementation of activities to promote Rational Drug Use and reduce Anti-Microbial Resistance.

Medicines Regulatory Authority

There are only 3 staff members in the Medicines Regulatory Authority:

1. **Principal Pharmacist – Product Evaluation**
   The position is responsible for product evaluation, manufacturer & supplier assessment and issuing import & export authorisations. Fiji relies on the assessment carried out by other national regulatory authorities as our unit is under-resourced. Fiji only accepts products that are from PIC/S countries and if the products are manufactured outside PIC/S countries, then the manufacturing plants must be GMP certified by a PIC/S member country, or WHO, UNICEF, & other partners.
2. **Principal Pharmacist – Compliance/Inspection**
   The position is responsible for ensuring compliance to legal requirements by all pharmaceutical importers through regular inspections, handling and investigating complaints. The position also ensures that at least 10 random samples are sent abroad for testing annually, since Fiji does not have any testing facility.
3. **Admin Support Officer**
   This officer provides all the administrative support such as issuing of licences and permits, communication & banking.

※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.

② Legislation on pharmaceutical administration

−Please briefly bulletined major laws/acts

◆National Level

- Medicinal Products Act 2011administered by Ministry of Health & Medical Services
- Pharmacy Profession Act 2011administered by Ministry of Health & Medical Services

◆Local Level

- Public Hospitals & Dispensaries Act administered by Ministry of Health & Medical Services
- Medicinal Products Act 201 administered by Ministry of Health & Medical Services

◆PIC/S

Yes 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

・Systems, Regulations, etc.

・ Medicinal Products Act 2011administered by Ministry of Health & Medical Services

・ National Medicinal Products Policy 2013 administered by Ministry of Health & Medical Services

There is only 1 manufacturing company in Fiji called Douglas Pharmaceuticals and it is certified by Therapeutic Goods Administration (TGA) Australia. However the Ministry of Health & Medical Services through its Medicines Regulatory Unit issues annual manufacturing licence based on valid GMP certification by TGA. Douglas Pharmaceuticals mostly manufacture for the export market. Fiji imports all of its medicines that are manufactured & certified by PIC/S member countries.

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

◆Drug Import/Export

・Systems, Regulations, etc.

・Medicinal Products Act 2011 & Drafted Medicine Registration Regulations administered by the Ministry of Health & Medical Services.

・In Fiji, all pharmaceutical importers are licensed. There are 72 registered pharmacy businesses, 19 registered wholesalers which are eligible to import medicines at the moment. However we are also currently developing our processes, to issue Import Licences only to pharmacy business that actually do importation, as some only retail but purchase stock from other registered wholesalers. Export licence is issued mostly for narcotics to our neighbouring Pacific Island Countries. Most of these countries import their own pharmaceuticals directly from overseas suppliers but may import from Fiji if necessary during an emergency.

◆Marketing Authorization

・Systems, Regulations, etc.

・Medicinal Products Act 2011administered by Ministry of Health & Medical Services

Fiji is currently developing its Drug Registration System, software has been purchased and a number of products have been provisionally registered however the system has not been fully utilized yet due to many reasons such as limited resources and technical skills to effectively implement and maintain the system. For the public sector health facilities, all imports are approved by the Medicines Regulatory Unit which is based at the Fiji Pharmaceutical & Biomedical Services. The Fiji Ministry of Health only imports medicines that have been manufactured by plants that have been GMP certified by a regulatory body in a PIC/S country or has been registered in a PIC/S country. Fiji uses the “Prequalification system’ to prequalify manufacturers.

※Example: Good Quality Practice

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

・Systems, Regulations, etc.

・Drug selection is carried out by the Fiji National Medicines & Therapeutics Committee which is also administered by the Ministry of Health & Medical Services. The committee comprises of physicians from all medical disciplines such as Internal Medicine, Surgery, Obstetrics & Gynecology, Peadiatrics and Microbiology. Other smaller disciplines are also represented. Medicine procurement in the public sector is carried out by the Finance & Procurement division of the ministry, after evaluation and assessment by the technical teams. Only registered medicine retailers are allowed to sell medicines. Supermarkets may sell general sale medicines and vitamins. There is still however a lot to do to improve in this area.

◆Medicine Safety (post-marketing)

・Systems, Regulations, etc.

・As part of our quality assurance activities, we send a minimum of 10 samples for laboratory testing annually. We normally used the TGA test facility, but we have also used Health Science Authority in Singapore. Last year alone we tested over 23 samples, out of which 7 products were confirmed to be below acceptable quality standards and had to be recalled. This allowed us to relook at our product selection process. There isn't any regulation specifically targeted at Post-Marketing but it can be looked at.

※Example: Good Pharmacovigilance Practice

◆Relief System for Adverse Drug Reactions

・Systems, Regulations, etc.

There is no National Pharmacovigilance Centre in Fiji but all reports of Adverse Drug Reactions are reported on a yellow form which is then sent to the Medicines Regulatory Unit or the Essential Medicines Unit. There still needs to be some improvement and development in this important area, There is a lot of underreporting by clinicians and also the patients/customers which is probably due to lack of awareness and knowledge on the importance of Pharmacovigilance.

④ Drug Pricing

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

Medicines or drugs are supplied free of charge in all public health facilities. There are a total 224 of public health facilities in Fiji. These include 3 tertiary/referral hospitals & 2 specialist hospitals whilst the rest include smaller primary health care hospitals, health centers and nursing stations. The public can access free medicines as long as they are seen by an in-house physician.

In the private sector, there is a list of price-controlled medicines, containing 70 medicines. The prices are fixed by the Fijian Competition & Consumer Commission which is an in dependent statutory body responsible which seeks to protect consumers and businesses from restrictive and unfair trade practices.

There is also a government initiative called the Free Medicines Program, whereby 142 medicines can be accessed free of charge from either the public sector or private sector pharmacies.

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	200(2018)
2.	Number of GMP inspector (National & Local)	0 (2018)
3.	Number of pharmaceutical manufacturers / manufacturing sites	1(2018)
4.	Number of traditional medicine manufacturers / manufacturing sites	0(2018)
5.	Number of pharmaceutical importers	19(2018)
6.	Number of pharmaceutical wholesalers	19(2018)

※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	8 years
Secondary	5 years
High school	years

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

University / college:	years
Professional education:	4 years
Practical training:	1 year
Duration of training by each facility:	1 years
Hospital pharmacy:	52 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	1 day
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.

Practical training after obtaining Bachelor's degree in Pharmacy in mandatory and is taken in 52 weeks. There are 7 competence standards that must be completed successfully including a research project. The 7 competence standards are:

1. Practice pharmacy in a professional manner
2. Promote the rational and optimal use of medicines
3. Provide primary healthcare
4. Apply management and organisation skills
5. Research and provide information
6. Dispense medicines
7. Prepare pharmaceutical products (non-sterile)

* 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:

20 people / per year

The alumni's placement rate (%)

a. Hospital: 90 %
b. Community Pharmacy: 10 %
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.

Reporting of Adverse Drug Reaction can be made by any health practitioner or a patient through a medical professional. An ADR form is filled at the facility and then sent to the pharmacy department of that facility or to the nearest Medicine Information Pharmacist at the Tertiary Hospital, and subsequently to the Medicines Regulatory Authority in Suva.

Severe Side Effect/ADR (reported by patient/carer/consumer)

↓

Pharmacist at nearest HF (or other medical staff if no pharmacist available)

↓

Medicines Information Pharmacist (at the Tertiary Hospital)

↓

Medicines Regulatory Authority (MRA)

The report is analysed to determine if it is an administration error, a normal side effect of the drug or a product quality issue. If product quality is suspected, the MRA would look at severity of the event and either quarantine the product or advise to use other batches. Since there is no testing facility in Fiji, Fiji sends all its testing requirements to TGA in Australia. Test results would determine next course of action.

Regulatory Systems
on Ensuring Access to Quality Medicines

INDIA

Regulatory Systems on Ensuring Access to Quality Medicines (JFY2018)
No. J18-04225

Presentation
by

Navdeep Rinwa (D1802792),
Joint Secretary in the Department of Pharmaceuticals,
Government of India
13th July,2018 at JICA Tokyo

Introduction of my work

- Member of the Indian Administrative Service
- Joint Secretary to the Government of India in the Department of Pharmaceuticals
- Worked in the Department of Health & Family Welfare just before the present posting
- Policymaking, International Cooperation, CMD of IDPL, PMBJP scheme, Review against decisions of NPPA, Pricing of Drugs
- Schemes for promotion of the pharmaceutical Industry
- Handling FDI proposals in Pharmaceuticals and Medical Devices

Good Practices

- Fixation of Ceiling Prices under DPCO
- PMBJP Scheme
- First Nationwide Drug Survey conducted
- CDSCO declared as functional National Regulatory Authority by WHO
- Streamlining of the Clinical Trial Process
- Intelligence cell set up in CDSCO

Good Practices-continued

- Establishment of Pharmacovigilance system made mandatory for all MAH since 2016
- IPC made the 6th WCC for Pharmacovigilance in Public Health Programmes and Regulatory services for the entire globe.
- Establishment of NIPERs
- E-Governance adopted in CDSCO
- Setting up of Public Relations Office in CDSCO

Challenges

- Regulation of Medical Devices
- Pricing of Patented Drugs
- Popularization of Unbranded Generics
- Upgrading all manufacturing units to WHO GMP standards

Regulatory Systems on Ensuring Access to Quality Medicines (J1804225)

Inception Report : Part-I (INFORMATION SHEET)

Name of the Participant : Navdeep Rinwa

Participant's Country : India

Working as a Joint Secretary in the Department of Pharmaceuticals

Regulatory Control over Drugs

Drugs fall under the Concurrent list of the Constitution of India. Drugs are regulated under the Drugs and Cosmetics Act,1940, which is a Central Act, administered by both the Central and State Governments, and it is extended to the whole territory of India.

The regulatory control over the import, manufacture, distribution and sale of drugs, cosmetics and notified medical devices in the country is exercised under the provisions of the Drugs and Cosmetics Act, 1940 & the Drugs and Cosmetic Rules, 1945.

The manufacture, sale and distribution of drugs in the country is primarily regulated by the State Drug Control Authorities appointed by the State Governments while control over drugs imported into the country and introduced for the first time is exercised by the Central Government through CDSCO.

The objective of the drug regulatory system is to ensure availability of safe, effective and quality drugs, cosmetics and medical devices based on scientific excellence and best possible regulatory practices.

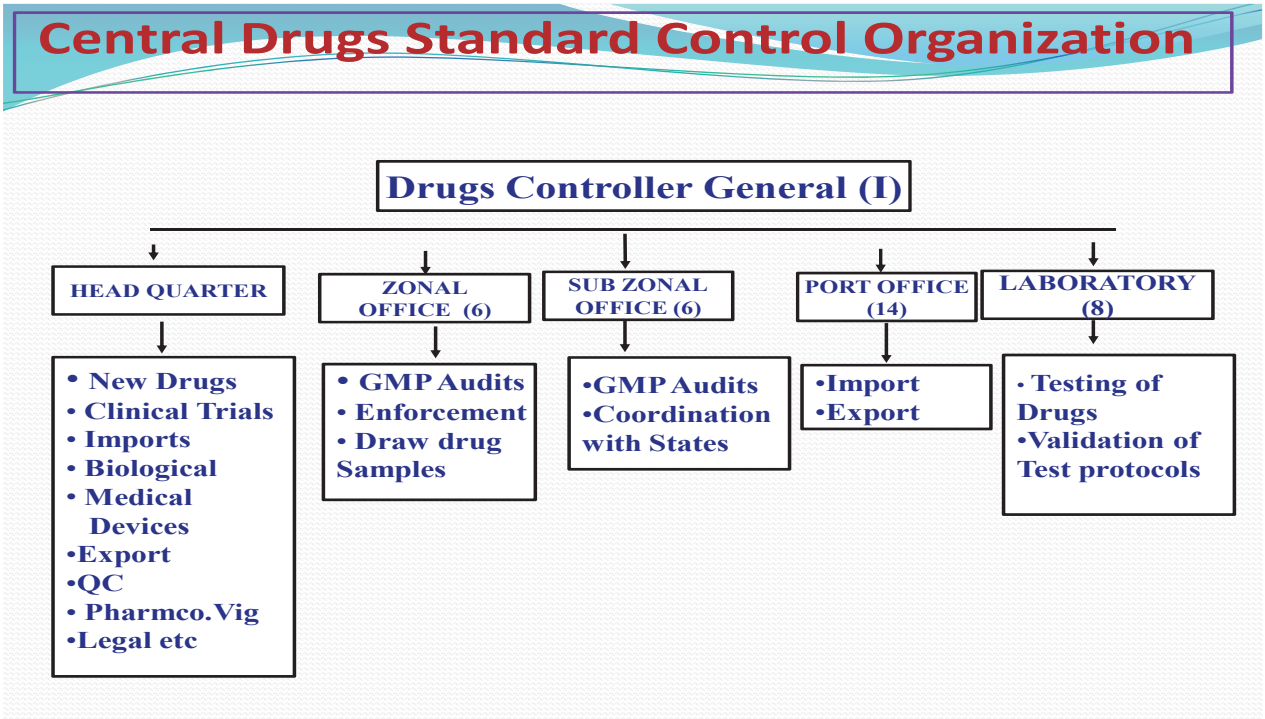
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

The Central Drugs Standard Control Organization (CDSCO) headed by the Drugs Controller General (India) is the Central Authority for regulating the quality of drugs marketed in the country under the Drugs and Cosmetics Act, 1940. This organization comes

under the administrative control of the Ministry of Health and Family Welfare (MoHFW), Government of India

1. ORGANIZATION

Organizational Chart:



The Drugs Controller General (India) is the head of Central Drugs Standard Control Organisation (CDSCO). The CDSCO with its Headquarters in New Delhi has 06 Zonal offices, 06 Sub-Zonal offices, 07 Central Drugs Testing Laboratories and 09 Air Port & 14 Sea port Offices (Including Inland Container Depots) as given below:

<table>
<tr><th colspan="2">CDSCO (HQ) – DELHI</th></tr>
<tr><td>ZONAL OFFICES (6)
• North Zone-Ghaziabad
• East Zone-Kolkata
• West Zone-Mumbai
• South Zone-Chennai
• Zone-Hyderabad
• Zone-Ahmedabad</td><td>SUB- ZONAL OFFICES (6)
• Sub Zone-Bangalore
• Sub Zone-Jammu
• Sub Zone-Goa
• Sub Zone-Indore
• Sub Zone-Baddi
• Sub Zone-Guwahati</td></tr>
<tr><td>LABORATORIES (7)
• CDL-Kolkata
• CDL CRI-Kasauli
• CDTL-Mumbai
• CDTL-Chennai
• CDTL-Hyderabad
• RDTL-Chandigarh
• RDTL-Guwahati</td><td rowspan="2">SEA PORTS (14)
• Mumbai
• Nava Sheva
• Chennai
• Tuticorin
• Cochin
• Kolkata
• Kandla
• Hazira
• Goa
• Vishakhapatnam
• Krishnapatanam
• Tughlkabad (ICD)
• Patparganj (ICD)
• Kodhiyar (ICD)</td></tr>
<tr><td>AIR PORTS (9)
• Delhi
• Mumbai
• Chennai
• Kolkata
• Hyderabad
• Bengaluru
• Ahmedabad
• Goa
• Vishakhapatnam</td></tr>
</table>

Responsibilities of the CDSCO:

Approval of New Drugs /Medical Devices

Import of Drugs/Medical Devices/ Cosmetics

Clinical Trials

Standards for Drugs

Amendments to Act and Rules

Pharmacovigilance

Responsibilities of the State Drug controllers:

License for Manufacture, Sale and Distribution of Drugs

Monitoring quality of Drugs and Cosmetics

Investigations and Prosecutions

2. Legislation on Pharmaceutical Administration

National Level: The regulatory control over the import, manufacture, distribution and sale of drugs, cosmetics and notified medical devices in the country is exercised under the provisions of the Drugs and Cosmetics Act, 1940 & Rules, 1945.

Local Level: The manufacture, sale and distribution of drugs in the country is primarily regulated by the State Drug Control Authorities appointed by the State Governments while control over drugs imported into the country and introduced for the first time is exercised by the Central Government through CDSCO

PICS – India is not a member of PICS.

3. Regulatory Services

- Pharmaceutical Manufacturing:

Systems, Regulations: Good Clinical Practices, GMP, GLP, Pharmacovigilance, New Drug Approvals are administered by Central Level.

GLP, GMP, License for Manufacture, Sale and Distribution, Monitoring quality of Drugs and Cosmetics, Investigations and Prosecutions are primarily administered at State Level.

- Drug Import/Export:

Drug import/export are regulated at central level i.e by CDSCO

- Marketing Authorization:

New Drugs: Central Level

Generic Drugs: State Level

Monitoring of Quality of drugs by both Centre and State level

- ❖ Drug Distribution: Administered at State Level
- ❖ Medical Safety (Post Marketing: Pharmacovigilance) by Central Level.
- ❖ Relief Systems for Adverse Reactions: At present there is no relief system in existence .

4. Drug Pricing:

Drugs have been declared as one of the essential commodities under the Essential Commodities(EC) Act. The EC Act is administered under the department of Consumer Affairs and Public Distribution. The EC Act empowers concerned departments to issue control orders in respect to commodities declared as essentil commodities under the EC Act. Accordingly, the department of pharmaceuticals has issued the drugs (prices control) order (DPCO) to regulate the prices of medicines. The department of pharmaceuticals has entrusted the task of regulating the prices of drugs to the National Pharmaceutical Pricing Authority(NPPA), an autonomous body under the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India.

Mechanism of Price Control

- Unlike the DPCO,1995, which adopted a cost-based approach for price fixation in respect of scheduled drugs, the DPCO,2013 adopts a market-based approach for price fixation.
- The National List of Essential Medicines (NLEM), 2015, is adopted as the primary basis for determining essentiality, and is accordingly incorporated in the First Schedule to the DPCO, 2013, which constitutes the list of scheduled medicines for the purpose of price control.
- Third, the price control is applied to specific formulations with reference to the medicine (active Pharmaceutical ingredient), route of administration/dosage form and strength as contained in the First Schedule.
- Under the market-based approach, the ceiling price of a scheduled drug is determined by first working out the simple average of price to retailer (PTR) in respect of all generic versions of that particular drug formulation having a market share of 1 percent and above, and then adding a notional retailer margin of 16 percent to it.

5. Statistical Data:

S. No.	Subject	Number (Approx.)
I	Number of Pharmacists:	10,00,000
II	Number of GMP Inspectors (National and Local):	1,750
III	Number of manufacturers/manufacturing sites:	10,000
IV	Number of traditional medicine manufacturers/manufacturing sites	9000
V	Number of Pharmaceutical Importers:	3,500
VI	Number of pharmaceutical wholesalers	2,00,000

6. Education and License of Pharmacists in India

There are four distinct levels of pharmacy education in India namely, diploma, graduate degree, post graduate degree and doctorate. A host of pharmacy education programmes are available in India at these four levels. Diploma in Pharmacy (D Pharm), Bachelor of Pharmacy (B Pharm), Master of Pharmacy (M Pharm), Master of Science in Pharmacy [MS (Pharm)], Master of Technology in Pharmacy [(MTech (Pharm)], Doctor of Pharmacy (D Pharm), and Doctor of Philosophy in Pharmacy (PhD). The entry point for D Pharm, B Pharm and Pharm D programmes is after completion of 12 years(5 primary, 7 secondary and 2 higher secondary) of school education in science. The D Pharm programme consists of 2 years of didactic course work followed by 500 hours of practical training to be completed within three months in either a hospital or a community setting. The B Pharma programme consists of 4 years of study in a college affiliated with a university. The B Pharm degree holders can complete M Pharm degree in 2 years, the second year of which is devoted to research leading to a dissertation in any pharmaceutical discipline. A PhD degree in pharmacy involves minimum three years of study and research. The Pharm D programme is of 6 years duration including one year of internship. The pharm D (post baccalaureate) programme involves three years of study. The syllabus of the all these courses is mainly focused to cater to the needs of the pharmaceutical industry. The pharmacists with UG and PG qualification prefer working in industry rather than a community pharmacy due to better salaries and therefore most of the community pharmacists in India are diploma holders.

At present, 1075 educational institutions with annual admission capacity of 64935 students for Diploma in pharmacy course and 1113 institutions with annual admission capacity of

1,91,591 students for degree in pharmacy are approved by the Pharmacy Council of India. India is one of the few countries that allow candidates earning both, a 2 year diploma as well as a 4 year degree programme in in pharmacy to practice as an independent pharmacist

Regulatory Systems
on Ensuring Access to Quality Medicines

INDONESIA

BADAN POM

Drug Regulatory Authority

Badan Pengawas Obat dan Makanan
(Badan POM)

(National Agency Of Drug and Food Control – NADFC)

Republic of Indonesia

DEWI NOPITASARI

Japan, Juli 2018

Vision and Mission

BADAN POM RI

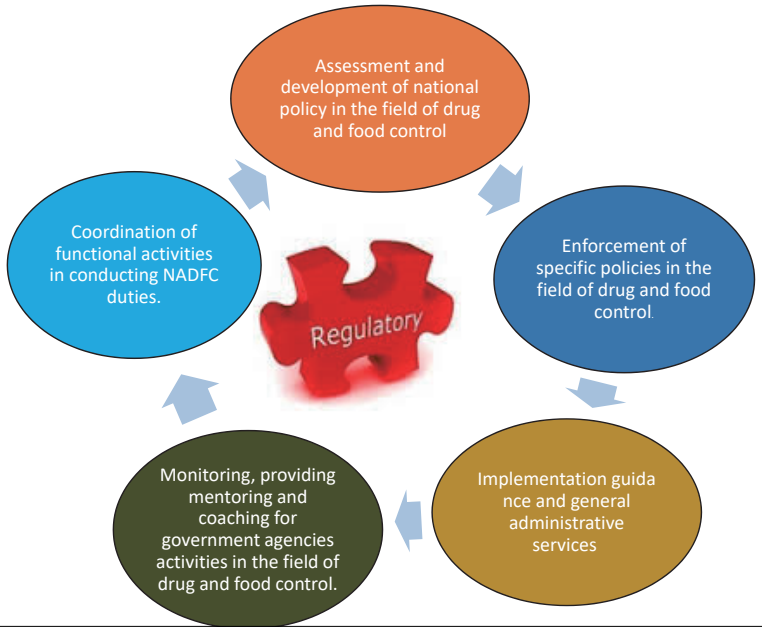
VISION

Safe Food and Medicine to Improve Public Health and National Competitiveness.

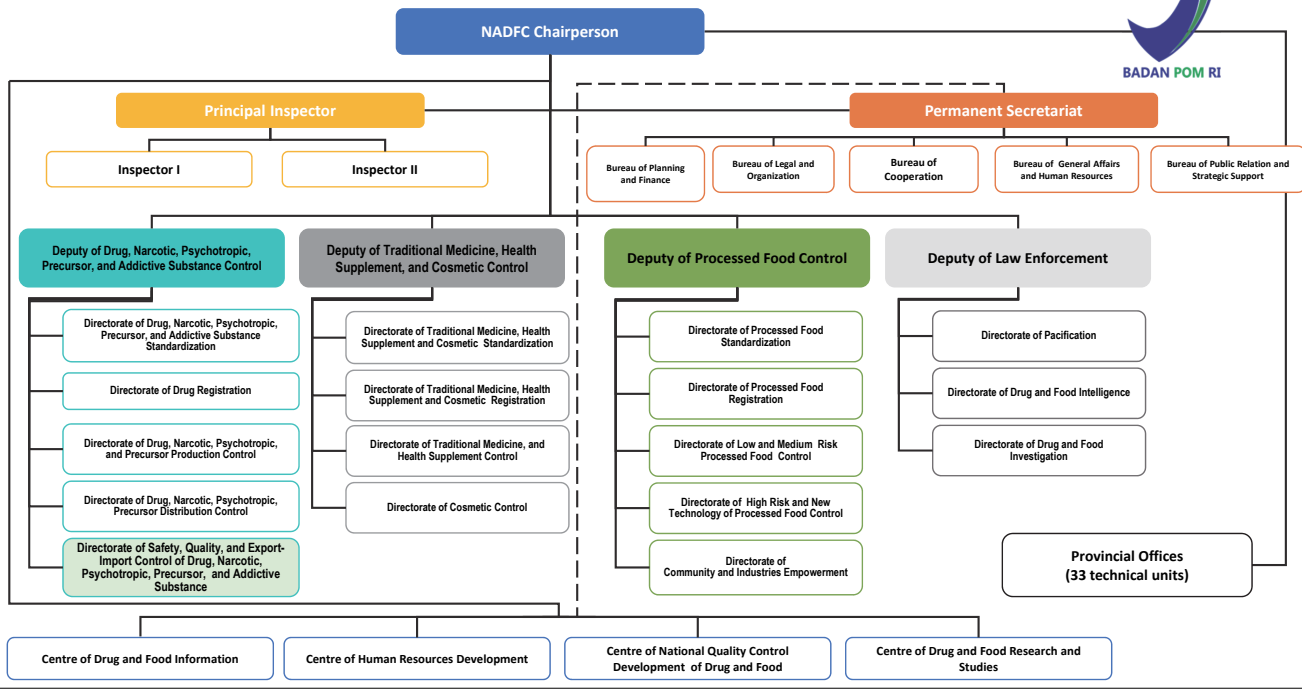
MISSION

1. Intensifying Risk-based Drug and Food Control System to protect public health
2. Encouraging Self Reliance of Bussiness Actors in ensuring Drug and Food Safety and strengthening partnership with stakeholders
3. Enhancing NADFC institutional capacity.

REGULATORY FUNCTION



ORGANIZATION STRUCTURE



Department

Directorate of Drug, Narcotics, Psychotropics, Precursors and Addictive Substances Control, NADFC, consists of 4 Sub Directorates:

1. Safety Control of Narcotics, Psychotropics, and Precursors
2. Export and Import Control of Narcotics, Psychotropics, and Precursors
3. Tobacco Products Control

4. Quality, Information & Promotion Control of Narcotics, Psychotropics, and Precursors

- Preparing materials for policy-making and policy implementation in the field of quality, promotion, and drug information control
- Preparing norms, standards, procedures, criteria, technical guidance and materials supervision in the field of quality, promotion, and drug information control
- Preparing guidance of drug sampling
- Evaluating drug testing results from regional offices and taking follow up actions
- Evaluating report of drug promotion and label control from regional offices and taking follow up actions
- Evaluating drug promotion/advertisement prior to publication
- Evaluating CAPA submitted by pharmaceutical manufacturers
- Providing national report of quality, information and promotion control

Job Tenure

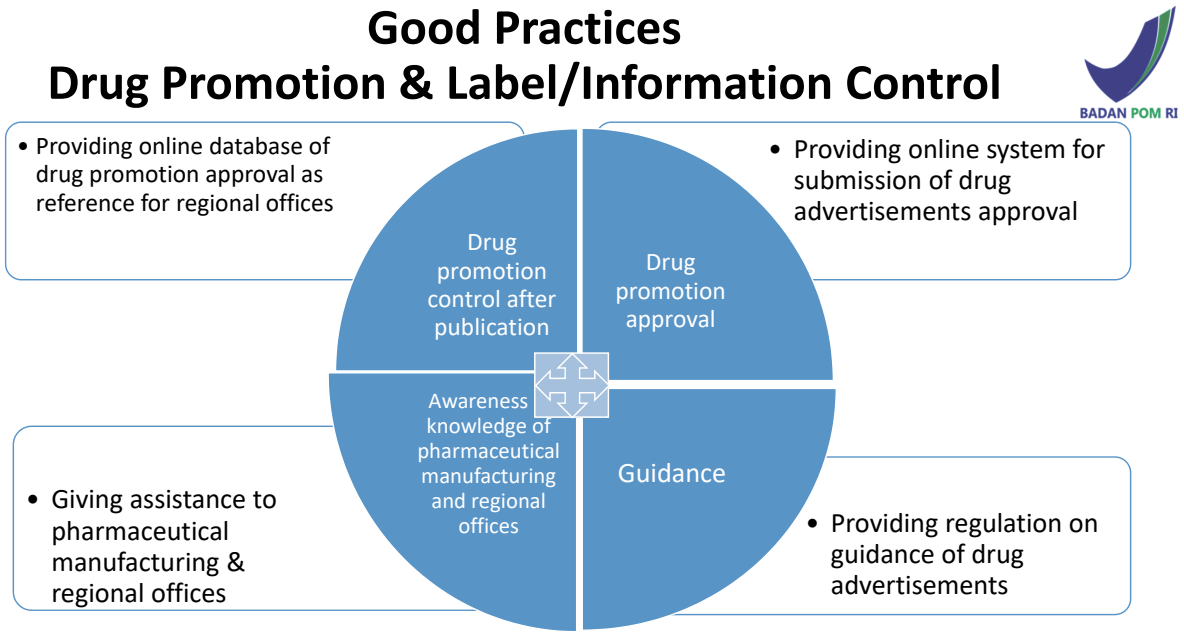
- Joined with NADFC since 2010 → Placed in Directorate of Distribution Control of Therapeutic Products
- Evaluator of Drug Promotion Control and GDP Inspector (2010-Feb 2018)
- Drug and food inspector-second level (since 2015)
- Moved to Directorate of Safety, Quality and Export Import Control of Drug, Narcotics, Psychotropics, Precursors and Addictive Substances) in March 2018 → Evaluator of Drug Promotion and Labelling Control

Roles and Position of Pharmacists in Indonesia

1. Undertaking pharmaceutical work in **procurement of pharmaceutical preparations** in production facility, distribution facility and pharmaceutical care facility → ensuring the safety, quality, benefits and efficacy of Pharmaceutical Preparation
2. Undertaking pharmaceutical work in **production of pharmaceutical preparations** → ensuring compliance with the **GMP** (responsible person in production, QC, and QA Departement)
3. Undertaking pharmaceutical work in **distribution of pharmaceutical preparations** → ensuring compliance with the **GDP** (responsible person in drug distribution facility)
4. Undertaking pharmaceutical work in **pharmaceutical care** → ensuring compliance with the **pharmaceutical care standard** (responsible person in Pharmacy, Hospital Pharmacy Installation, Community Health Center, Clinic, Drug Store, Shared Physician Practice)

In undertaking pharmaceutical work, pharmacist shall ensure and maintain the implementation of Quality Management System

Good Practices
Drug Promotion & Label/Information Control



CURRENT ISSUE & CHALLENGE

BADAN POM RI

Current Issue

Changing trend of drug promotion/advertising from traditional media to online media including on social media

Challenge

- Needs regulation for law enforcement
- Needs infrastructure and human resources for monitoring
- Needs collaboration with other ministry/agency i.e. Ministry of Communication and Informatics

Interest and Expectation

BADAN POM RI

a. Acquiring information about:

- **The regulatory management in Japan for access to quality medicines including the system of quality, information/label and promotion control**
- **The actual operations both in governmental and medical institutions for ensuring quality of medicines**
- **Utilization of information technology in Japan in quality, information/label and promotion control including online drug promotion**

b. Doing observation at pharmaceutical company and pharmacy

Through this programme, I hope to be able to:

- **Improve my knowledge in roles of Regulatory System on Ensuring Access to Quality Medicines.**
- **Improve the system of online drug promotion control**

Regulatory Systems on Ensuring Access to Quality Medicines (JFY 2018)

Inception Report

Name : Dewi Nopitasari

Country : Indonesia

Organization/Division: National Agency of Drug and Food Control (NADFC) / Directorate of Safety, Quality, and Export-Import Control of Drug, Narcotic, Psychotropic, Precursor and Addictive Substance

National Agency of Drug and Food Control Republic of Indonesia (NADFC) is assigned and functioned as national regulatory authority on pharmaceutical administration in Indonesia.

Vision of NADFC: Safe Food and Medicine to Improve Public Health and National Competitiveness.

Mission:

1. Intensifying Risk-based Drug and Food Control System to protect public health
2. Encouraging Self Reliance of Bussiness Actors in ensuring Drug and Food Safety and strengthening partnership with stakeholders
3. Enhancing NADFC institutional capacity.

Organizational Chart

The organizational chart of NADFC at national & provincial offices (Attachment 1).
Organization of Directorate Of Drug Registration (Attachment 2).

Legislation on Pharmaceutical administration

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.

Regulatory services

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
Standard : Indonesia GMP Code 2012 Edition

Drug import/export system

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)

Standard : Regulation of the Minister of Health and Head of NADFC Regulation on Export and Import of Narcotic, Psychotropic, and Pharmaceutical Precursor

Merketing authorization

Administered by : Directorate of Drug Registration

Standard : Regulation of the Minister of Health on Drug Registration, Head of NADFC Regulation on Criteria and Procedure of Drug Registration

Drug distribution

Administered by : Directorate of Drug, Narcotic, Psychotropic, Precursor, and Addictive Substance Distribution Control

Standard : Indonesia GDP Code 2012 Edition, Head of NADFC Regulation on the Procedure of GDP 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)

Standard : Regulation of the Minister of Health on Pharmaceutical Industries, Head of NADFC Regulation on the Implementation of Pharmacovigilance for Pharmaceutical Industry

Relief System for Adverse Drug Reactions

None

Drug Pricing

Drug pricing policy is regulated and controlled by Minister of Health

Statistic Data

1. Number of pharmacists: ± 70.000 (2018)
2. Number of GMP inspector (National & Local): 111 personal (2018)
3. Number of pharmaceutical manufacturers / manufacturing sites: 210 (2017)
4. Number of traditional medicine manufacturers / manufacturing sites: ± 80 (2017)
5. Number of pharmaceutical importers: ± 185 (2017)
6. Number of pharmaceutical wholesalers: ± 2200 (2018))

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 years (including practical training in national regulatory agency, hospital pharmacy, community pharmacy, and pharmaceutical company)
   Age at graduation: 23-24 years old

3. Are there any national examinations for pharmacists in your country?
   Yes, consist of academic exam (1 day) and practical exam (1 day)

4. Which of the followings must you fulfil to obtain a pharmacist's license?
   Practical training is necessary to prepare for the national examination

Side Effect Report

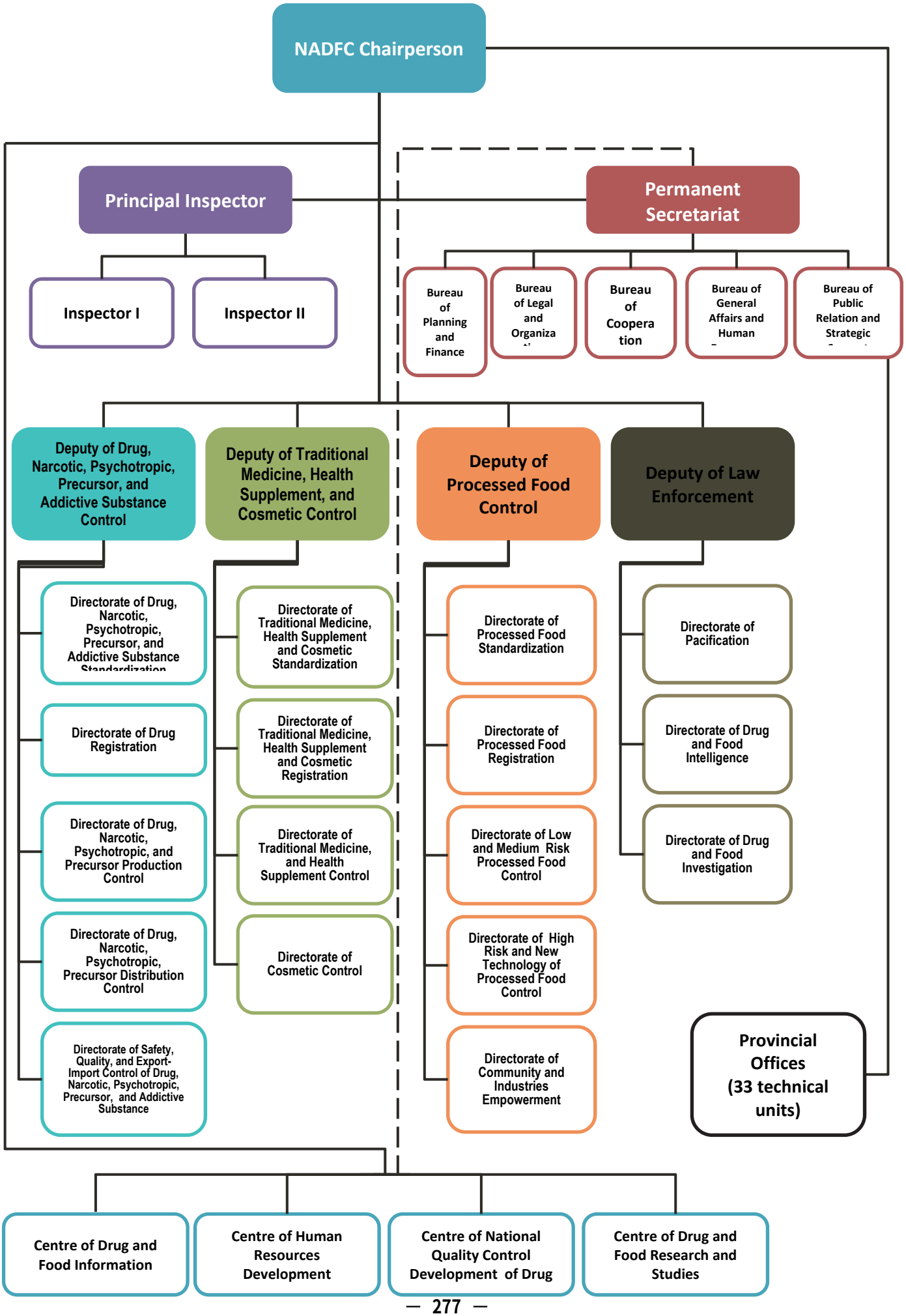
The monitoring system of side effect report conducted by NADFC consists of :

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).

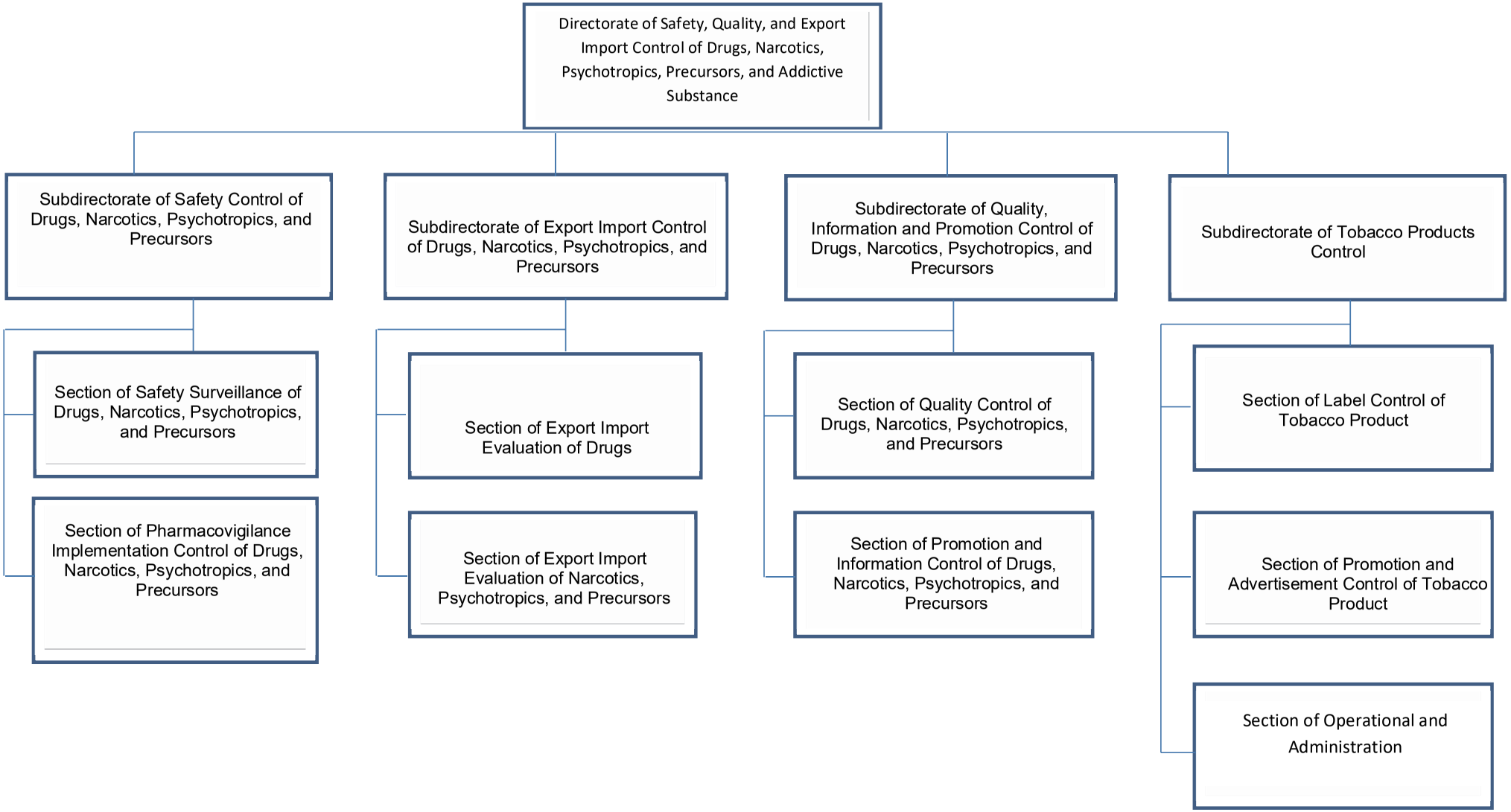
The rule and responsibility for side effect report as follows:

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

The organizational chart of NADFC at national & provincial offices



Organization of Directorate of Safety, Quality, and Export-Import Control of Drugs, Narcotics, Psychotropics, Precursor and Addictive Substances



BADAN POM

NATIONAL AGENCY FOR DRUG AND FOOD CONTROL (NADFC) REPUBLIC OF INDONESIA

BADAN PENGAWAS OBAT DAN MAKANAN (BADAN POM) REPUBLIK INDONESIA

ANGGI TIARANI

JICA Training Course : Regulatory Systems on Ensuring Access to Quality Medicines (J1804225)

Tokyo, July 2018

1

BADAN POM

Vision

Safe Food and Medicine to Improve Public Health and National Competitiveness.

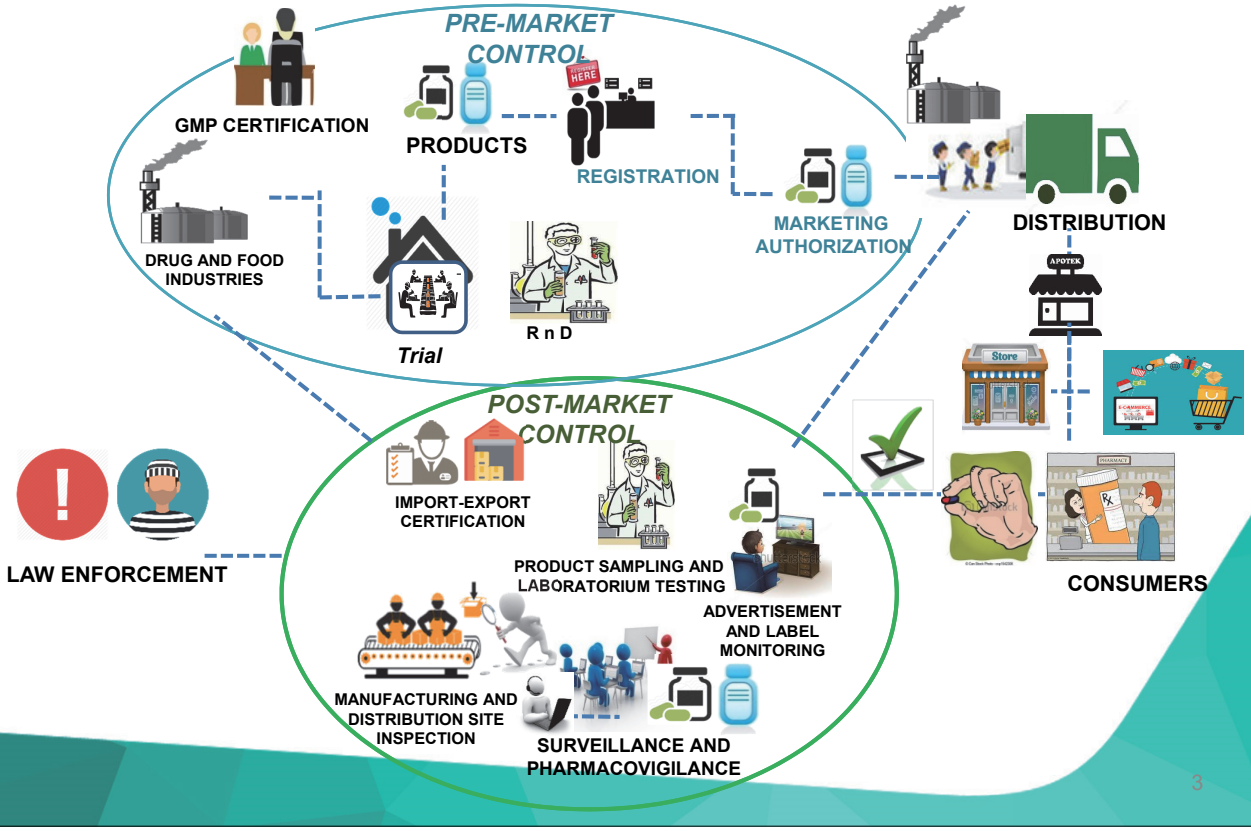
Mission

- Intensifying Risk-based Drug and Food Control System to protect public health
- Encouraging Self Reliance of Business Actors in ensuring Drug and Food Safety and strengthening partnership with stakeholders
- Enhancing NADFC institutional capacity.

2

FULL SPECTRUM OF DRUG AND FOOD CONTROL

BADAN POM

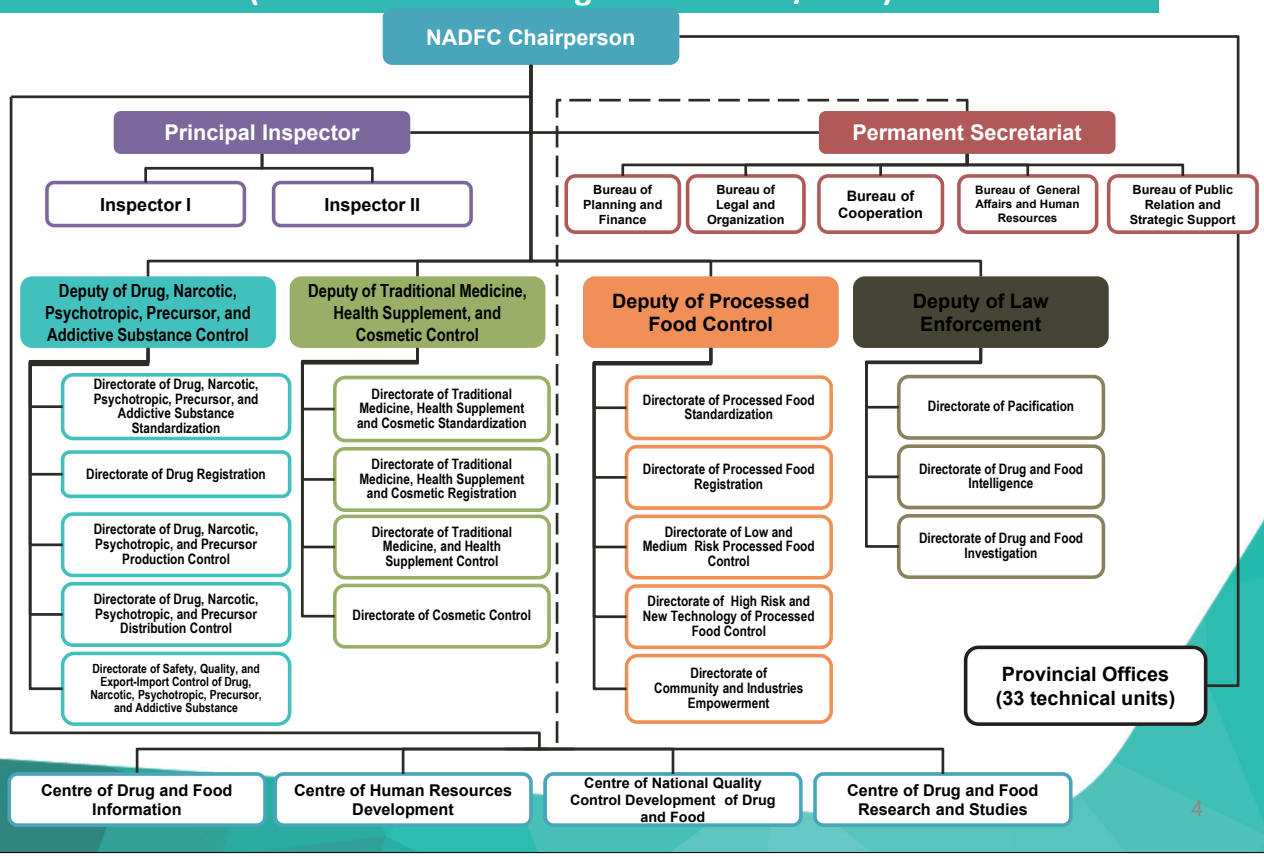


3

ORGANIZATIONAL STRUCTURE

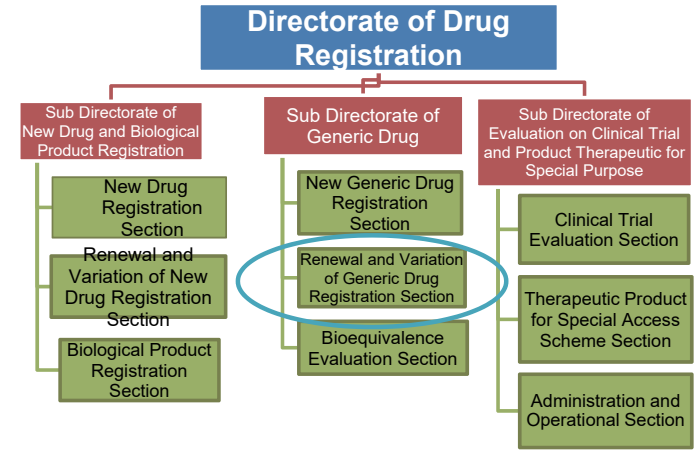
(as Head of NADFC Regulation No 26/2017)

BADAN POM



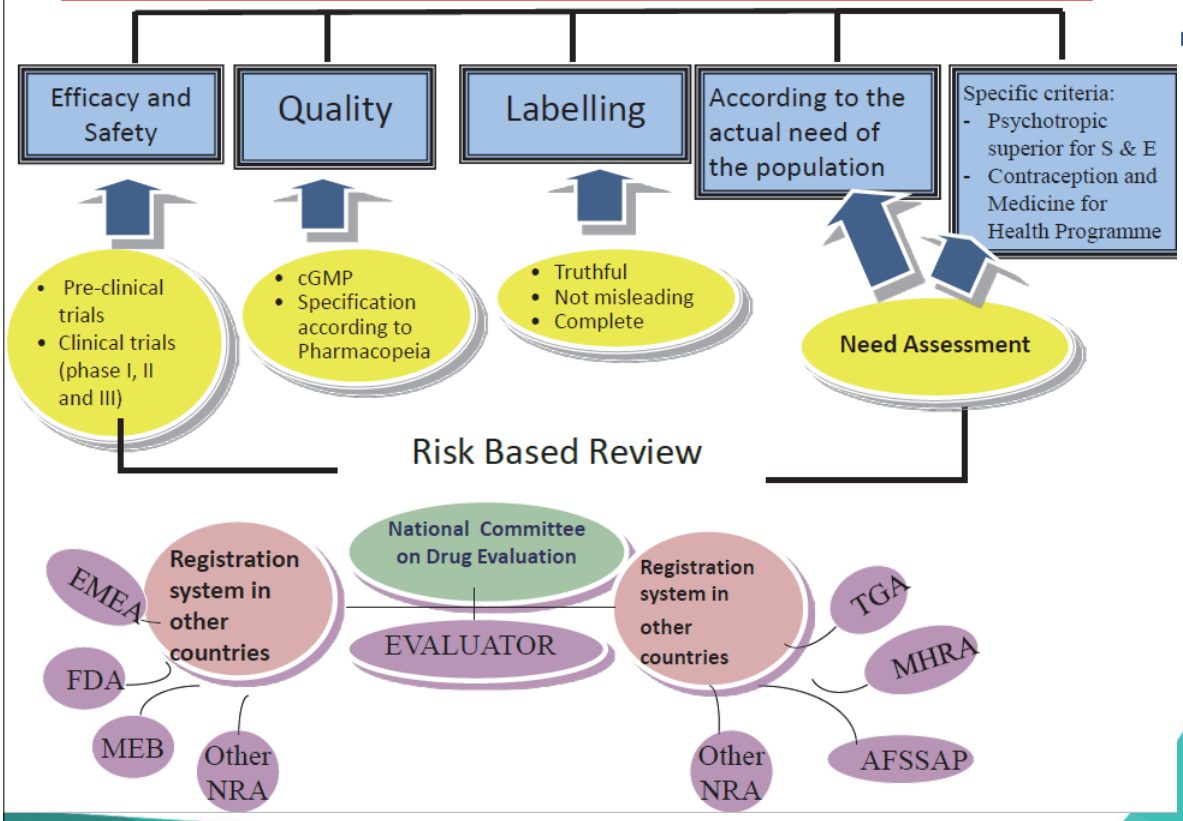
4

Job Tenure

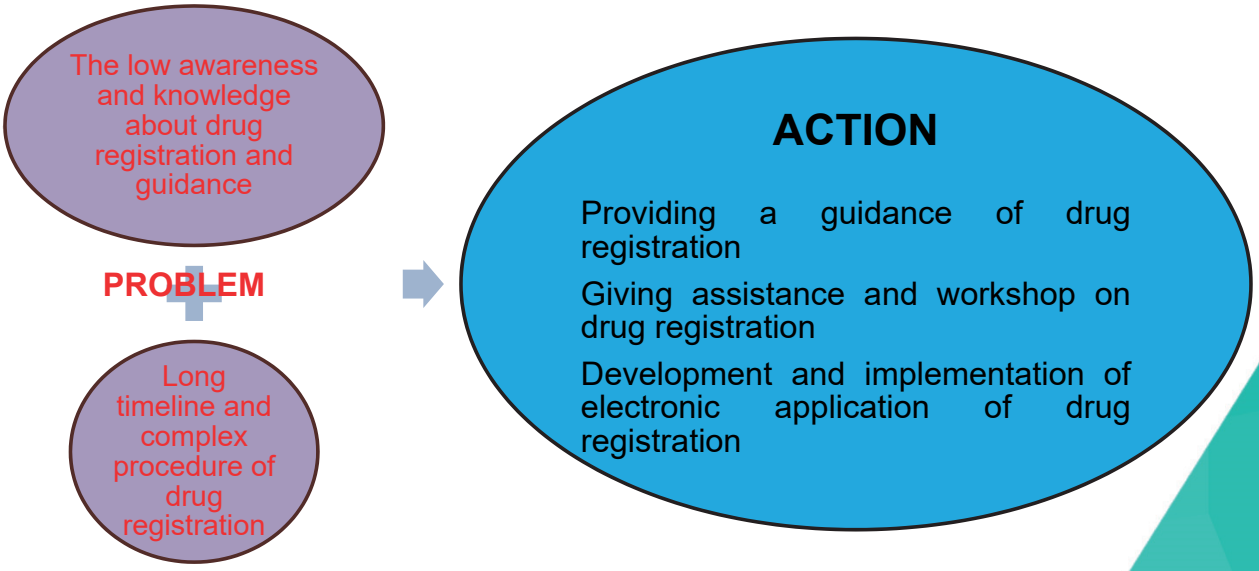


- Joined with NADFC since 2005
- Placed in Directorate of Drug and Biological Product Evaluation
- General Staff at Directorate of Drug and Biological Product Evaluation as variation of generic drug evaluator (2005-2013)
- Senior Staff at Directorate of Drug and Biological Product Evaluation as variation of generic drug evaluator (2013-2018)
- Senior Staff at Directorate of Drug Registration as variation of generic drug evaluator (2018-now)

CRITERIA FOR MEDICINE EVALUATION



THE IMPLEMENTATION OF GOOD REGISTRATION PRACTICE



7

IMPLEMENTATION

ON GOING PROJECT

- Random inspection prior to marketing authorization
- Electronic application of drug registration (new AeRO)
- Conducting coaching clinic on drug registration
- Conducting desk consultation of drug registration

ACHIEVEMENT

- Improvement pharmaceutical industry's awareness and knowledge in drug registration
- Simplification on drug registration by electronic application and deregulation of drug registration
- Ensuring drug quality, safety, and efficacy distributed in society

8

CURRENT ISSUE AND CHALLENGE

Current Issue

The lack of equal understanding on drug registration between NADFC officer and pharmaceutical industry

The long timeline and complex procedure of drug registration

The lack of coordination among NADFC and other related sectors

Challenge

Limited human resources to achieve timeline goal

The competency of the evaluator to conform to the updated drug regulation

Implementation of electronic application of drug registration

INTEREST AND EXPECTATION

Acquiring information about:

- **The regulatory management in Japan for access to quality medicines including regulatory system, inspection system, as well as trends of international collaboration among regulatory authorities**
- **The actual operations both in govermental and medical institutions for ensuring quality of medicines**
- **Lectures on countermeasures against counterfeit medicines and the problems related which may lead to public health issue.**

Doing observation at pharmaceutical company and pharmacy

Through this programme, I hope to be able to:

- **improve my knowledge in roles of Regulatory System on Ensuring Access to Quality Medicines.**
- **observe and identify process that can be improved in drug regulatory system.**

Regulatory Systems on Ensuring Access to Quality Medicines (JFY 2018）

Inception Report

Name : Anggi Tiarani

Country : Indonesia

Organization/Division: National Agency of Drug and Food Control (NADFC) / Directorate of Drug Registration

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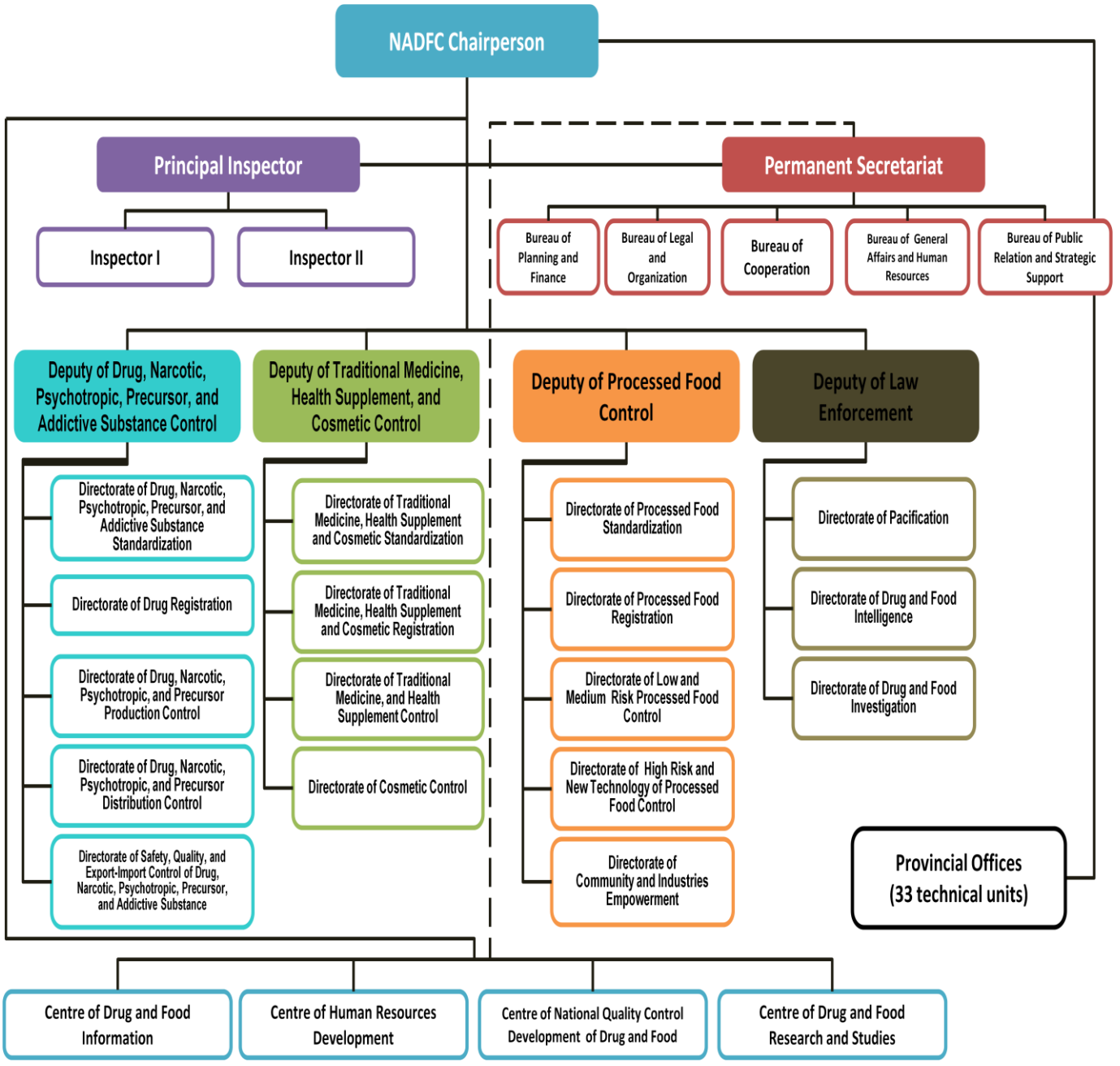
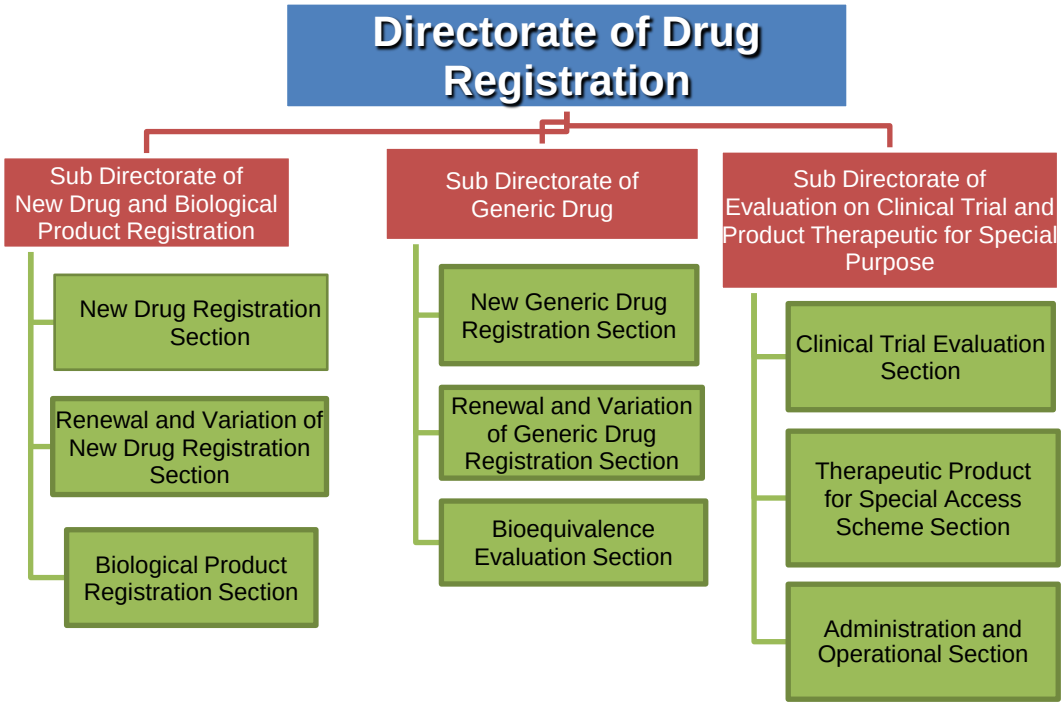
Attachment 1

The organizational chart of NADFC at national & provincial offices



Attachment 2

Organization of Directorate Of Drug Registration



Regulatory Systems
on Ensuring Access to Quality Medicines

IRAQ

Republic of Iraq

Ministry of Health

The state company for marketing drugs and medical appliances (Kimadia)

Pharmacist : Wijdan Hussain Sabeh Al-Allaq

(Senior Chief Pharmacist)

The state company for marketing drugs and medical appliances
(Kimadia)

The State Company for Marketing Drugs and Medical Supplies

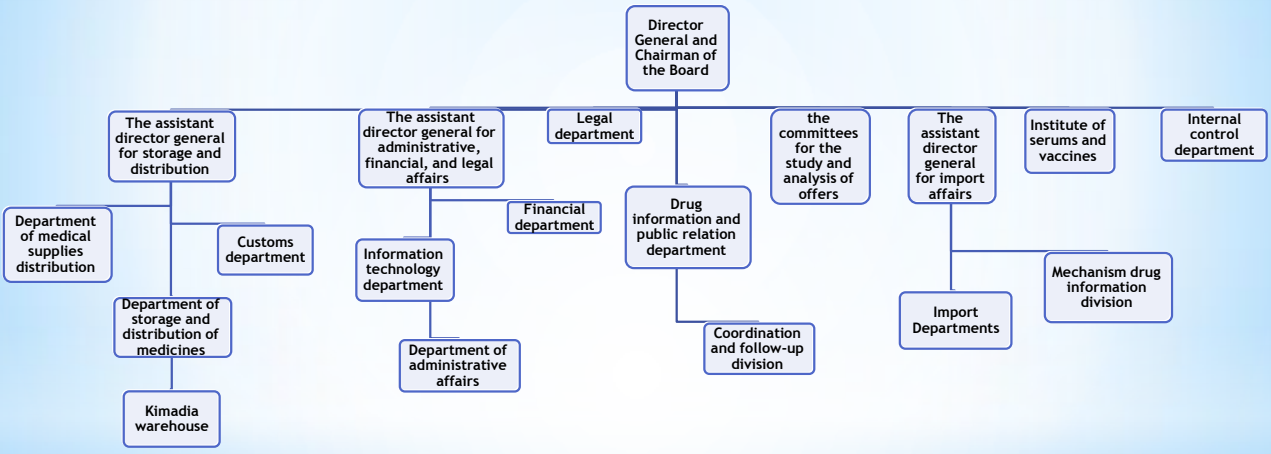
(KIMADIA)

- The State Company for Marketing Drugs and Medical Supplies was established in 1964 Governed by public companies Law no. 22 in 1997 and its internal system no. 1 in 1999 and its entirely owned by the state and linked to the ministry of health , it is the only authorized company in the Ministry of Health to import, store and distribute medicines, supplies, medical equipment, vaccines and chemicals to all health institutions in Baghdad and the rest of the provinces of Iraq, and distribute them to all hospitals, health centers and Popular clinics.

Vision: Providing medicines and medical supplies of high quality with lowest cost to all citizen over the year.

Mission:Providing medicines and medical supplies for all beneficiaries by importing them from Arab and foreign countries in addition to national governmental and private factories through the optimal use of available resources.

Organization Chart of Kimadia



* The main departments

The laws in which the company operates

1- Federal Budget Law .

2-Iraqi Civil law No. 40 in 1951 .

3- Public companies Law no. 22 in 1997.

4- Law No. 60 in 1998 for the scientific Bureaus and the instructions No. 4 in 1998.

5- The law of practicing the profession No. 40 in 1970.

6- Public Health Law No. 89 in 1981.

7- The Government Debt Collection Law No. 56 in 1977.

8- The Law of Governmental Contracts No. 87 in 2004 and Instructions for executing government contracts No. 2 in 2014.

The Ministry is currently working on the preparation of special instructions and controls for the purchase of medicines, medical devices and supplies, taking in consideration the privacy of these materials and currently under consideration and study with the higher authorities in order to shortening many formal procedures that do not conflict with the objective and scientific aspect of the provision of these materials and thus contribute to the provision of medical service in accordance with the objectives and mission of our ministry.

The Mechanism of Purchase in Kimadia

- The contracting process takes about one year from the arrival of the annual needs of medicines (represent health institution needs for the next year) until the signing of contracts and arrival of the medicines and distribution to the health institutions ,this process goes through the following stages:
- Announcement Invitation: General Tenders , Direct invitations or invitation of one bid to the monopolistic companies , also invitations for direct purchase from the national (governmental and private) manufacturing factories.

* All companies must introduce their offers according to the Standard Bidding Documents attached with the invitation conditions.

- Study Offers by the committees for the study and analysis of the offers and making recommendations.
- Preparing and organizing Contracts by Import departments.
- Insurance of financial allocations.
- Open documentary Credit.
- Arrival of medicines to Kimadia Warehouse.
- Send Samples to the national center for drug control and research (NCDCR) for analysis.
- Release and distribution of medicines from warehouses of Kimadia to the health institution after its success in the analysis.

* The Above processes done by Special instruction & laws.

The Future Vision of KIMADIA

1- Developing cooperation in the scientific field with the research institutions for medicine and exchange of experiences between our company and the other side who wish to cooperate.

2. Entry of Kimadia as a shareholder with the national and foreign companies producing the medicine and appliances under an agreement between two sides .

Office of assistant of director general affairs

Responsible for follow up of:

- The study and analysis of the offers from the producing companies in the study committees.
- All contracts of the import departments.
- The arrived items to the stores and their success in laboratory tests and evaluation.
- Coordinate the work between the departments of the company.

All the above mentioned duties to ensure the distribution of high quality medicine to our health institutions continuously.

Good Practice

- Training in hospitals (consultant clinic pharmacy)
- Training at Samarra governmental pharmaceutical factory
- Medicine import department (contracts).
- Laboratory import department(contracts after study the offers)
- Kimadia warehouse especially for chemotherapy and immunosuppressant.
- committee for the study and analysis of drugs offers for many of producing companies and for the national factories (governmental and private).
- Medical appliances import department .
- Training course at ST.Jude Brussels Medical Advanced Technology Center and the program field is(ST.Jude combined vascular & cardiac surgery training.
- Office Of Assistance Director General For Import Affairs.
- ICD-10 training course at the directorate of planning and resource development.
- Visiting many of manufacturing company at many countries.

Difficulties/Lessons Learned from Past Experience

- Some of medicines doesn't success in analysis at the National Center for Drug Control and Research (NCDCR) or not possible to do some tests because of lack of equipment in the center or lack of experiences to do these tests especially for the unconstitutional medicines.

- Inaccurate estimation of the annual requirements from health institutions.

- Selection of registered medicines of high quality and effective with lowest price at the committee for the study and analysis of drugs offers.

- Do not receive offers for some medicines like (medicines for rare diseases and antidote) and difficulties to get offers for these items even after doing direct invitation to the producing company.

Interests

-To increase the experience after viewing the latest system that applied in an advanced country such as the state of Japan to supply safe medicines of high quality and to provide the best health services for the Iraqi citizens.

-To know what the bases that we depend on to select the safe and highly effected medicine and to prevent trading of counterfeit medicines in order to create healthy environment and raise the level of pharmaceutical services in the country.

- Gaining the experiences from the participating countries in this program.

To Contact With Us

Visit our website

www.kimada.iq

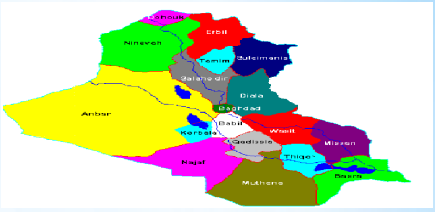
You can contact us via our E- mails below

dg@kimadia.iq

dg1@kimadia.iq

dg2@kimadia.iq

gen.relat@kimadia.iq



Regulatory Systems on Ensuring Access to Quality Medicines (JFY 2018)

Duration course 8th,July - 8th, August, 2018

Pharmacist: Wijdan Hussain Sabeh Al-Allaq

Country: Republic of Iraq

Ministry of Health/The state company for marketing drugs and medical appliances/ Office of assistance director general for import affairs

Republic of Iraq Ministry of Health

Demographic data

- Total population: 37,139,519 million in 2017 (7,916,847 million in Baghdad.).
- Population growth rate 2.2
- Urban population is about 69.8% , rural population is about 30.2% of the total.
- 40,5% of the population is under 15 years of age and 5,0% is over 60 years.
- Life expectancy at birth estimated 70.3 (68.3 for males and 72.3 for females).

Vital events indicator

- Crude birth rate per (1000) of the population is (28.05)
- Percentage of births inside health institutions is 83.5%
- Percentage of births less than 2.5 Kg. is 6.6%
- Percentage of caesarean section deliveries is 35.2%

• This information from annual statistical report 2017/Republic of Iraq/ Ministry of Health

Ministry of Health

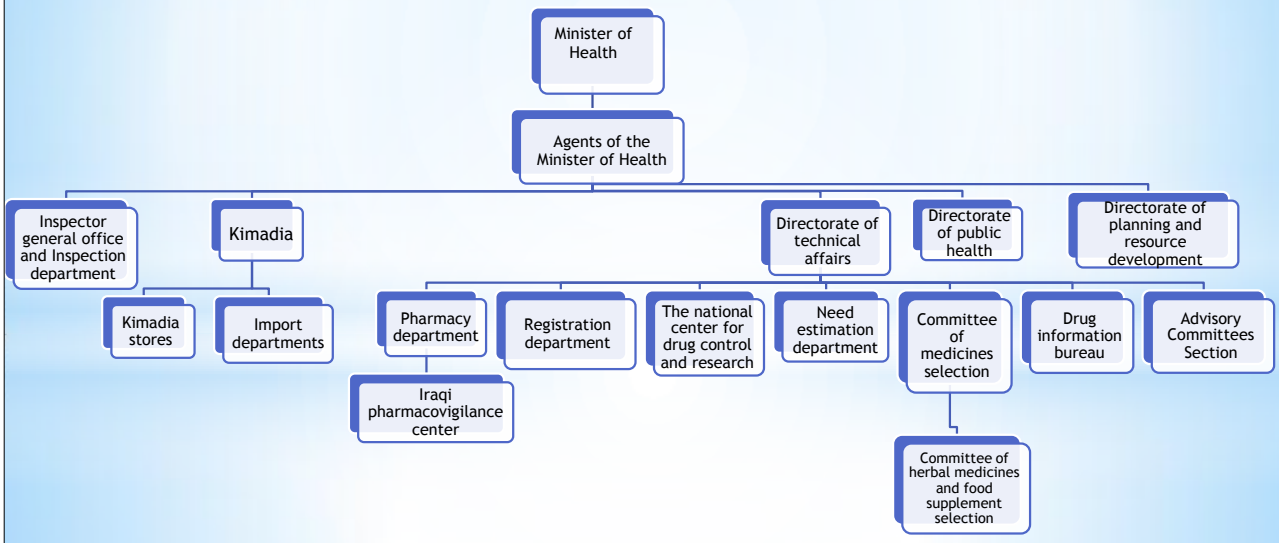
Vision

Comprehensive efficient and applicable Health Information System.

Mission

The Ministry of Health works to provide the infrastructure and logistic supplies to build a statistical information base and an integrated, sustainable Health Information System to insure access to health information by decision makers, policy makers and researchers in the field of health to improve the comprehensive coverage, quality and efficiency of health care with highest quality.

Organization Chart of Ministry of Health*



* The main departments

Health services and Medicines regulation departments in the Iraq Ministry of Health:

All departments in the ministry play important role to regulate and control all health services and medicines regulation in cooperation between them for the safety of the Iraqi citizens , listed below the main tasks of the main departments briefly:

- Directorate of planning and resource development : concerned with affairs of health staff and the planning of health policy and record all the data base of the ministry and responsible for training developing of health personnel by doing training courses like (ICD-10) and training courses for clinical pharmacists and workshops.

-Directorate of public health: health promotion and planning for health education for citizen and preparing for epidemics .

- Kimadia: the only authorized for import and distribution of medicines, medical appliance, laboratory reagents& equipment , medical equipment.

- Directorate of technical affairs: the most important department to control the health system and the important departments:

1- Committee of medicines selection: responsible for endorsement and selection of the medicines and arrange them in the essential list with their specification to be imported by Kimadia , Committee of herbal medicines and food supplement selection related to this committee .

2-Need estimation department : collect the annual estimation of the medicines, medical appliance, laboratory reagents& equipment , medical equipment for all health institution.

3- Registration department: responsible for registration of medicines and the manufacturing company with special conditions to guarantee the high quality of the medicines

4-The national center for drug control and research (NCDCR): responsible for the analysis and evaluate all the imported items for governmental and private sector.

5-Pharmacy department : responsible for organization and control trading process of medicines and medical appliances and follow up the pharmaceutical issues for governmental and private sector , also responsible for organization of import licenses to the scientific bureaus, ,and Iraqi pharmacovigilance center is one of the important part in this department.

- Inspector general office and Inspection department: a supervisory authority cooperate with all departments.

Legislation on Pharmaceutical Administration

The laws in which the ministry operates

There are many laws that arrange the work in the ministry like :

- Federal Budget Law .
- Iraqi civil law No.40 in 1951.
- Law of the ministry of health No.10 in 1983.
- The law of practicing the profession No. 40 in 1970.
- Public Health Law No. 89 in 1981.
- Law of cancer council No.63 in 1985.
- Law of narcotics No.68 in 1965.
- Law of psychological health No.1 in 2005.
- Public companies Law no. 22 in 1997.
- Law No. 60 in 1998 for the scientific Bureaus and the instructions No. 4 in 1998.
- The Government Debt Collection Law No. 56 in 1977.
- The Law of Governmental Contracts No. 87 in 2004 and Instructions for executing government contracts No. 2 in 2014.

The Ministry is currently working on the preparation of special instructions and controls for the purchase of medicines, medical devices and supplies, taking in consideration the privacy of these materials and currently under consideration and study with the higher authorities in order to shortening many formal procedures that do not conflict with the objective and scientific aspect of the provision of these materials and thus contribute to the provision of medical service in accordance with the objectives and mission of our ministry.

PIC/S : NO

Regulatory Services

- **Pharmaceutical Manufacturing:**

-The ministry of health has taken several measures aimed at supporting the national pharmaceutical industry while supporting investment in the pharmaceutical production sector in order to secure a number of varieties domestically .

-National production currently covers only 20% of the country need .

-All the national factories products must be registered at the registration department .

- The number of the national pharmaceutical factories is (26).

- Samarra pharmaceutical factory is one of the largest factory specialized in the pharmaceutical industry in the country which was founded in 1959, and the graduated pharmacists train during the first year after graduation in its manufacturing department & in the evaluation and quality control department.

Regulatory Services

- **Drug Import/Export :**

-The state company for marketing drugs and medical appliances (Kimadia) is the only authorized company in the Ministry of Health to import, store and distribute medicines, supplies, medical equipment, vaccines and chemicals to all health institutions in Baghdad and the rest of the provinces of Iraq , in cooperation with other departments of ministry of the health.

-The scientific bureaus are responsible for import the medicines and medical appliances for the private sector.

Regulatory Services

- **Marketing Authorization, Drug Distribution** :

- Departments of storage and distribution of medicines and medical appliances in Kimadia are responsible for the distribution of medicines to all the health institution after successful in the analysis in the national center for drug control and research(NCDCR).
- In the private sector the scientific bureaus are responsible for distribution the medicines and medical appliances to the private sector after successful in the analysis in the national center for drug control and research.
- The items that allowed to be imported are only the registered items in the essential lists which has been listed before by the national committee for selection of the medicines.

Regulatory Services

- **Medicine Safety (post-marketing) & Relief system for adverse drug reaction:**

- Iraqi pharmacovigilance center in the pharmacy department in the ministry of health is responsible for follow up the adverse effects (ADR)of the medicines , herbal medicines and appliances after marketing and after used by patients, and this center depend on :

- The medical staff when they report any side effects or (ADR) appears on the patients .
- The community in documenting and registration the side effects that appears when they use the medicines by communicate through the websites of the centers , so that the center can study and identify the cause do the scientific action to prevent or reduce them in the future , and the web site of Iraqi pharmacovigilance center is (iraqiphcv@moh.gov.iq) .
- The pharmaceutical companies which make conducts field studies continuously to follow up their products after marketing and to introduce their reports for drug safety and efficacy(as mentioned in the next page) by introducing continues reports includes therapeutic recommendations for proper use by the medical staff like the other countries and to reduce the side effects and to follow up the percentage of risks against benefits of medicines to reach to the proper use of the medicines .

- Iraqi pharmacovigilance center send a copy of the reports to the Uppsala Monitoring centre for international scientific research in Sweden which associated closely with WHO to adopt them in the world drug control program.

Instructions of the pharmacovigilance

- Instructions of the pharmacovigilance: All the pharmaceutical companies must :

1- apply pharmacovigilance system to the company organizational structure and must introduce official commitment to the registration department to depend and maintained this system.

2- prepare pharmacovigilance system master file (PSMF) for all the medicines and must be available when requested by the Iraqi pharmacovigilance center .

3-prepare updated periodic safety reports {periodic benefit risk evaluation report, periodic safety (PSUR-PBRER)} including the detection of variables and follow-up the efficacy of the medicines and introduce to Iraqi pharmacovigilance center.

4-Select one of the medical staff as local safety responsible (LSR) to carry out tasks and responsibilities for pharmacovigilance.

* The Iraqi pharmacovigilance center do periodical visits to the scientific bureaus that represent the pharmaceutical companies in Iraq to continue applying pharmacovigilance system and decisions will be taken against them if not applied.

Drug pricing

Drug pricing is done through a specialized ministerial committee called the pricing committee which includes members from the pharmacy & registration departments in the directorate of technical affairs with a member of the pharmacists syndicate.

Statistic Data of Ministry of Health 2017

Items	Number
Total number of governmental hospitals & Specialized centers with inpatients	273
Total number of private hospitals	127
Total number of governmental hospitals' beds	44527
Number of human resources works in health Field	252723
Number of human resources works in Ministry of health	216681
Total number of physicians	31451
Number of dentists	9524
Number of pharmacists	10939
Number of nursing staff	64297
Number of paramedical staff	59961
Number of medical collages	28
Number of collages of dentistry	43
Number of collages of pharmacy	37

Education and license of pharmacists in the republic of Iraq

The study	The duration
Primary school	6 years
Secondary school	6 years
High school (collage of pharmacy)	5 years

The pharmacist registered at the syndicate of pharmacy and can practice the profession directly after graduation from the collage of pharmacy and take the license to open the own pharmacy after three years of graduation from the collage of pharmacy according to the law of practicing the profession no. 40 in 1970 , also there are many training courses organized by the ministry to develop the pharmacists skills especially the clinical pharmacists.

Statistic Data of Syndicate of Iraqi Pharmacists 2018

Items	Number
Number of pharmacies	12500
Number of the scientific Bureaus	400
Number of the whole store	680

Side effect reports

There are many reports arrived to Iraqi pharmacovigilance center about the medicines in the pharmaceutical market and we take some examples of them:

- There was a report of serious symptoms due to the use of (plavix 75mg tab.) that used in the private sector and after analyze it in the laboratories of the manufacturing company(SANOFI pharmaceutical company)they found it doesn't contain the active ingredient and the necessary action was taken by Iraqi pharmacovigilance center and notify the health institution not to use this product for the safety of the citizens.

-SANOFI pharmaceutical company has reported Iraqi pharmacovigilance center about the existence of counterfeit (Daonil 5mg tab.) in the private sector and they do analysis to the counterfeit batches at their company laboratories and found these tablets doesn't contain any active ingredient and the necessary action was taken by Iraqi pharmacovigilance center.

Novartis pharmaceutical company has reported Iraqi pharmacovigilance center about the existence of counterfeit medicine { Exoforge(valsartan+amlodipine)5/160mg tab.} and they notice that because their original products contain Serial NO. and Barcode and Iraqi pharmacovigilance center notify the health institution not to use this product for the safety of the citizens.

* Iraqi pharmacovigilance center notified the inspection department in the ministry and in the health institutions (governmental and private) about the adverse effect reports to cooperate in controlling the situation for the safety of the citizens.

Regulatory Systems
on Ensuring Access to Quality Medicines

MYANMAR

Republic of Union of Myanmar

Ministry of Health and Sports

Department of Food And Drug Administration

Dr Mg Mg Thi Ha Htwe

1. Introduction of the work

(1) Organization and department

- Ministry of Health and Sports
- Department of Food and Drug Administration

(2) Job tenure

- Assistant Director, Kayin State FDA

(3) Regulatory services that I am engaged in

(a) Pre- market assessment

- GMP inspection of food factories

(b) Post market assessment

- pharmacies inspection (GPP)
- pharmaceutical warehouse inspection (GSP)
- Inspection on food shops and stores relating to food and cosmetic safety
- Testing samples of food, drug and cosmetic in mini-laboratory
- Public awareness about food, drug and cosmetic safety

(4) roles and position of pharmacists in country

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

2. Good Practice

Experiences about Good Practices

Achievement

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

2. Good Practice

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

3. Difficulties/Lessons Learned from Past Experience

1. Many armed forces and illegal border trade
2. Light penalty for violation of the law
3. Weakness of activities of Township food and drug supervisory committees
4. Limited resources (man power, facilities, finance, etc)
5. Different penalties in different states and regions

4. My interests

(1) GMP inspection training
(2) Proper supply chain system
(3) Administrative management in pharmaceutical regulatory system

Part I: INFORMATION SHEET

Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2018）

Name: Mr. Mg Mg Thi Ha Htwe
Country: Republic of Union of Myanmar
Organization/Department/Division: Department of Food and Drug Administration, Ministry of Health and Sports

1. **Organizational Chart- Attached (Annex-1)**
2. **Legislation on pharmaceutical administration**

◆National Level

・Public Health Law (1972)
administered by Myanmar Food and Drug Board of Authority
・National Drug Law (2014 Amendment)
administered by Myanmar Food and Drug Board of Authority
・Narcotic Drugs and Psychotropic Substances Law (1993)
administered by Myanmar Food and Drug Board of Authority
・Traditional Drug Law (1996)
administered by Myanmar Food and Drug Board of Authority

◆Local Level

・Public Health Law (1972)
administered by State and Region Food and Drug Supervisory Committee
・National Drug Law (2014 Amendment)
administered by State and Region Food and Drug Supervisory Committee
・Narcotic Drugs and Psychotropic Substances Law (1993)
administered by State and Region Food and Drug Supervisory Committee
・Traditional Drug Law (1996)
administered by Department of Traditional Medicine

◆PIC/S

- No

3. **Regulatory Services**

◆Pharmaceutical Manufacturing

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

◆Drug Import/Export

・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

・ASEAN Common Technical Dossier (ACTD)
administered by Myanmar Food and Drug Board of Authority

・Laboratory analysis and confirmatory clinical trials
administered by Myanmar Food and Drug Board of Authority

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

・Good Clinical Practice
administered by Department of Health

◆Medicine Safety (post-marketing)

・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 Department of Health

◆Relief System for Adverse Drug Reactions

・Adverse Drug Reactions Monitoring System
administered by Department of Food and Drug Administration and Department of Health

4. Drug Pricing

There are no price control and drug price mechanism at public sector in my country.

5. Statistic Data

1. Number of pharmacists 3300(year 2018)
2. Number of GMP inspector (National & Local) 10 (year 2018)
3. Number of pharmaceutical manufacturers / manufacturing sites 9/ Yangon, Pyin Oo Lwin,Kyaut Sae, Sagaing Township
4. Number of traditional medicine manufacturers / manufacturing sites About 100
5. /capital cities (year 2018)
6. Number of pharmaceutical importers 210 (year 2018)
7. Number of pharmaceutical wholesalers > 700 (year 2018)

6. 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:	1weeks (Pharmaceutical factory)
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

(4) Number of pharmaceutical university or college graduates: 250 people/per year

The alumni's placement rate (%)

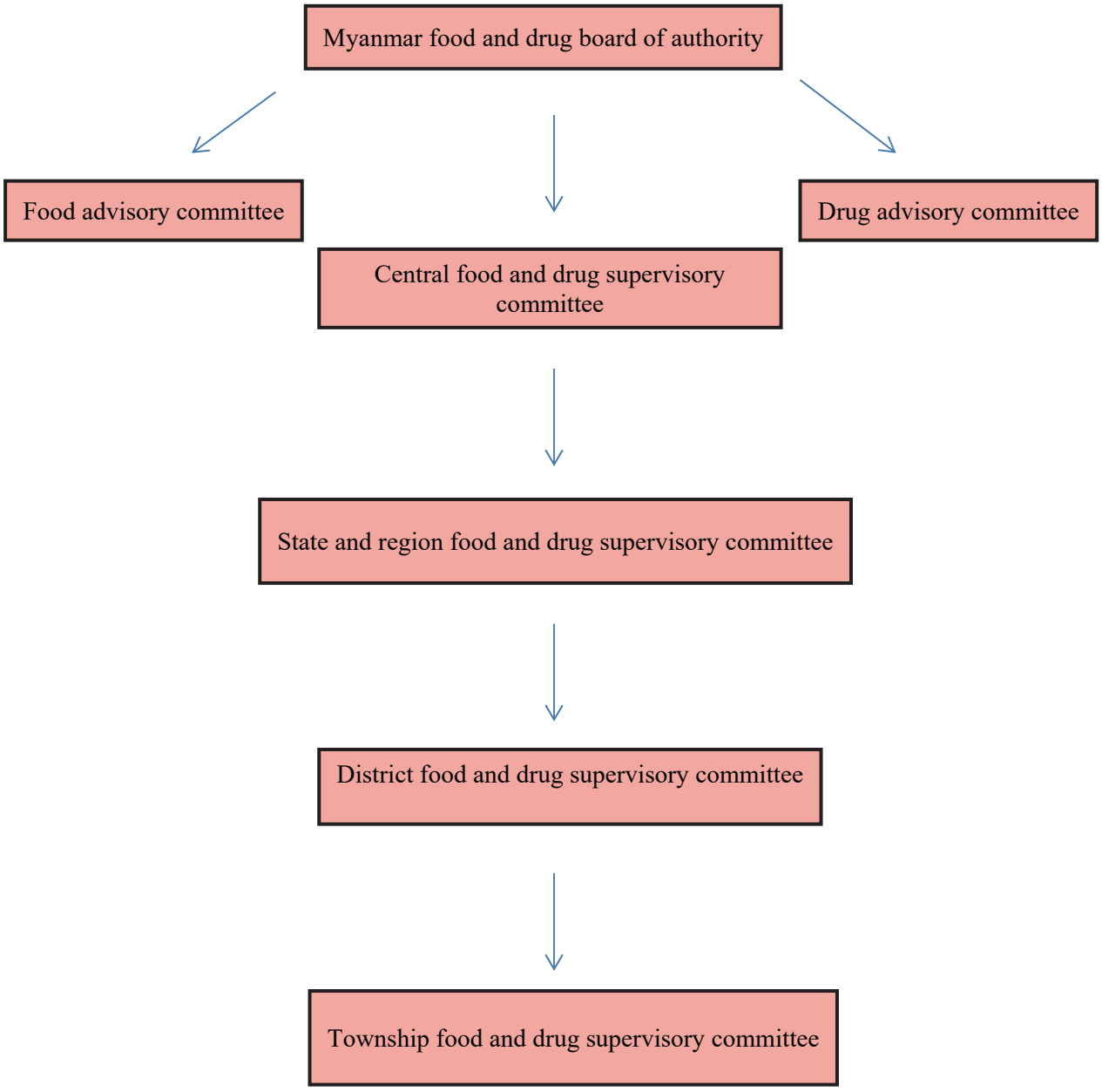
a.	Hospital:	10 %
b.	Community Pharmacy:	30 %
c.	Government Organization:	5 %
d.	Enterprise:	20 %
e.	Others:	35 %

(5) Side effect report

When a severe side effect case is occurred in a medical institution, the head or medical superintendent of that institution informed to the department of health. And then, members of that department and the department of food and drug administration make an inspection team where members of department of health inspect the signs and symptoms of side effects, nature of underlying disease and medical staff ' use of medicine while members of department of food and drug administration inspect the quality and safety of medicine. According to their findings, conclude the cause of side effect and take action.

Annex-I

1. **<u>Organizational Chart</u> 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 the 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. Obeying 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 action taking of township food and drug supervisory committees relating to food and drug
5. Obeying 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 taking action the offences relating to all matters of food and drug
3. Obeying the order and directive issued by the superior food and drug supervisory committee

Regulatory Systems
on Ensuring Access to Quality Medicines

SAMOA

SAMOA

NATIONAL HEALTH SERVICES
PHARMACY DIVISION

LEOLASI TAFUA-RIVERS
Principal Pharmacist Outpatient

Regulatory Systems on Ensuring Access to Quality Medicines

INTRODUCTION-SAMOA

Population: 195,125

Population Growth Rate:
0.703% Annually

Age Dependency Ratio:
73.375% Working-Age Population

Infant Mortality Rate:
14.8/1000 live births

Life Expectancy:
75.013 years

globaledge.msu.edge (2016)

Healthcare Treatment
Private OR Public

PRIVATE

- 14 Private Medical Clinics (approx. 16 Full-time Dr's)
- 8 Private Pharmacies
- 2 Dental Clinics
- 1 Physiotherapist
- 3 Alternative Therapy
- Numerous Traditional Healers

Samoa Healthcare Sector Plan 2007-15

PUBLIC HEALTHCARE

NATIONAL HEALTH SERVICE (NHS)

'To deliver an efficient, effective and affordable service to Samoa'

NHS operates as a government corporate entity.

Funding for this service is 100% from government, a small % from cost recoveries.

Cost recovery is minimal with services practically fully subsidised.

A. Two Main Hospitals

I. Tupua Tamasese Meaole National Hospital in Apia, Upolu (TTM)

II. Malietoa Tanumafili II in Tuasivi, Savaii (MTII)

B. Six District Hospitals

C. Two Community Health Centers

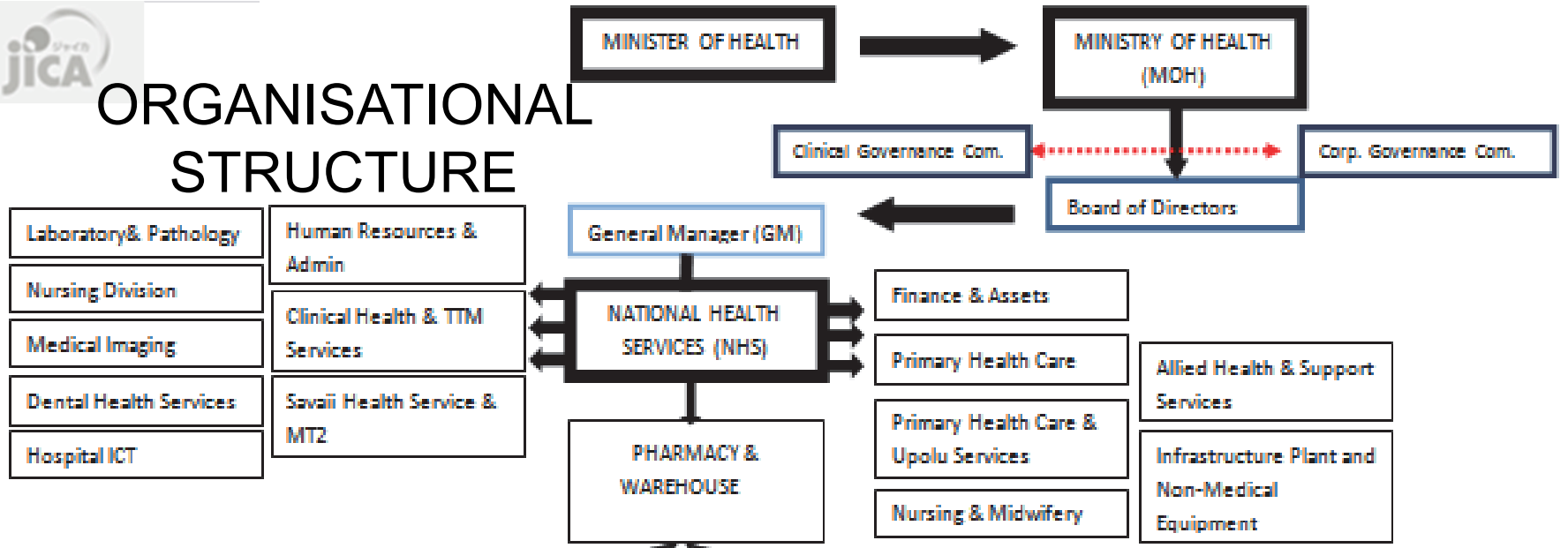
NHS Annual Report 2013-14

Roles of a Pharmacist in Samoa

PUBLIC AND PRIVATE

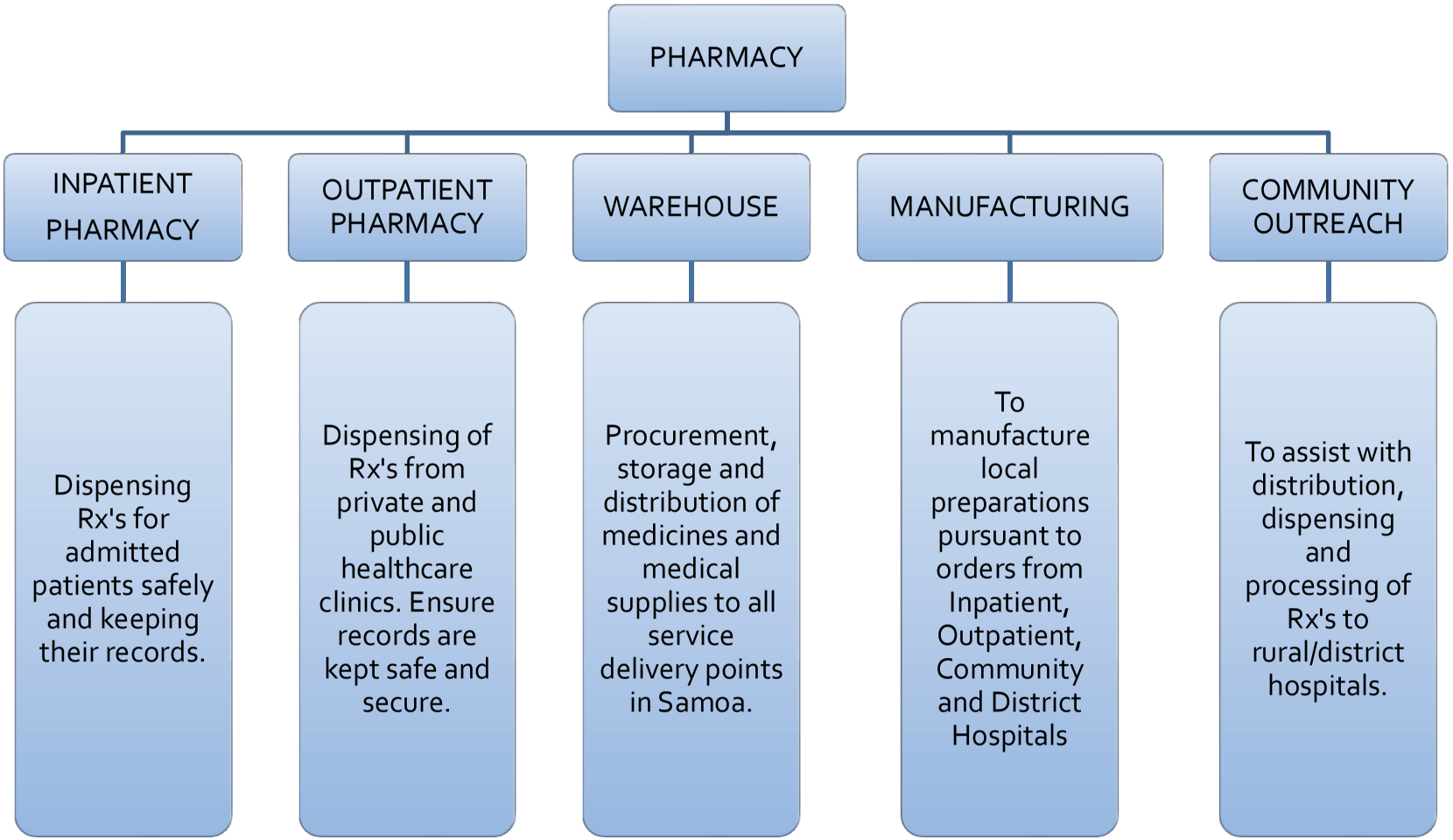
- DISPENSE RX' S
- COUNSEL PATIENT AND PROVIDE FREE HEALTHCARE ADVICE
- SELF CARE SERVICE
- MEDICINE USE REVIEW
- SMOKING CESSATION

ORGANISATIONAL STRUCTURE



INPATIENT SERVICES	OUTPATIENT SERVICES	PHARMACEUTICAL WAREHOUSE	PHARMACEUTICAL MANUFACTURING	COMMUNITY OUTREACH
Dispensing for admitted patients when required› Control and keep records for all medicines dispensed to admitted patients.	To ensure best customer service and the safe and secure handling of prescriptions received into the pharmacy. This covers the receipt of all prescriptions presented to the pharmacy.	Effective and efficient operation of the central medical stores with regards to its roles and responsibilities by procurement, storage and distribution of medicines and medical supplies to all service delivery points in Samoa.	To ensure the good quality of locally made preparations (aseptic technique) using BP and USP standard grade ingredients and make sure that the right preparation is prepared accordingly as requested. Preparations are for Inpatient, Outpatient, Community Teams and District Hospitals.	To assist with distribution, dispensing and processing of prescriptions to rural/district hospitals. Increase access and availability of safe, effective and affordable medicine.

NHS PHARMACY DIVISION



GOOD PRACTICE

- **Standard Operating Procedures (SOP’ s) developed**
- **Established an Essentials Medicines List (EML) updated every 3 years**
- **Ensure adequately trained staff on hand to implement good practice and maintain professional standards**

GOOD PRACTICE

Projects: Developing ongoing guidelines to manage and regulate not only the procurement, but the prescribing and dispensing process.

Countermeasures: Standard operating procedures developed and reviewed by departments to help manage problems that may arise and resources

DIFFICULTIES/LESSONS LEARNED FROM PAST EXPERIENCE

- Managing limited resources
- Short Staffed
- Inadequate Training
- Drug shortages
- Medicine quality compromised

ISSUES

1. Interested in Regulatory Systems Japan employs
2. Challenge applying knowledge learned given vast differences between countries involved
3. Language barrier


THANK YOU
FAAFETAI LAVA
10
独立行政法人 国際協力機構

Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2018）
Inception Report Guideline

As indicated in the General Information, all participants are requested to prepare an Inception Report (Part I and Part II), and send it to JICA TOKYO and JICWELS (E-mail: ticthdop@jica.go.jp; jigyo@jicwels.or.jp) **by 25 June, 2018**. Please include 'course title' and 'course number (J1804225)'in the e-mail.

This report consists of two parts: **Part I** and **Part II**. The main purpose of this report is to collect information in regard to pharmaceutical regulatory services of your country and more to help each participant to understand and compare other countries' situations. Your report given here will be shared among all participants to prepare for active discussions throughout the program. In each part, "why, what, when and how" to be used is explained. Please follow the directions in each part.

Part I: INFORMATION SHEET

Why? To clarify and share the basic information on each country and yourself among all participants.
What? Information that overviews pharmaceutical administration framework/pharmaceutical management, services, relating laws and regulations in your country.
When? Prepare your own reports before coming to Japan, and we will share them with other participants after arrival in Japan.
How? Collect necessary information in your country and prepare reports and presentation materials.
Deepen understanding by comparison with other countries.

Note)
For your reference, you can refer to the past participants' Information Sheet of the following countries uploaded to the website below (only from Monday 11 to Sunday 17, June). However you should be aware that making your own report by yourself is required.

- *Mongolia, Philippines, PNG, Sri Lanka*
  Website: http://jica.gigapod.jp/gf02d4966c4c6c56037ce8b6d65dacf6e3ceecee0
  Login ID: jica Password: Jicwels123

Part II: PRESENTATION

Why? To share the basic information on your country and yourself among all participants in the limited time.
What? Introduction of the work, Good Practice, Difficulties/Lessons learned from past experiences, Your expectation to the program
When? Prepare your presentation before coming to Japan. Inception Report presentation is scheduled on **13th July**.
How? Each participant will get to know each other and different situation in other countries.

Note: 1) Please prepare presentation within 10 slides by using the attached format.
2) Each presentation is allocated about 15min. including Q/A.

Part I: INFORMATION SHEET

Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2018）

Name: Leolasi Tafua-Rivers

Country: Samoa

Organization/Department/Division: National Health Services/Pharmacy 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.

※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.

Please view chart attached. (FLOW CHART 1)

② **Legislation on pharmaceutical administration**

−Please briefly bulletined major laws/acts

◆National Level

- The Pharmacy Act 2007 administered by the Ministry of Health
- The Drugs Act 1967 administered by the CEO of the Ministry of Health and/or Minister of Health
- Food Act 2015 administered by the Ministry of Health
- Health Ordinance 1959 administered by Minister of Health
- Healthcare Professions Registration and Standards Act 2007 administered by Ministry of Health
- Ministry of Health Act 2006 administered by Minister of Health
- Narcotics Act 1967 administered by CEO Ministry of Health and/or Minister of Health
- National Health Service Act 2014 administered by Ministry of Health
- The Poisons Act 1968 administered by Minister of Health
- Samoa National Medicines Policy administered by Ministry of Health

◆Local Level

- National Health Service Guidelines administered by Ministry of Health

◆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

There are standard operating procedures (SOP's) for pharmaceutical manufacturing. These may vary slightly in private practice but the baseline principles remain the same. In NHS pharmacy we operate under the NHS guidelines to manufacture extemporaneous compounds. We use an aseptic technique with BP and USP standard ingredients to make sure the right preparation is prepared at the right dose for the right patient at the right time. The guidelines encompass the receipt of prescription, compounding, calculations, record-keeping and presentation of finished product.

Regulations:

The Drugs Act 1967 allows for the manufacture of medicines for the treatment of a patient pursuant to a prescription issued by a medical practitioner. A medical practitioner meaning they are qualified and registered in accordance with Medical Practitioners Act 2007 and the Healthcare Professions Registration and Standards Act 2007.

The manufacture of the medicine will be in accordance with Samoa National Medicines Policy 2008 stipulating that the medicines reaching the patient meet approved specifications and standards.

Administrators: Ministry of Health

1. It is the direct authorization of the pharmacist that ensures medicines released satisfy all legal requirements.
2. The pharmacist will act under the Pharmacy Act of 2007 which is administered by the Ministry of Health.

◆Drug Import/Export

Systems:

Import of Drugs: NHS SOP for the receipt of imported drugs and the procedure, in which they are processed, stocked and distributed.

Export of Drugs: Not applicable as we do not export medicines.

Regulations:

The Drugs Act 1967 and Food Act 2015 govern the importation of new drugs into Samoa.

The Poisons Act 1968 govern the license or authority to import poison, sale and packing of poisonous substances

The Narcotics Act 1967 govern the restrictions on the import and export of narcotics and controlled precursors.

Only medicines registered in Samoa will be permitted to be procured and distributed in the country as stipulated in the Samoa National Medicines Policy 2008. Any new medicines to be introduced must satisfy the legal restrictions listed above.

Administrators: Ministry of Health

◆Marketing Authorization

Systems

There is no set system in place for controlling advertising and promotion of medicines.

However, there is legislation indicating that all advertising and promotion of medicines must conform to the requirements of the Pharmacy Act 2007, Poisons Act 1968, Drugs Act 1967 and the National Medicines Policy 2008. Children should not be used in advertising. Ensure advertising is ethical and conform to governing legislation. Promotion of pharmacy-only and prescription-only will be restricted to professional medical, pharmaceutical, dental, veterinary, or nursing publication.

New Drugs:

If a new drug is to be introduced into Samoa, they must first get approval from the CEO of the Ministry of Health. This application must satisfy legal requirements prior to any authorization. If the drug is already marketed in Samoa and there is a slight change to the formula to alter activity. Approval must be sought first as well. There are also further legal restrictions for openly advertising the drug,

Regulations: This is in accordance with the Drugs Act of 1697, Poisons Act 1968, Food Act 2015 and Samoa National Medicines Policy 2008.

Administrators: The Minister and/of Minister of Health

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

Systems: The NHS guidelines provide an SOP for drug selection, procurement and sale.

Regulations: It must satisfy the legal requirements stipulated in the MOH Act 2006 (regulation), Drugs Act 1967 (importation and reports on side effects), Poisons Act 1968(importation, sale, custody of poisons), Narcotics Act 1967 (importation, license in dealing narcotics and delivery) and the Pharmacy Act 2007(fulfill professional standards).
Administrator: Ministry of Health

◆Medicine Safety (post-marketing)
Systems: There are currently no medicine safety systems in place to monitor and evaluate efficacy, safety and quality of medicines.

Regulations: However, as part of the Samoa National Medicines Policy 2008 and Plan of Action, performance of medicines registered in the country will be monitored for safety, efficacy and quality. This has yet to be established. Also in concordance with the Drugs Act 1967 a report of side-effect profiles of medicines registered before importation unless this is a profile widely known and published in a medical and/or pharmaceutical journal.

Administrators: Ministry of Health

◆Relief System for Adverse Drug Reactions
Systems: There are currently no medicine safety systems in place to monitor and evaluate adverse drug reactions.
Regulations: However, as part of the Samoa National Medicines Policy 2008 an Adverse Medicine Reaction Monitoring System including suitable Adverse Medicine Reporting procedures was proposed however this has yet to be established.
This is also in concordance with appropriate professional medical treatment standards, Pharmacy Act 2007.
Administrators: Ministry of Health

④ **Drug Pricing**

−Please describe about price control and drug price mechanism at public sector in your country.
Public Sector:
NHS Pharmacy currently uses a formula from NHS Finance to calculate the price for medicines for in the outpatient area and distribution to private clinics and ministries. On average the mark-up for Outpatient medicines is 20% and for distribution to private clinics and/or other ministries is 60%. This formula from finance incorporates shipping, handling and other overhead costs.

Private: No price control in place.

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 0 (year)
2. Number of GMP inspector (National & Local) 0 (year)
3. Number of pharmaceutical manufacturers / manufacturing sites 0 (year)
4. Number of traditional medicine manufacturers / manufacturing sites 0(year)
5. Number of pharmaceutical importers 5 (year)
6. Number of pharmaceutical wholesalers 0(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: 1: Please see associated flow chart. (FLOW CHART 2)

（2） Number of staff

a. Number of pharmacists: 6
b. Number of clinical pharmacists: 1
c. Number of technicians: 17

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

a. Oral medicine: 211
b. Injections: 109
c. Medicines for external use: 62

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

a. For inpatients:73
b. For outpatients:300

（5） Equipment of the pharmacy in your hospital

a. Does your hospital have a dispensary room? Yes

If "Yes", how large is it?

Yes 38.30 ㎡

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

No

c. Does the pharmacy have computers?

Yes

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

Purpose: Dispensing prescriptions, processing orders, receipt of orders, creating prescription reports, staff administration work

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

No

e. Do you prepare TPN (Total Parental Nutrition)

No

f. Can you use Internet at the pharmacy?

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

No

※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 8 years

Secondary 5 years

High school (Otherwise called Secondary School) N/A years

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

University / college: 4 years

Professional education: N/A years

Practical training: 1 years

Duration of training by each facility: N/A years

Hospital pharmacy: N/A weeks

Community pharmacy: N/A weeks

Pharmaceutical company: N/A weeks

Others: weeks

Age at graduation: 22 years old

（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.

There is a practical training period of 1 year that I carried out in New Zealand under the PSNZ

Internship program to register as a pharmacist in New Zealand and obtain a license to practice as a pharmacist. If graduates return to practice in Samoa, they observe a grace period under observation of a registered pharmacist in Samoa 1 year before they are issued a practice license in community or hospital as approved by the Pharmacy Board. For Fijian graduates, they must satisfy three years before a license to practice in Samoa is issued. I currently have a license to practice in Private pharmacy and Hospital pharmacy.

* 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:

0 people / per year

The alumni's placement rate (%)

a. Hospital: 50%
b. Community Pharmacy: 40%
c. Government Organization: 10 %
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.

Side Effect Report
Patient reports side-effect to Pharmacy
Pharmacy reviews patient information on file, assesses risk to patient
Leaves note on patient file (Inpatient-physical file) and Outpatient on system.
Calls patients regular Dr to report side effect and request course of action
Patient will either be admitted immediately or referred to their acting physician for further care
IF side-effect is a new occurrence for this medicine, pharmacist involved in procurement of medicine is notified to inform drug manufacture and request their tests for safety, efficacy and side-effect profile.
The last call is if the Chief Pharmacist is unsatisfied with quality/safety/efficacy and any recurring side-effects that outweigh benefits of medicine. The medicine can be removed, returned to manufacturer and lines for that medicine discontinued.

Annex2

Preparation for Attendance

for

JICA Knowledge Co-Creation Program

" Regulatory Systems on Ensuring Access to Quality Medicines"

(JFY 2018)

Dear participants,

We are delighted to have you for the captioned JICA program!
This program is organized by JICA in cooperation with Japan International Corporation of Welfare Services (JICWELS).

Every participant is advised to read the following instructions carefully and well prepare for the program. Please kindly check the attached Annex2-1 ***Preparation Sheet*** and email it back to JICA TOKYO & JICWELS (E-mail: jigyo@jicwels.or.jp, ticthdop@jica.go.jp) **by 25 June, 2018.**
For your information, **we are schedule to have a trip to Toyama prefecture from 22 to 26 July during the program**. It is located around 450km northeast from Tokyo. In this regards, **it is recommended to prepare a travel bag and other necessary things for this short trip so that you can leave your large baggage / suitcase at JICA Tokyo.**

☐ Food restraint

Please kindly let us know your food restraint which you are not able to take due to religion, allergy, or any other reasons.

☐ Prayer room

Please kindly let us know if you need a prayer room during the lunch time or the break time. The prayer room is available in JICA Tokyo, however, it would be difficult to find one at other study visit sites. Therefore, we will try to arrange it in beforehand, according to your request.

☐ Laptop Computer

A PC equipped with "Word" and "Power point" is necessary for preparation of reports and / or power point presentations from the beginning of the program. If there are some compelling reasons for not bringing a PC, please let us know. We will arrange a rental laptop-computer for your study during the program. Please note however, if you fail to inform us by the above date, it will take at least one week after his/her arrival to lend him/her a PC.

☐ Size for your white coat (uniform) and indoor shoes

We are scheduled to visit a pharmaceutical manufacture and pharmacy during the program, and all participants are requested to change into an uniform and indoor shoes based on the GMP regulation in Japan.

Annex2-1: Preparation Sheet

(**Name:Leolasi Tafua-Rivers**
Country:Samoa)

➢ Food restraint

× OK	☐Not OK	Beef
× OK	☐Not OK	Pork
× OK	☐Not OK	Chicken
× OK	☐Not OK	Egg
× OK	☐Not OK	Fish (cooked)
× OK	☐Not OK	Fish (raw)
× OK	☐Not OK	Shrimp
× OK	☐Not OK	Scallop (shell)
× OK	☐Not OK	Cheese
× OK	☐Not OK	Alcohol
× OK	☐Not OK	Milk
× OK	☐Not OK	Coffee
× OK	☐Not OK	Tea
× OK	☐Not OK	Green tea

Special remarks ( )

➢ Prayer room

Please check the box if you request an arrangement of prayer room, or not.

×	Yes
	No

➢ Laptop Computer

Please check the box if you request an arrangement of PC, or not.

	Yes
×	No

➢ Size for your white coat (uniform) and indoor shoes

Please check the box and write your size information in ( ) below.

Your height(180cm cm / ft and in)

Clothes size….Most likely an XL-XXL

☐	S
☐	M
☐	L
☐	LL
☐	XL

Shoe size (28.5cm)

【For your reference】

MEN's Shirts

Japan	S	M	M	L	L	LL,XL	LL,XL	LL,XL
U.S. & U.K.	14 1/2	15	15 1/2	15 3/4	16 1/4	16 1/2	17	17 1/2
EU	37	38	39	40	41	42	43	44

MEN's Shoes

Japan （㎝）	25.5	26	26.5	27.5	28.5	29.5	30.5
U.S. & Canada	7 1/2	8	8 1/2	9	10 1/2	11 1/2	12 1/2
U.K.	7	7 ½	8	8 1/2	10	11	12
EU	40	41	42	43	44	45	46 1/2
Inches	10	10 8/1	10 1/4	10 2/1	10 3/4	11	11 1/4

WOMEN's Dress & Suits

Japan	7(S)	9(M)	11(L)	13(LL)	15(XL)	17	19	21
U.S.& Canada	4	6	8	10	12	14	16	18
U.K.	6	8	10	12	14	16	18	20
EU	34	36	38	40	42	44	46	48

WOMEN's Shoes

Japan （㎝）	23.5	24	24.5	25	25.5	26
U.S. & Canada	7 1/2	8	8 1/2	9	9 1/2	10
U.K.	5	5 1/2	6	6 1/2	7	7 1/2
EU	38	38 1/2	39	40	41	42
Inches	9 5/8	9 3/4	9 7/8	10	10 1/8	10 1/4

Regulatory Systems
on Ensuring Access to Quality Medicines

THAILAND

THAILAND

THAI Food and Drug Administration

Pairoj Osatapirat



1. Introduction of the work

Roles and position of pharmacists in Thailand


Hospital Pharmacy

Community Pharmacy

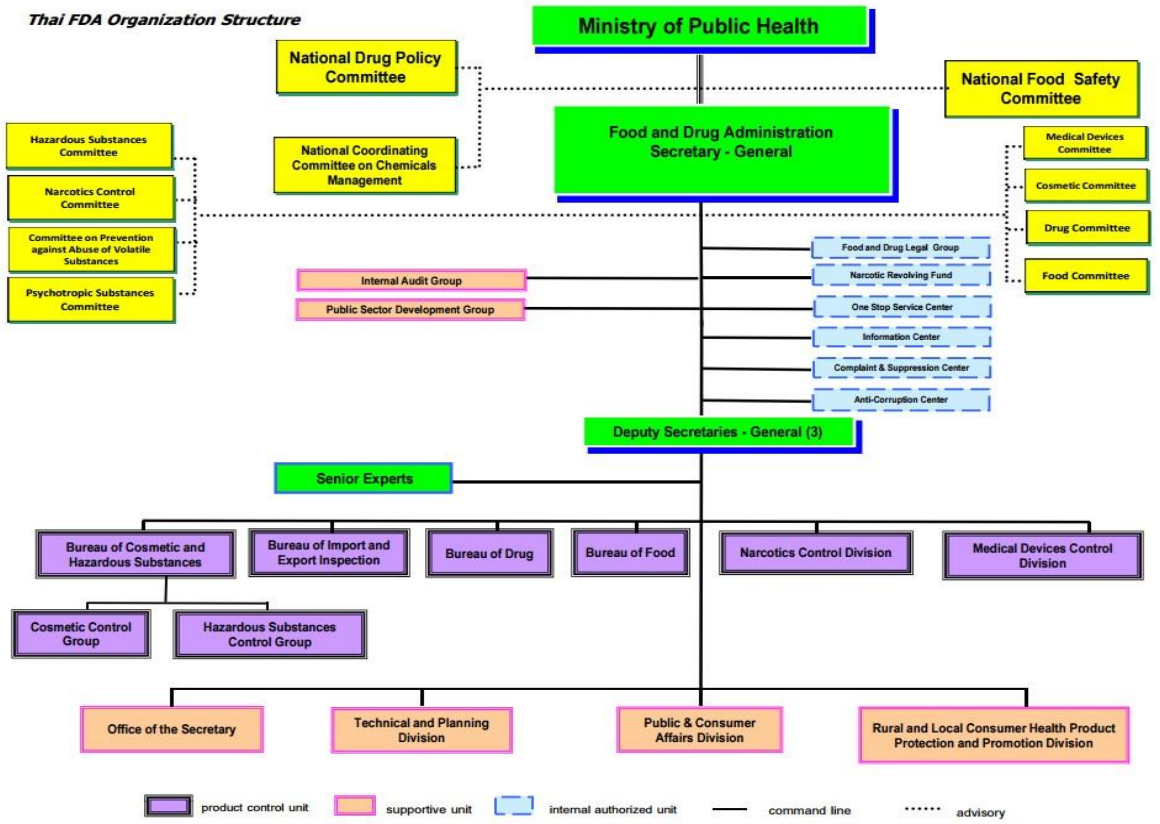
Consumer Protection (i.e. Thai FDA)

Enterprise (i.e. Marketing)

Industry (i.e. Production, QA, QC, R&D)

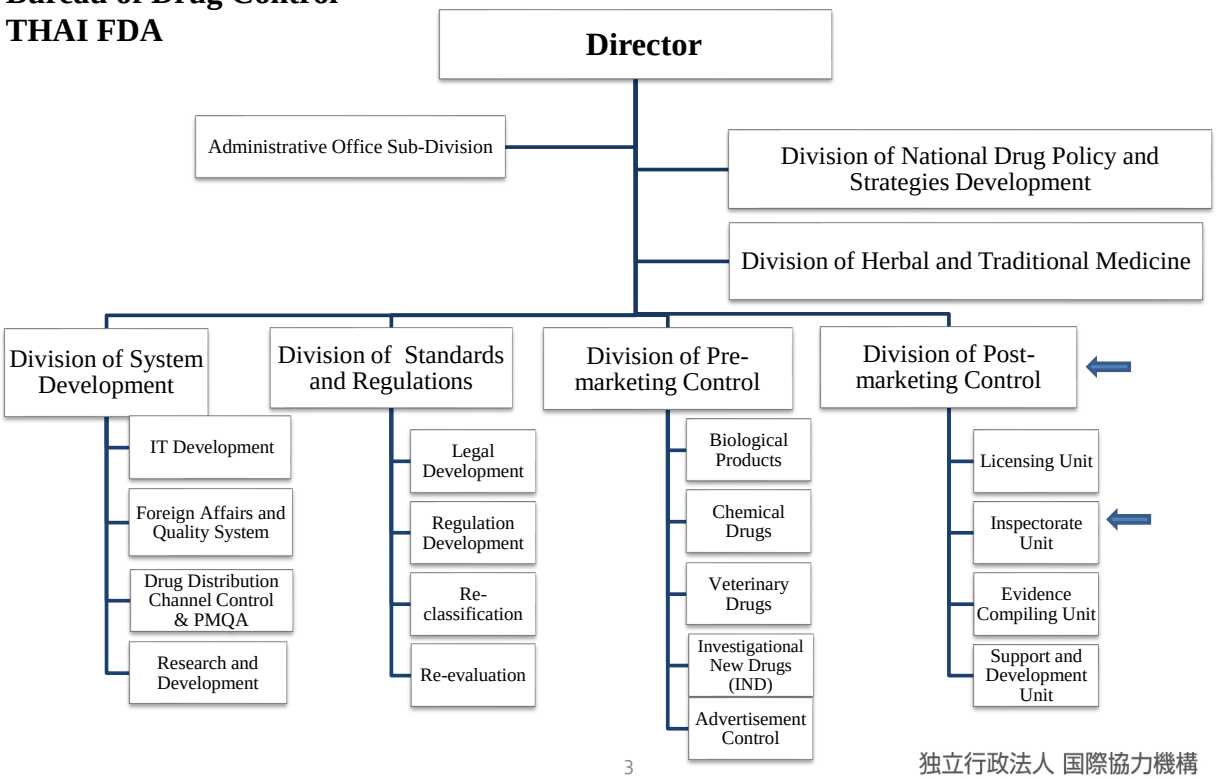
Others (i.e. RA, CRA, PV)

1. Introduction of the work



1. Introduction of the work

Bureau of Drug Control
THAI FDA



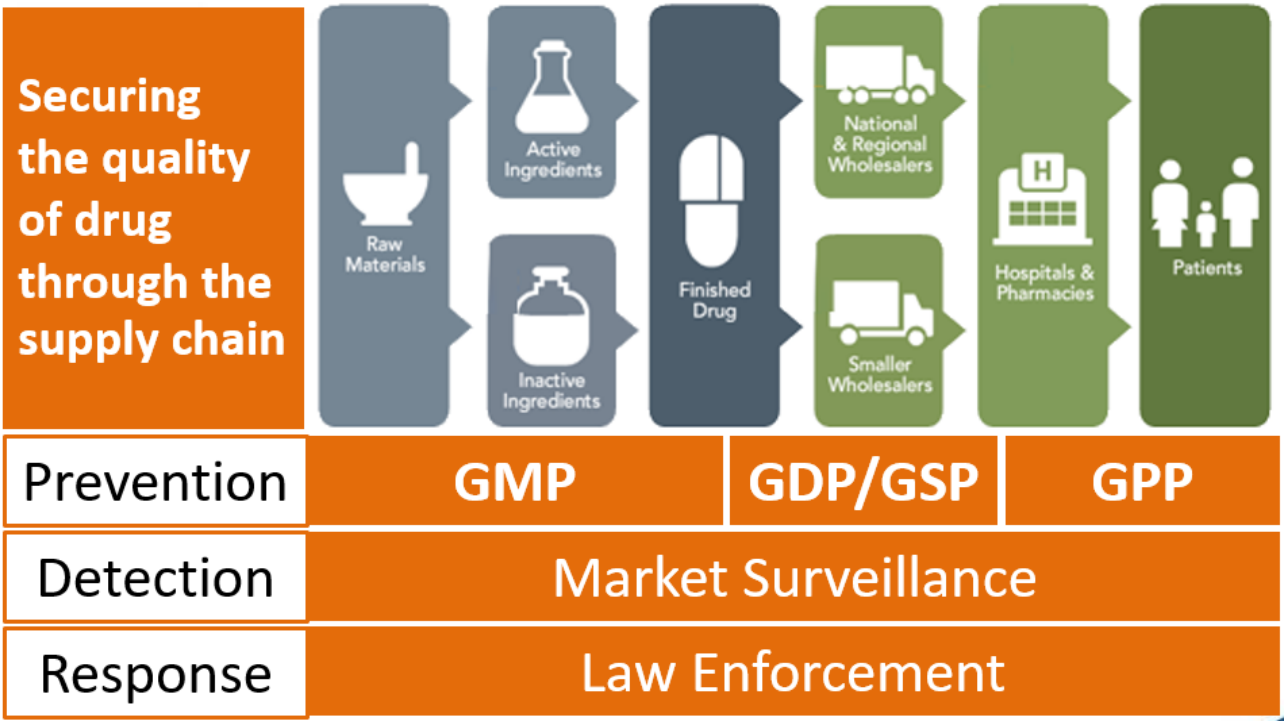
独立行政法人 国際協力機構

1. Introduction of the work

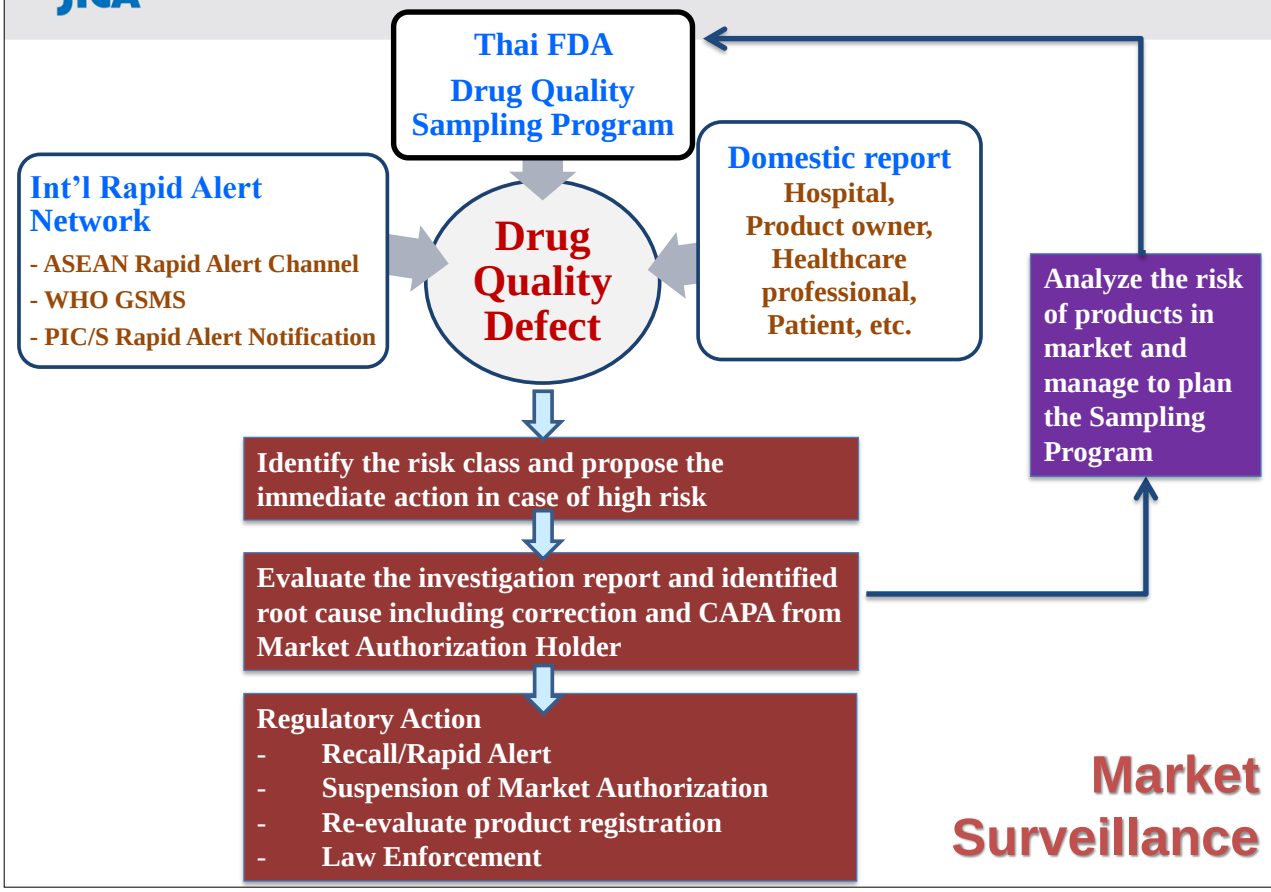
Job tenure & Regulatory Services

- To monitor and conduct surveillance of the quality of the medicinal products available in the market in order to comply with the approved standard and requirements
- To monitor the use of marketed drugs for unexpected health risks, taking action if risks are detected by informing the public, investigating the root cause, removing the drugs from the market (following the recall & rapid alert system), and informing the consumer soon
- To ensure that all local manufacturers of modern medicine and high-risk traditional medicine are in compliance with GMP requirements for quality assurance of their drugs (adopted PIC/S GMP Guide), and also the overseas manufacturers are met GMP clearance standard which equivalent to GMP requirements for domestic manufacturers

1. Introduction of the work



1. Introduction of the work



2. Good Practice

Management of Drug Quality defect

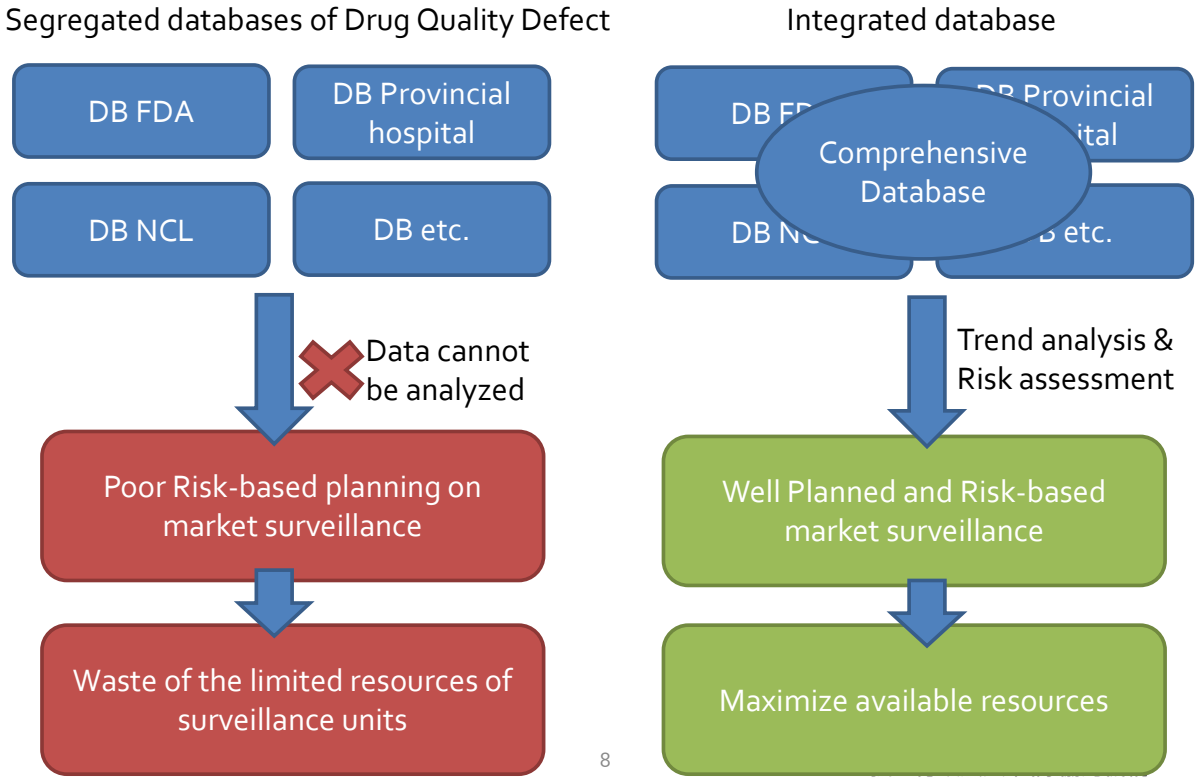
Problem:

Lack of comprehensive database that can be analyzed and identify the risk of Drug Quality Defect.

Solution & Ongoing development:

Develop the database of Drug Quality Defect which enable us to improve the tracking process. In addition, The database is expected to be analyzed for future planning in order to prevent Drug Quality Defect.

2. Good Practice



8

3. Difficulties/Lessons Learned from Past Experience

Number of registered drug: Over 20,000 items

Number of samples per year committed with NCL:
Pre-planned sampling program – 400 samples/year
Emerging risk sampling – 100 samples/year

Cost: 12M Baht/year

Key challenge to maximize available resources:

- Sampling of medicines prioritized/risk-based
- Limited to a small number of registered medicines
- Activities occur at central level; little coordination with provincial or other stakeholders

9

独立行政法人 国際協力機構

4. Your interests

Expectation from this program

(1) The knowledge on the effective regulatory systems for detecting the defective medicinal products in the pharmaceutical supply chain.

(2) Experiences shared with other participants should be useful for our further improvement on securing medicinal product quality through the supply chain in my country. The open discussion between experts from different countries should also generate the new idea for monitoring the pharmaceutical supply chain in quality perspective.

(3) The best practice on Management of Drug Quality Defect including the effective detection method such as sampling program or reporting system.

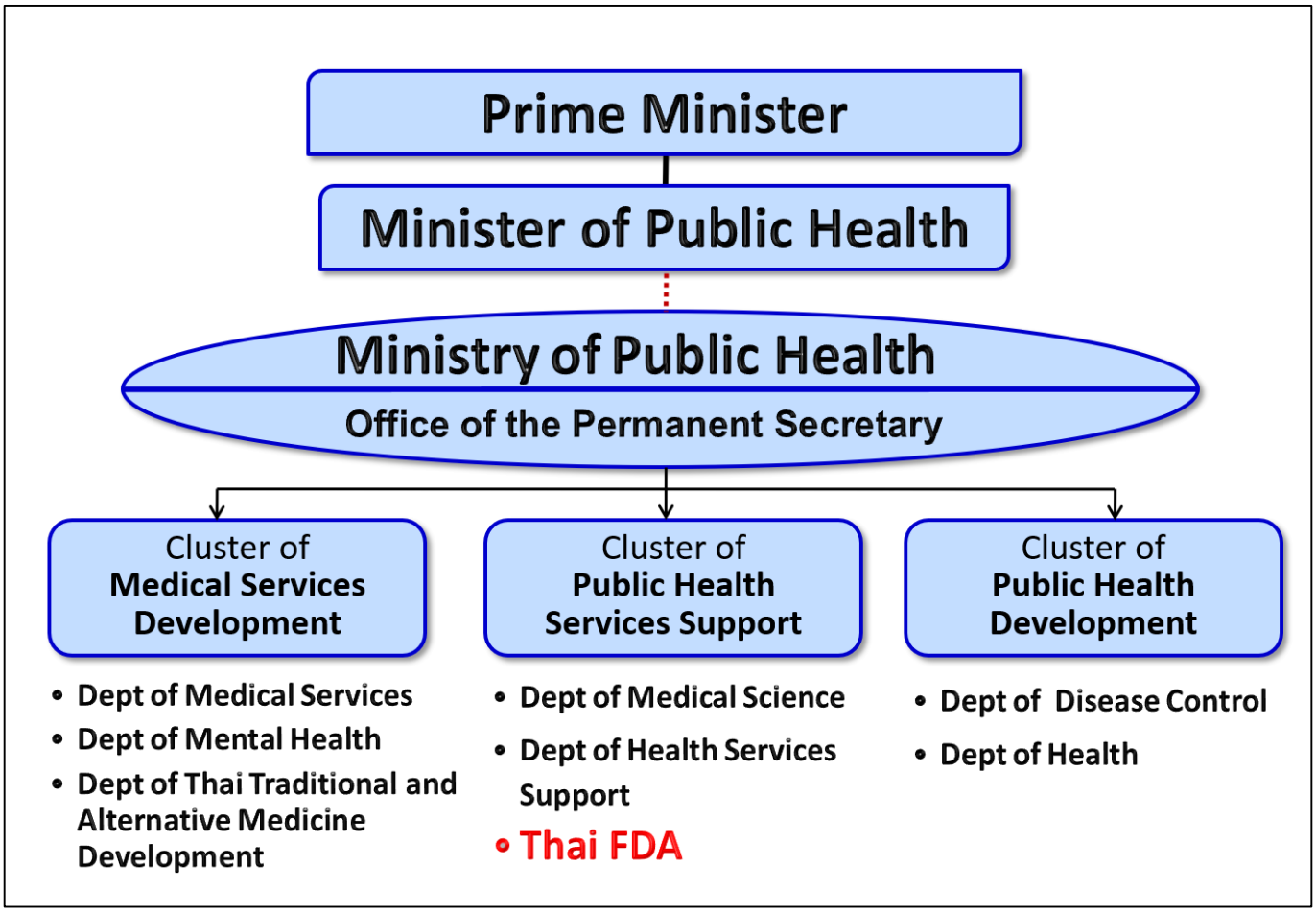
Mr. Pairoj Osatapirat

Thailand

Thai Food and Drug Administration (Thai FDA)/ Bureau of drug control/ Post-Marketing control Division

① Organizational Chart

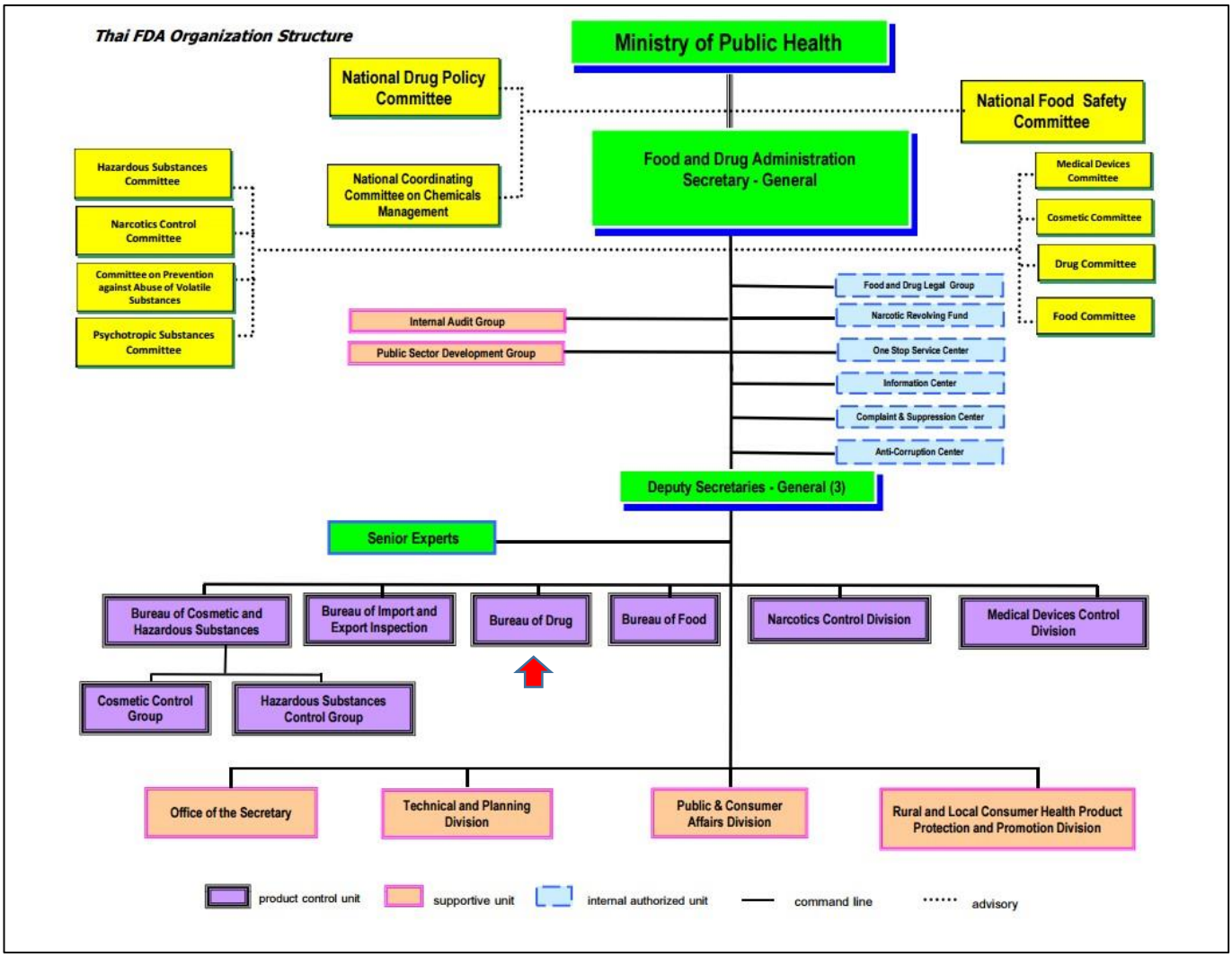
The organizational chart of pharmaceutical administration at national level in Thailand



Thai FDA is responsible as National Regulatory Authority (NRA) of pharmaceutical products in Thailand. The FDA is under the cluster of Public Health Service Support belonging to the Ministry of Public Health.

The Cluster of Public Health Service Support comprises of three departments: Thai FDA, Health Service Support and Medical Sciences. This group of departments working on an integrated program to achieve greater efficiency and effectiveness on public health services. The Department of Medical Science plays an important role as National Control Laboratory (NCL).

The organization chart of Thai FDA



Bureau of Drug Control plays the key role as National Regulatory Authority to administer the pharmaceutical products in Thailand. The administrative function is including National Regulatory System, Registration and Marketing Authorization, Licensing Premises, Market Surveillance and Control, Regulatory inspections and Regulatory oversight of clinical trials.

② Legislation on pharmaceutical administration

◆ National Level

- Drug Act, B.E. 2510 (1967) and Amendment No.2 (1975), No.3 (1979), No. 4 (1985) and No. 5 (1987) administered by Thai FDA
- Narcotic Act, B.E. 2522 (1979) and Amendment No.2 (1985), No.3 (1987) and No. 4 (2000) administered by Thai FDA
- Psychotropic Substance Act B.E. 2559 (2016) administered by Thai FDA

◆Local Level

- None

◆PIC/S

- Yes, participated since 1 August 2016

③ **Regulatory Services**

◆Pharmaceutical Manufacturing

Thai Food and Drug Administration (Thai FDA) oversees pharmaceutical manufacturers in Thailand. The current GMP regulation is outlined in Ministerial Notification regarding the GMP requirement for modern drug manufacturing and traditional drug manufacturing B.E.2559, issued on 18 May 2016. The said notification was signed by Minister of Public Health. It is mandatory and applicable to be implemented to all manufacturers of medicinal products regardless of origin (domestic or foreign manufacturers) by which the GMP Guidelines are equivalent to PIC/S GMP Guide PE 009-12.

◆Drug Import/Export

The medicinal products importation activities are mandated under the Drug Act. A person or establishment who wants to import medicinal products should apply for license and Thai FDA will consider and grant the license respectively. Then the licensee is required to apply for product registration for each medicinal product that proposed to be imported into the country.

When the importation is planned to be taken, the licensee for importing of medicinal product should follow the procedure for handling of importation including the guideline for License per invoice submission that is available in the website of the Bureau of Import and Export Inspection of Thai FDA, http://www.fda.moph.go.th/sites/logistics/SitePages/LicensePerInvoice.aspx. The licensee is required to fill out and record all relevant data for importation through the National Single Window (NSW) prior to the medicinal products are delivered from origin to Thailand.

The domestic pharmaceutical manufacturer who wants to export their medicinal products to the overseas countries should follow national laws regulations as required by those destination countries.

◆Marketing Authorization

The Thai FDA has implemented ASEAN common technical dossier, ACTD by which ASEAN application form shall be supplemented. However, the requirement of ACTD is a minimum requirement for application of medicinal product whereas full package of ACTD or ICH CTD will be required for New Chemical Entity (NCE), biotechnology product and vaccine. All requirements are publicly available on Thai FDA website.

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

For wholesale distribution of medicinal products (including APIs): Those who want to wholesale distribute medicinal products including APIs must apply for a wholesale license, or a license to sell medicines prior to undertaking the wholesale activity.

Regarding drug selection and procurement, all medical institutes in public sector must follows the regulation on Procurement Act, B.E 2560.

◆ Medicine Safety (post-marketing)

Thai FDA establishes a center namely Health Product Vigilance Center, HPVC which work for vigilance activities of all healthcare products administered by Thai FDA.

Day-to-day operations of the HPVC including:

- Collection, collation and analysis of adverse reactions (ARs) and adverse events (AEs) data associated with use of drugs and medical devices.
- Assessment of AEs to identify patterns of the product safety problem.
- Detection of signals and assessment for causal association between the signals and suspected health products.
- Provision of data related to safety of health products to Thai FDA and committees or sub committees responsible for the products.
- Work with the Bureau of Epidemiology of the Disease Control Department of the Ministry of Public Health on adverse events following immunization (AEFI).
- Conduct or management of research on ARs and AEs.
- Submission of ARs and AEs reports to WHO UMC.
- Coordination with various units within and outside the Ministry of Public Health to improve awareness, management and communication on safety of health products.

◆Relief System for Adverse Drug Reactions

HPVC has a guideline for Market Authorization Holder for reporting Adverse Events and also vigilance activities. Also, HPVC has planning about PV activities in every year for example; Signal detection and assessment working group meeting, monitor product safety news (everyday), Risk communication among reporter and Thai HPVC and Healthcare Professionals. In addition, The information/reports from other countries/international bodies such as UMC reports (Vigibase) are considered in the related ADR committee. After that ADR committee will conclude cases for finding the regulatory actions that may/may not be related to other countries' regulatory action.

④ Drug Pricing

Prices of medicinal products are regulated when they are listed on the National List of Essential Drugs (NLED), a "maximum list" from which government hospitals are expected to select their individual hospital formulary. The prices of the drugs on this list are subject to a median price policy. In addition, the Ministry of Finance has implemented a notification setting prices for government hospitals. However, these prices only apply to persons under the Civil Servant Medical Benefit Scheme CSMBS. The Ministry of Public Health has implemented a notification on how much government hospitals are allowed to charge patients. The Drug Act is currently being revised, and these revisions may well include cost-effectiveness as a required element for drug registration.

⑤ Statistic Data

1.	Number of pharmacists	38,389	(2017)
2.	Number of GMP inspector (National & Local)	20	(2018)
3.	Number of pharmaceutical manufacturers / manufacturing sites	175	(2018)
4.	Number of traditional medicine manufacturers / manufacturing sites	223	(2018)
5.	Number of pharmaceutical importers	566	(2018)

6. Number of pharmaceutical wholesalers 58 (2018)

※Hospital pharmacy only

⑥ **Information on your hospital pharmacy**

Not applicable

※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	3 years
Secondary	3 years
High school	6 years

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

University / college:	6 years
Professional education:	2 years (included in the above 6 years)
Practical training:	1 year
Duration of training by each facility:	1 year
Hospital pharmacy:	6 weeks
Community pharmacy:	6 weeks
Pharmaceutical company:	6 weeks
Others:	6 weeks
Age at graduation:	approximately 22-25 years old

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

Yes,

Academic Exams	2 days
Clinical Exams	1 days

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

The practical training is mandatory.

- General pharmacy administration and services (Hospital & Pharmacy) > 400 hours
- Professional training specified by major subject > 1,600 hours

5. Number of pharmaceutical university or college graduates:

1,820 pharmacist's license obtained in 2017.

The alumni's placement rate (%)

a.	Hospital:	40.4 %
b.	Community Pharmacy:	17.0 %
c.	Government Organization:	5.7 %
d.	Enterprise:	22.0 %

e. Others: 14.9 %

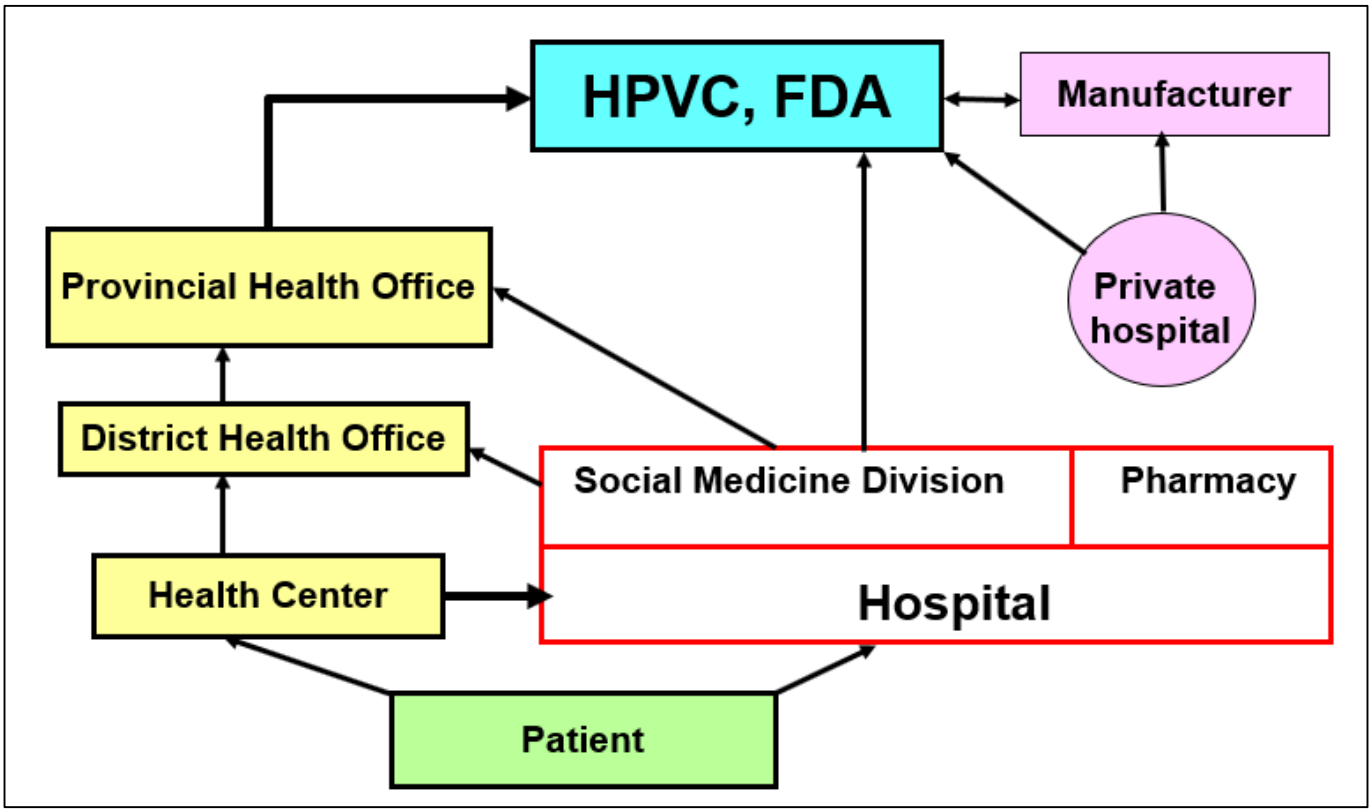
Reference: 1. https://www.pharmacycouncil.org/index.php?option=content&menuid=33

2. Past...Present...Future of Pharmacy Education in Thailand (Part II), PECT, IJPS, Vol.10 No.2 May-Aug 2014, page 120

⑧ **Side effect report**

In case of serious ADR/dead occurred, Pharmacovigilance advisory sub-committee and Signal detection and assessment working group would assess drug products with consideration of vigilance data. HPVC consider vigilance data with specific standard which we do case by case. For example: withdrawal of Phenylbutazone. Because there were the evidences that shown significant risk of aplastic anemia whereas NSAIDs can be used instead of phenylbutazone. The specific standard that we provided for considering this case were severity of ADRs, reversibility, frequency of ADRs, risk occurrence in dread disease, chances for ADR occurrence in general population, any known risks, alternative medicine, chances of misuse and committee's suggestion.

Diagram of ADR reporting process from medical institutes to HPVC



-End of report-

Regulatory Systems
on Ensuring Access to Quality Medicines

UGANDA

UGANDA

NATIONAL MEDICAL STORES

ANTHONY KABONGE DDAMBA

独立行政法人 国際協力機構

1. Introduction

ESTABLISHMENT

NMS was incorporated by an Act of Parliament in 1993 to ensure the economic **procurement, storage** and **distribution** of quality and efficacious essential medicines and health supplies primarily to **public health facilities** in Uganda. NMS also has a statutory advisory responsibility to the National Drug Authority (NDA), the Ministry of Finance, Planning and Economic Development (MoFPED), the Ministry of Health (MoH) and the Ministry of Local Government (MoLG) on the estimation of drug needs and the distribution and use of medicines in the public health services.

VISION

"A population with adequate and accessible quality medicines and medical supplies"

MISSION

"To effectively and efficiently supply essential medicines and medical supplies to Public Health Facilities in Uganda"

独立行政法人 国際協力機構

1. Introduction

KEY POINTS OF NMS

- Distributes Essential Medicines and Health Supplies [EMHS] to all 3,000+ Public Health Facilities in Uganda
- Total throughput per annum is roughly 250 million USD (approximately 27,502,375,000 yen)
- Total Client touch-points/visits roughly 20,000 annually.

SUMMARY JOB RESPONSIBILITIES AND TENURE

- 39 years old Ugandan
- Registered in 2003 to practice Pharmacy in Uganda by the Pharmacy Council
- Member of the Pharmaceutical Society of Uganda.
- Practiced Pharmacy in the areas of Community Pharmacy, Manufacturing and Supply Chain Management for the last 15 years
- Head the Client Services Department where I provide managerial leadership and oversight to the Client Services Team of 33 members.

1. Introduction

DEPARTMENT OF CLIENT SERVICES

- NMS has a Headquarters in Entebbe and has 9 Regional Offices in Uganda.
- The Department of Client Services has 33 employees who have the following responsibilities:
  1. **Ensuring timely delivery of all EMHS while ensuring adherence to set standards**
  2. **Provide advisory services which include:**
     - **Analysis of needs**
     - **Procurement planning**
     - **Ordering and delivery of EMHS**
     - **Capacity building and assisting Health Facilities at all levels of care improve and maintain good storage practices (GSP) and Rational Use of Medicines**
  3. **Manage Complaints and Feedback**
  4. **Monitoring and evaluation of programs and interventions to Health Facilities**
  5. **Advising the Government of Uganda on:**
     - **Estimation of drug needs**
     - **Optimal distribution and use of medicines in the public health services**

1. Introduction

Each of the 9 Regional Offices is manned by Customer Care Staff who continuously monitor and evaluate the service offering of NMS in the Regions

1. Introduction

REGULATORY SERVICES INVOLVED IN MY ROLE

- Ensuring that distribution and use of medicines is in line with legal, professional and ethical standards of the practice of the Pharmacy in Uganda

ROLES AND POSITIONS OF PHARMACISTS IN UGANDA

- As of 2018, there are **450** Registered Pharmacists in Uganda
- Majority **(about 60%)** practice in **Community Pharmacy**
- Other areas of practice include:
  - **Hospital Pharmacy (20%)**
  - **Industrial Pharmacy (7%)**
  - **Regulation (5%)**
  - **Academia (2%)**
  - **Ministry of Health (1%)**
  - **Others (5%)**

2. Good Practice

KEY ACHIEVEMENTS

1. Developed systems for better Supply Chain Needs Analysis, Planning and Inventory Management to all 3,000-plus Health Facilities through leading drives to:
   - Introduce the Research and Monitoring & Evaluation Functions to NMS
   - Introduce the 9 Regional Offices
2. Member of Steering Committee on Projects including Enterprise Resource Planning Systems
3. Led the Department in adopting the ISO 9001:2008 and ISO 9001:2015 Quality Management Standards
4. Developed policy and procedure manuals
5. Managed the introduction of new products through all the regulatory requirements
6. Led the project of installing and validating two new manufacturing lines at the manufacturing plant in line with Good Manufacturing Practice standards

3. Difficulties/Lessons Learned from Past Experience

CURRENT CHALLENGES (WHICH ARE IMPROVING)

1. Low number of pharmacists in the country
2. Very low concentration of pharmacists in the Rural Hospitals
3. Low capacity of Manufacturing Industries in Uganda
4. Low distribution of community pharmacies in rural or small towns

CURRENT CHALLENGES (WHICH ARE GETTING WORSE)

1. Increasing medicine counterfeits
2. Poor prescribing habits by Prescribers e.g., polypharmacy and excessive use of antibiotics
3. Self-prescription
4. Drug abuse

LESSONS LEARNT

1. Value of setting up strong central warehouses
2. Value in having sufficient number of Pharmacists in Hospitals, especially in the areas of Clinical Pharmacy and Good Storage Practice

4. My Interests

1. How to effectively manage the quality of drugs/medicines within the country when the number of professional pharmacists is low

THANK YOU

ANTHONY KABONGE DDAMBA

NATIONAL MEDICAL STORES

Part I: INFORMATION SHEET

Regulatory Systems on Ensuring Access to Quality Medicines (JFY 2018)

Name: ANTHONY KABONGE DDAMBA

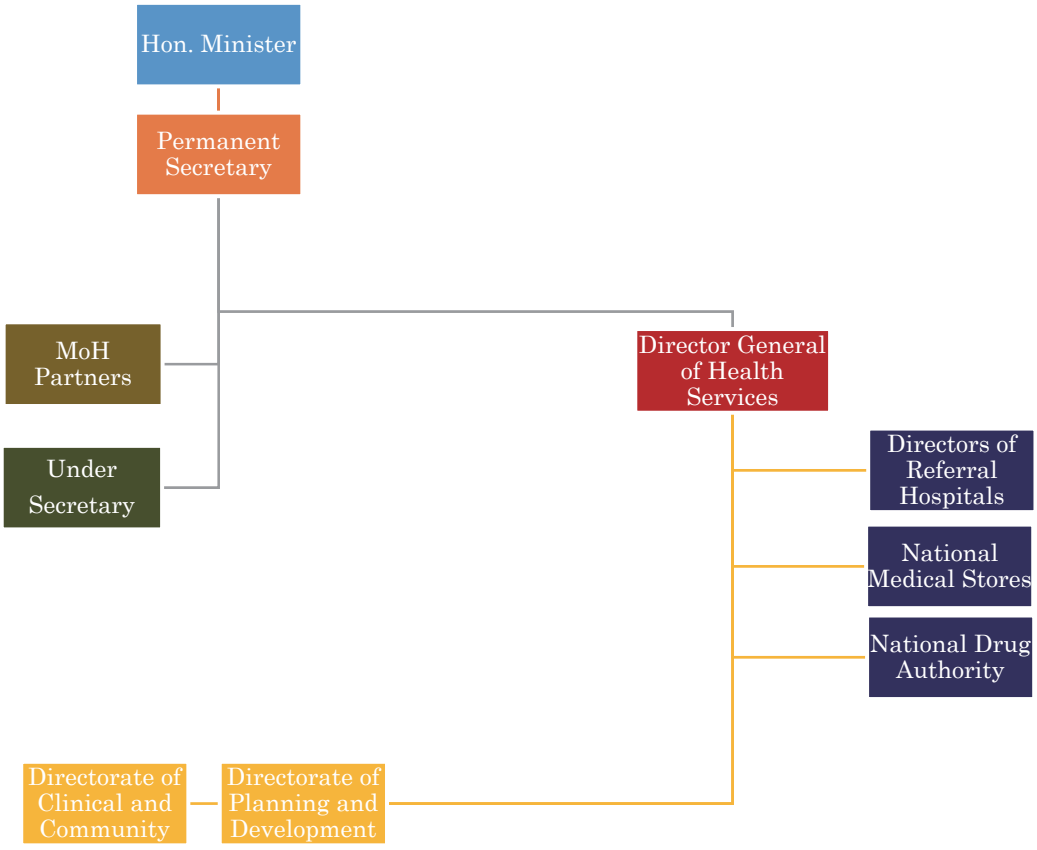
Country: UGANDA

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.

NATIONAL ORGANIZATION OF THE MINISTRY OF HEALTH - UGANDA



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

1. Cabinet – Overall Executive Management of the Government. Set the political agenda
2. Parliamentary Committee on Health – Set laws in place. Determine budget allocated to the Health Sector. Carry out an oversight role to the Ministry of Health and Autonomous Institutions under it.
3. Ministry of Health – Policy formulation, oversight to the autonomous bodies
4. Autonomous Institutions that include:
   i. *National Drug Authority (NDA)* – is mandated to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda as a means of providing

satisfactory healthcare and safeguarding the appropriate use of drugs.

ii. *National Medical Stores (NMS)* – has a statutory advisory responsibility to the National Drug Authority, the Ministry responsible for Health, the Ministry responsible for Finance, Planning and Economic Development and the Ministry responsible for Local Government either on request or at the Board's own initiative on essential issues relating to the state of the Corporation and its future development, as well as to related matters, including the estimation of drug needs and the distribution and use of medicines in the public health service.

iii. *National Chemotherapeutics Research Laboratory* - undertakes the development of quality natural products and services for improved health care delivery by applying both indigenous and modern technologies.

iv. *Uganda Blood Transfusion Services* – a centrally coordinated department in the Ministry of Health to offer efficient central and decentralized services of safe blood collection, storage and distribution in Uganda.

v. *Referral Hospitals Boards* - provide the oversight role for the effective functioning of the hospital in order to deliver quality services.

5. District Executive Committees - provide oversight for policy implementation, planning and resource allocation and use for the health system at this level, in adherence to national laws.
6. Health Facility (General Hospital, HC IV, III & II) Management Committees which draw representation from the community members provide the oversight function for primary care facilities
7. Local Councils at Community level - ensure effective community participation in management of health services.

※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.

② **Legislation on pharmaceutical administration**

−Please briefly bulletined major laws/acts

◆National Level

- Narcotic Drugs and Psychotropic Substances (Control) Act 2016 administered by the Uganda Police
- National Drug Policy and Authority Act 1993 cap 206 administered by National Drug Authority
- National Medical Stores Act 1993 cap 207 administered by National Medical Stores
- Pharmacy and Drugs Act 1971 cap 280 administered by the Pharmacy Board

◆Local Level

・ _____ administered by _____

◆PIC/S

Yes _____ 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

- Good Manufacturing Practice administered by National Drug Authority (NDA)
- Licensing and Registration administered by NDA and Uganda National Bureau of Registration

◆Drug Import/Export

- Registration of Drugs administered by National Drug Authority (NDA)
- Drug Retention on the Drug Register administered by National Drug Authority (NDA)
- Importation, Export and Re-export of Drugs administered by National Drug Authority (NDA)
- Importation, Export and Re-export of Drugs administered by Uganda Revenue Authority (URA)

◆Marketing Authorization

- Certificate of Good Practice administered by National Drug Authority (NDA)
- Pharmacist Registration Certificate administered by Uganda Pharmacy Board
- Pharmacist Annual License to Practice administered by Uganda Pharmaceutical Council

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

- Registration of Drugs administered by National Drug Authority (NDA)
- Drug Retention on the Drug Register administered by National Drug Authority (NDA)
- Distribution of Drugs to Public Health Facilities administered by National Medical Stores (NMS)
- Distribution of Vaccines to All Health Facilities administered by National Medical Stores (NMS)

◆Medicine Safety (post-marketing)

- Systems, Regulations, etc.
- Good Pharmacovigilance Practice of Drugs administered by National Drug Authority (NDA)

◆Relief System for Adverse Drug Reactions

- Good Pharmacovigilance Practice of Drugs administered by National Drug Authority (NDA)

④ Drug Pricing

−The drug pricing in public health facilities is calculated at 8% mark-up of Essential Medicines and Health Supplies (EMHS) publicly procured by NMS under the Public Procurement and Disposal of Assets Act (PPDA)

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	456 year (2018)
2.	Number of GMP inspector (National & Local)	20+ year (2018)
3.	Number of pharmaceutical manufacturers / manufacturing sites	15 year (2018)
4.	Number of traditional medicine manufacturers / manufacturing sites	37 year (2018)
5.	Number of pharmaceutical importers	82 year (2018)
6.	Number of pharmaceutical wholesalers	462 year (2018)

※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 _____ 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.

⑦ Education and License of Pharmacists in your country

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

Primary	8 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:	2 years
Practical training:	2 years
Duration of training by each facility:	
Hospital pharmacy:	52 weeks
Community pharmacy:	26 weeks
Pharmaceutical company:	26 weeks
Others:	N/A
Age at graduation:	22 years old

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

Yes

Academic Exams	1 day
Clinical Exams	1 day

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.

addamba_transcript.pdf

* 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:

25-30 People / per year

The alumni's placement rate (%)

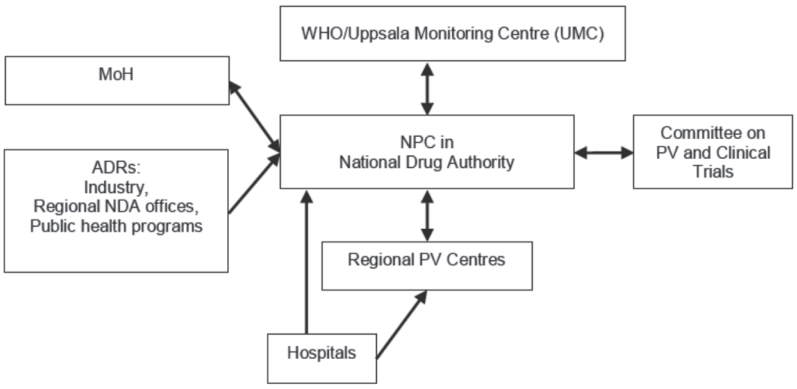
a.	Hospital:	20%
b.	Community Pharmacy:	60%
c.	Government Organization:	10%
d.	Enterprise:	5%
e.	Others:	5%

⑧ Side effect report

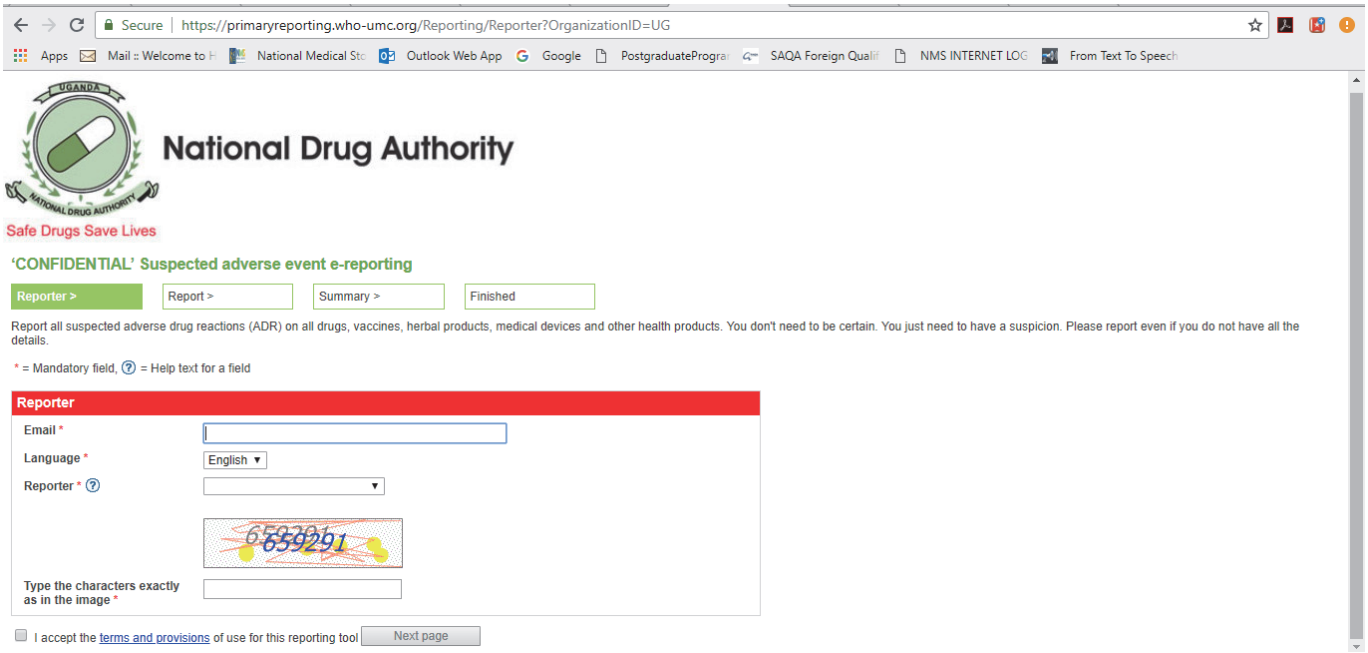
Please describe the flow of reporting system (from a medical institution to an administrative agency), when a

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.

UGANDA PHARMACOVIGILANCE REPORTING SYSTEM



Adverse Drug Reaction (ADR) communication channels in Uganda. Abbreviations: NPC= National Pharmacovigilance Centre; NDA= National Drug Authority; PV= Pharmacovigilance; MoH = Uganda Ministry of Health.



Regulatory Systems
on Ensuring Access to Quality Medicines

VENEZUELA

Venezuela

Central University of Venezuela
School of Pharmacy

Valentina De Freitas Assalone

1. Introduction of the work

I work at the Central University of Venezuela in the Pharmacy School as a professor of “Pharmaceutical Services in Regional Projects”

This subject is part of the curriculum of the Sanitary-Health Care Mention, it is an option in the fifth year of pharmacy studies.

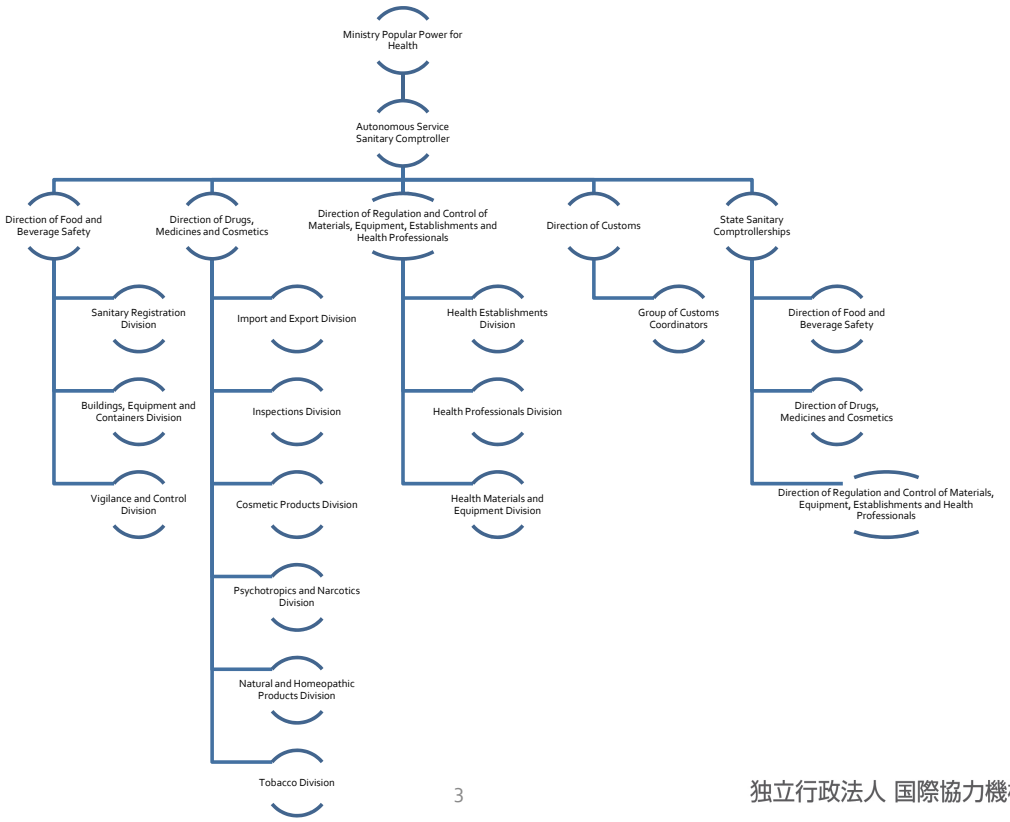
1. Introduction of the work

The curriculum of the Health Care Mention includes a subject called Health Surveillance, where everything related to regulatory systems is studied.

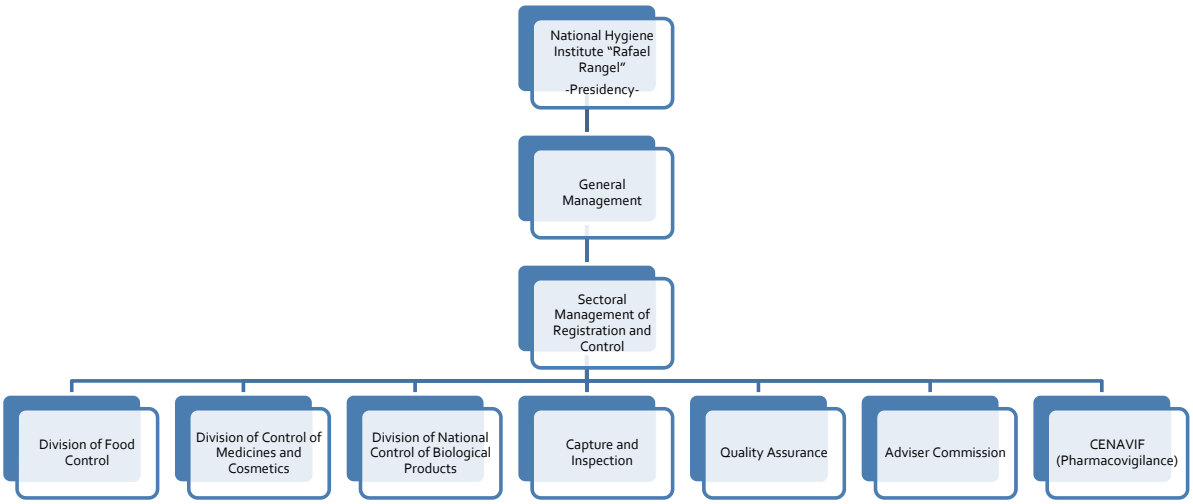
After the theory students spend five weeks rotating through the National Hygiene Institute

INSTITUTO NACIONAL DE HIGIENE

1. Introduction of the work



1. Introduction of the work



2. Good Practice

•My experience related to Good Practices is theoretical obtained through diploma courses and in the rotation within the National Hygiene Institute.

3. Difficulties/Lessons Learned from Past Experience

Difficulties

Currently in Venezuela the crisis in the matter of medicines, has generated the entry into the country of products through illegal routes without the revision and approval of the Regulatory Agency.

4. Your interests

(1) Know the management of the regulatory systems of other countries and their impact on the drugs that patients finally receive in the hospital and community pharmacies.

.

4. Your interests

(2) Observe the procedures in different work areas through the field visits must be an enriching experience, which will allow consolidating theoretical knowledge.

Part I: INFORMATION SHEET

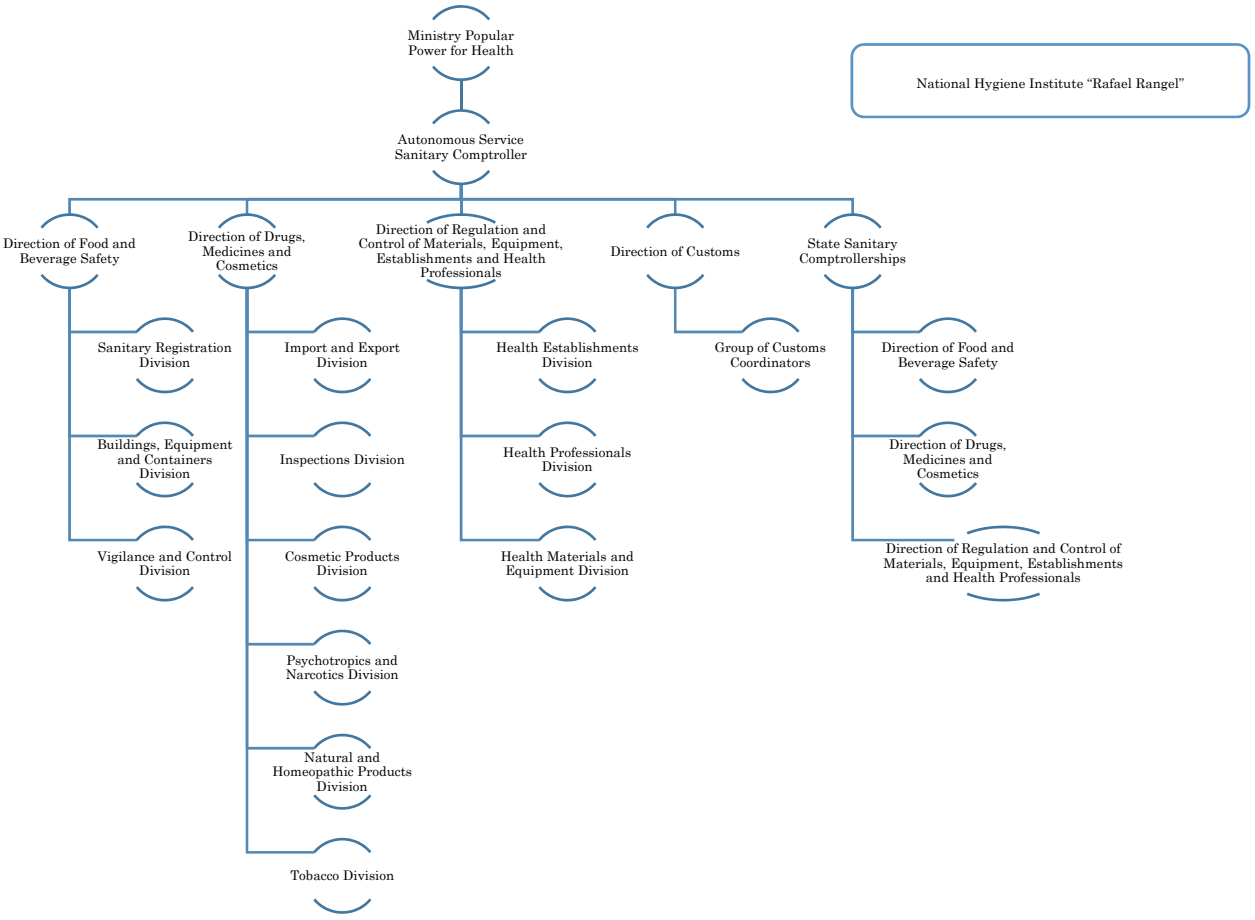
Regulatory Systems on Ensuring Access to Quality Medicines (JFY 2018)

Name: Valentina De Freitas Assalone

Country: Bolivarian Republic of Venezuela

Organization/Department/Division: Central University of Venezuela / School of Pharmacy/Sanitary-Health Care.

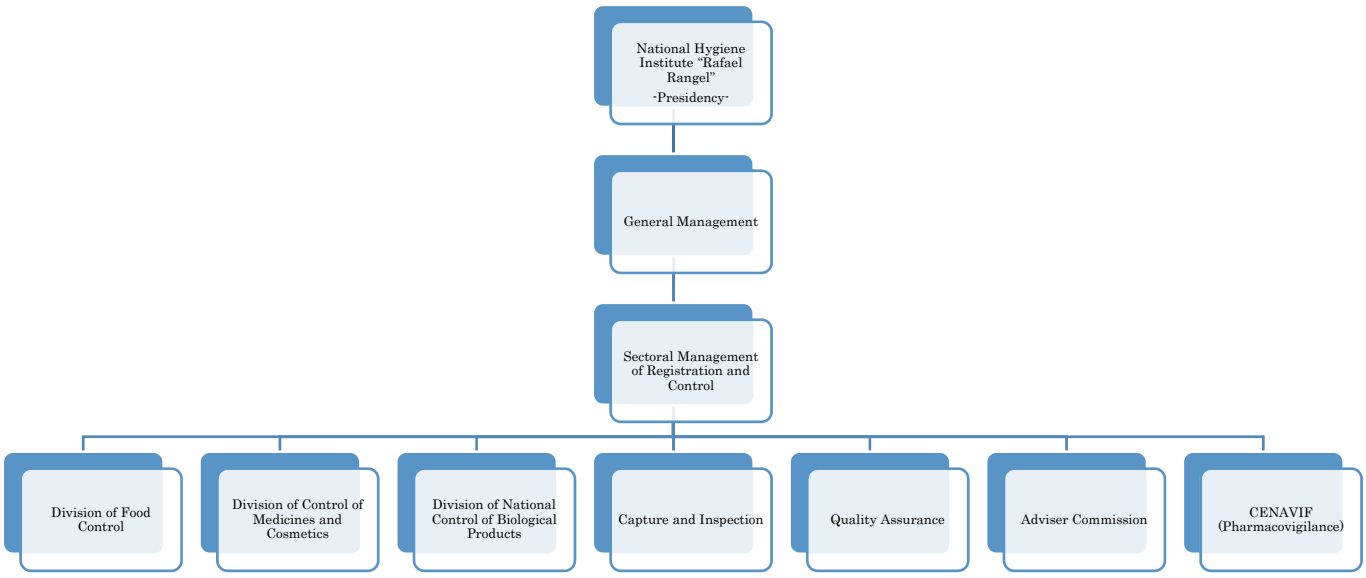
① Organizational Chart



The Ministry of Popular Power for Health through the Autonomous Sanitary Comptroller Service in the Bolivarian Republic of Venezuela is in charge of all the subjects related to the registration and control of products for human consumption: food, medicines, cosmetics, natural products, as of medical equipment and materials. It also controls the health professions and their establishments.

The National Hygiene Institute is a support agency for the Ministry of Popular Power for Health, exercising sanitary control over products for human consumption. The products are initially evaluated in the Institute and depending on their results the Ministry makes the final decision to give or not the sanitary registration.

Organization chart of the National Hygiene Institute (referent only to sanitary control)



Pharmacists work in each of the divisions of the Institute and as Sanitary Comptroller, from evaluating documentation, sample analysis to decision making in conjunction with doctors and other officials. Likewise, they are responsible for the inspections to the pharmaceutical establishments to verify the compliance with the regulations and the collection of samples.

※Hospital pharmacy

The hospital pharmacist is in charge in conjunction with the purchasing department of guaranteeing the medicines supply in health institutions, and participates in each of the stages of the supply system: selection, programming, acquisition, storage and distribution. Also fulfills functions in other pharmaceutical services such as pharmaceutical care, information and education about drugs and pharmacovigilance

② Legislation on pharmaceutical administration

◆At National and local level

・Pharmacy Exercise Law, administered by Ministry of Popular Power for Health through the Autonomous Service of Sanitary Comptroller

・Medicaments Law, administered by Ministry of Popular Power for Health through the Autonomous Service of Sanitary Comptroller

◆PIC/S

No

③ Regulatory Services

◆Pharmaceutical Manufacturing

・Good Manufacturing Practice, administered by the National Hygiene Institute "Rafael Rangel", and the Ministry of Popular Power for Health, through the Autonomous Service of Sanitary Comptroller.

◆Drug Import/Export

・Standards of the Pharmaceutical Products Review Board , administered by the National Hygiene Institute "Rafael Rangel" and the Ministry of Popular Power for Health, through the Autonomous Service of Sanitary Comptroller.

◆Marketing Authorization

・Standards of the Pharmaceutical Products Review Board administered by the National Hygiene Institute "Rafael Rangel" and the Ministry of Popular Power for Health, through the Autonomous Service of Sanitary Comptroller.

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

・Standards of Good Practice for the Distribution of Medicines by the Ministry of Popular Power for Health, through the Autonomous Service of Sanitary Comptroller.

◆Medicine Safety (post-marketing)

・Good Pharmacovigilance Practice administered by the National Hygiene Institute "Rafael Rangel"

◆Relief System for Adverse Drug Reactions

・Good Pharmacovigilance Practice administered by the National Hygiene Institute "Rafael Rangel"

④ **Drug Pricing**

- Medications in public hospitals are free; in addition, there is a list of medicines whose price is regulated by the State.

⑤ **Statistic Data** (waiting for information)

1. Number of pharmacists _____(year)
2. Number of GMP inspector (National & Local) _____(year)
3. Number of pharmaceutical manufacturers / manufacturing sites _____(year)
4. Number of traditional medicine manufacturers / manufacturing sites _____(year)
5. Number of pharmaceutical importers _____(year)
6. Number of pharmaceutical wholesalers _____(year)

※Hospital pharmacy only

⑥ **Information on your hospital pharmacy**

Caracas University Hospital (Is within the Central University of Venezuela)

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

a. Number of section chiefs: 0

b. Number of deputy chiefs: 1

c. Number of managers: 1

（２） Number of staff

a. Number of pharmacists: 24

b. Number of clinical pharmacists: 3

c. Number of technicians: 48

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

a. Oral medicine: (waiting for information)

b. Injections: (waiting for information)

c. Medicines for external use: (waiting for information)

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

a. For inpatients: (waiting for information)

b. For outpatients: (waiting for information)

（５） Equipment of the pharmacy in your hospital

a. Does your hospital have a dispensary room?

If "Yes", how large is it?

Yes _____ ㎡

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

Yes

Detail: The hospital has five units of intravenous mixtures with laminar flow hoods: Intensive Therapy, Anesthesiology, Pediatrics, Hematology and Parenteral Nutrition.

c. Does the pharmacy have computers?

Yes

Purpose: Inventory control system

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

No

e. Do you prepare TPN (Total Parental Nutrition)

Yes

f. Can you use Internet at the pharmacy?

Yes

Purpose: Communication and research.

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 2 years

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

University / college: 5 years
Professional education: 5 years
Practical training: 5 years
Duration of training by each facility: 6 months/1 year
Hospital pharmacy: 4 weeks
Community pharmacy: 4 weeks
Pharmaceutical company: 4 weeks
Others: _____ weeks
Age at graduation: 24 years old

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

Yes

Academic Exams _____ days
Clinical Exams _____ days

No X

（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.

_____

* 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:

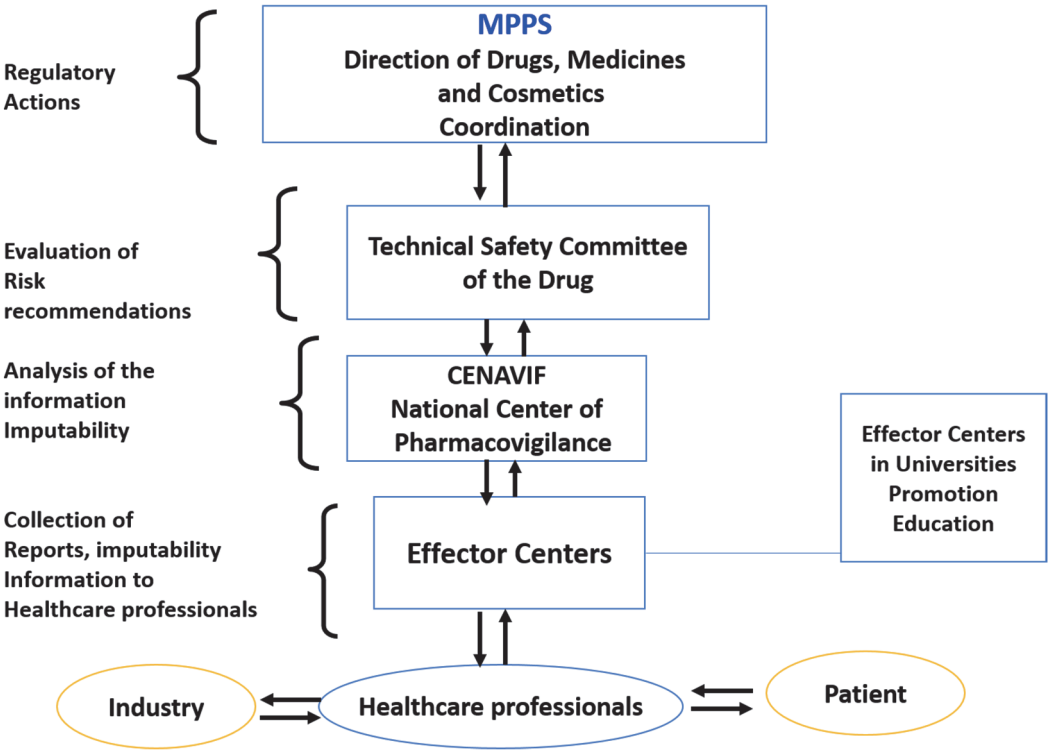
120 people / per year

The alumni's placement rate (%)

a. Hospital: 37%
b. Community Pharmacy: 19%
c. Government Organization: 13%
d. Enterprise: 23%
e. Others: 8% (Academy)

Currently, pharmacists as well as other professionals emigrates when obtain their professional title emigrates, therefore the statistics are affected by this fact

⑧ Side effect report



MPPS: Ministry of Popular Power of Heal by its initials in Spanish

Regulatory Systems
on Ensuring Access to Quality Medicines

ZAMBIA

Zambia

Zambia Medicines Regulatory Authority

Mr. Nyambe Lyoko

1. Introduction of the work

(1) My organization and Department

I work for the Zambia Medicines Regulatory Authority (ZAMRA) under the Marketing Authorisation Section.

(2) Job tenure

I work as Assistant Director – Marketing Authorisation (ADMA), which is permanent and pensionable job.

(3) The regulatory services that I am engaged:

I manage the following activities: -

a) registration of medicines and allied substances in order to achieve compliance to set standards of quality, safety and efficacy;
b) inspection and authorisation of clinical trials; and
c) pharmacovigilance - monitoring the quality and safety of medicines and allied substances;

1. Introduction of the work

(4) Roles and position of pharmacists in my country

In Zambia, pharmacists occupy various positions and play diverse roles, in both public and private sectors, in assurance of access to quality, safe and efficacious medicines and allied products.

Pharmacists work in various decision making positions including: regulators, inspectors, registration officers, procurement officers, managers of supply chain of medicines, quantification of country's medicines requirements, dispensing of medicines to patients, giving input on policy issues regarding medicines and pharmacy practice, managing private retail and wholesale pharmaceutical premises, and lecturing in colleges and universities.

In the above roles, pharmacists occupy various positions from officers implementing programs to managers/ chief executives making policy decisions.

2. Good Practice

I have a few experiences regarding Good Regulatory Practices.

Some of the examples include:

Achievements

1) Reduction of the backlog of product applications using the following mechanisms:
   a) Triaging of pending product applications into: human medicines, allied substances and veterinary medicines; and introducing abridged assessment procedure for low risk products such as nutritional supplements. This led to reduced timelines to registration for nutritional supplements from 18 to 24 months to below 9 months.
   b) Retreat sessions for evaluation of applications for registration of medicines. More products were reviewed within the sessions. This shortened the timeline to registration of medicines.
   c) Engagement of external experts from academia to review some dossiers where there was limited capacity within the Authority e.g. applications for registration of biological or biosimilar products. This enabled the Authority to make regulatory decisions on products, based on scientific opinion from experts.

2. Good Practice

Achievements ….cont'd

2) Reduced number of poor quality dossiers for registration of medicines

The Authority introduced and implemented a screening procedure for applications for registration of medicines. This has helped prevent receipt of poorly prepared dossiers by the Authority.

3) Increased collaboration on registration of medicines

The Authority participates in WHO prequalification and SRA collaborative registration procedure. In addition, the Authority is an integral member of the Zazibona regional grouping on collaborative registration procedure. Through these routes, the Authority has registered a number of medicines.

Further, the collaboration has opened new avenues for international collaboration and cooperation on various issues, including GMP inspections and monitoring of substandard.

2. Good Practice

Achievements ….cont'd

4) Contribution to the global database on counterfeit medicines and adverse drug reactions

The Authority is part of the global network on the fight against counterfeit medicines. Zambia has contributed a number of reports to the WHO Rapid Alert system and the VIGIFLOW.

5) Participation in proficiency testing

The national drug quality control laboratory of the Authority participates in the USP and WHO organized proficiency testing schemes, where they have been performing very well.

6) Development of a national antimicrobial resistance plan

Zambia developed and implemented a National Antimicrobial Resistance Plan. Which is a multisectorial strategy for tackling antimicrobial resistance. So far, a number of sensitization programs have been conducted.

2. Good Practice

Achievements ….cont'd

7) Increased number of technical staff in the Authority

Over the past two years the Authority has grown the number of its staff from slightly over 50 to over 100. Most of the filled positions are for technical officers working in the Registration, Inspectorate and Laboratory Departments. This has contributed to the efficiency seen in terms of executing the Authority's mandate.

8) Acquisition of support from the EU HSSP

The Authority is grateful to the EU which has granted financial and technical support to the Authority for the following areas:

- Construction of the National Drug Quality Control Laboratory and ZAMRA offices;
- Short term technical support e.g. trainings in assessment of product applications, quality management system, laboratory standards (ISO 9001) and internal auditors;
- Procurement of refrigerated vehicles for sampling medicines for use in post-marketing surveillance;
- Building of QMS and other systems for the national laboratory with view to getting WHO prequalification.

2. Good Practice

Achievements ….cont'd

9) Acquisition of support from the Global Fund

The Authority is grateful to the Global Fund for the financial support to the Authority that facilitated putting up of a modern incinerator and procurement of laboratory equipment, including an HPLC.

2. Good Practice

Solutions for past problems

- *Long list of pending applications:* Use of WHO/SRA collaborative registration procedure the timeline to register essential medicines (ARVs, antimalarials, vaccines, TB) has reduced;
- *Long list of pending applications*: Conducting retreats for review of dossiers has greatly reduced the backlog;
- *Limited storage space*: change of hard copy dossiers to electronic version has helped create space for new dossiers;

On-going projects to deal with current problems:

- *Limited capacity in biosimilar assessment*: one officer will be attached with the HPRA, Ireland to learn how to assess biological medicines;
- *Unregulated blood products*: ZAMRA will collaborate with ZNBTS to develop guidelines for regulation of blood and blood products;

Successful countermeasures against problems:

- Implementation of CTD guidelines has helped us collaborate better with other agencies as information is in the same format and easy to share.

3. Difficulties/Lessons Learned from Past Experience

✓ Problems that cannot be improved or solved

- *Lack of reliable medicines registration database*: This is an ICT challenge where we need in order to effectively manage the registration processes;

✓ Failed countermeasures to deal with the problems

- ZAMRA invited a few suppliers to showcase the database systems they have but none of these met the requirements for the Authority;

✓ Emerging or Re-emerging Problems, if any

- Anti-microbial resistance is a problem that needs concerted efforts in order to avoid emergence of highly resistant pathogens.

4. Your interests

(1) ZAMRA regards Japan as an SRA. Therefore, I would like to learn as much as possible the Japanese regulatory system and identify what best practices can be domesticated in Zambia. It would be nice to collaborate in the areas of registration and GMP with the regulatory authority in Japan;

(2) To establish networks for continued collaboration with Japan and participating countries in sharing regulatory information of mutual interest.

(3) To explore for solutions on acquisition of a database for managing applications for registration of medicines.

INCEPTION REPORT: JICA KNOWLEDGE CO-CREATION PROGRAM

Regulatory Systems on Ensuring Access to Quality Medicines (JFY 2018)

Name: Nyambe Lyoko (Mr)

Country: Zambia

Organisation/ Department/ Division: Zambia Medicines Regulatory Authority/ Department of Medicines Control/ Marketing Authorisation Section

INTRODUCTION

In Zambia, the Ministry of Health (MOH) carries the overall responsibility of providing healthcare to all Zambians. In order to effective carry-out its mandate, the Ministry collaborates with various stakeholders including cooperating partners (i.e. donors and non-governmental organisations) and the private sector; all of whom are contributing to universal health coverage.

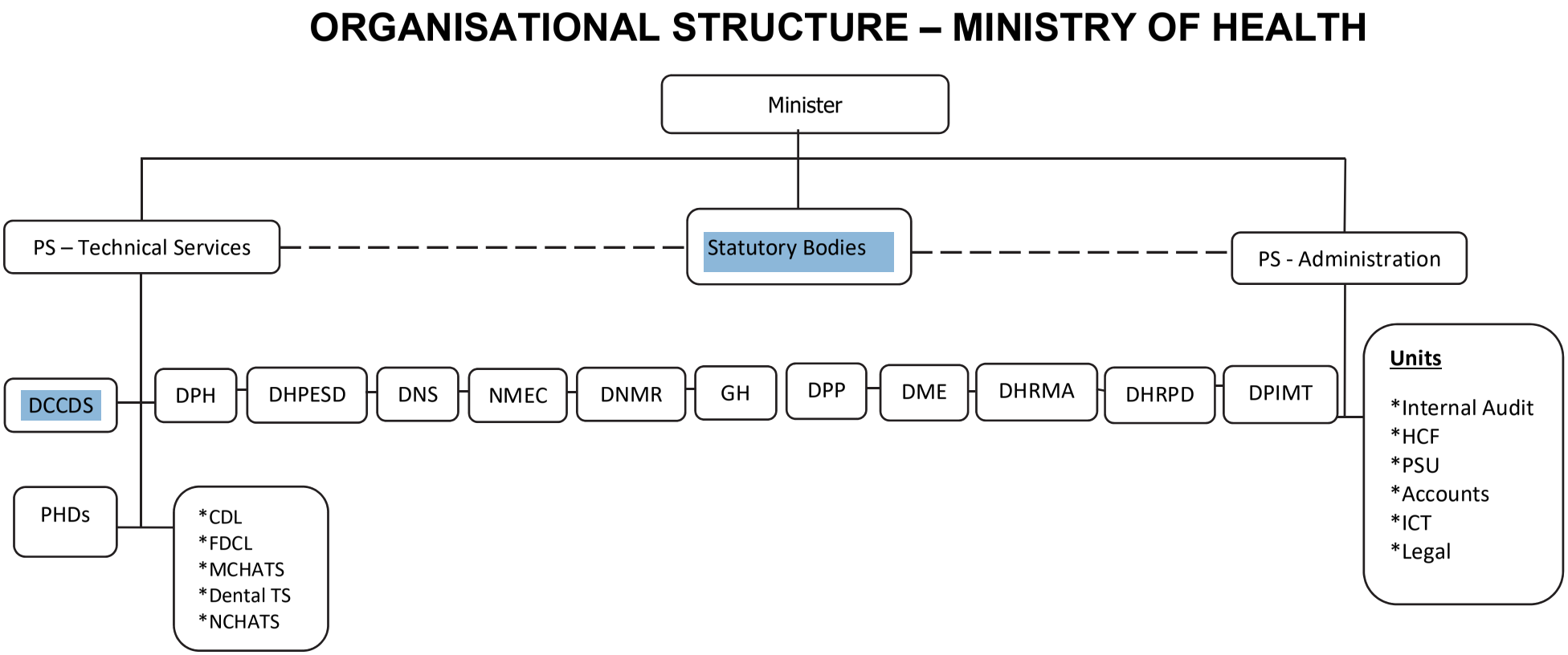
The Ministry of Health has various Directorates, Departments and Statutory Boards with specific functions and responsibilities. For instance, the Department of Clinical Care & Diagnostic Services is responsible for the provision of clinical and diagnostic services for improved health outcomes. The Zambia Medicines Regulatory Authority (ZAMRA) is a Statutory Board that is responsible for regulating and controlling of medicines and upholding of good practices regarding the manufacture, storage, distribution and sale of medicines and allied substances in Zambia.

The mandate of ZAMRA to regulate medicines and pharmaceutical premises is derived from the Medicines and Allied Substances Act (No. 3) of 2013. The Act continues the existence of the *Pharmaceutical Regulatory Authority* and re-names it as the *Zambia Medicines Regulatory Authority* (ZAMRA); provides for the functions and powers of the Authority; provides for the registration and regulation of pharmacies, health shops and agro-veterinary shops; provides for the registration and regulation of medicines and allied substances; provides for the regulation of the manufacture, importation, exportation, possession, storage, distribution, supply, promotion, advertising, sale and use of medicines and allied substances; and provide for the regulation and control of clinical trials.

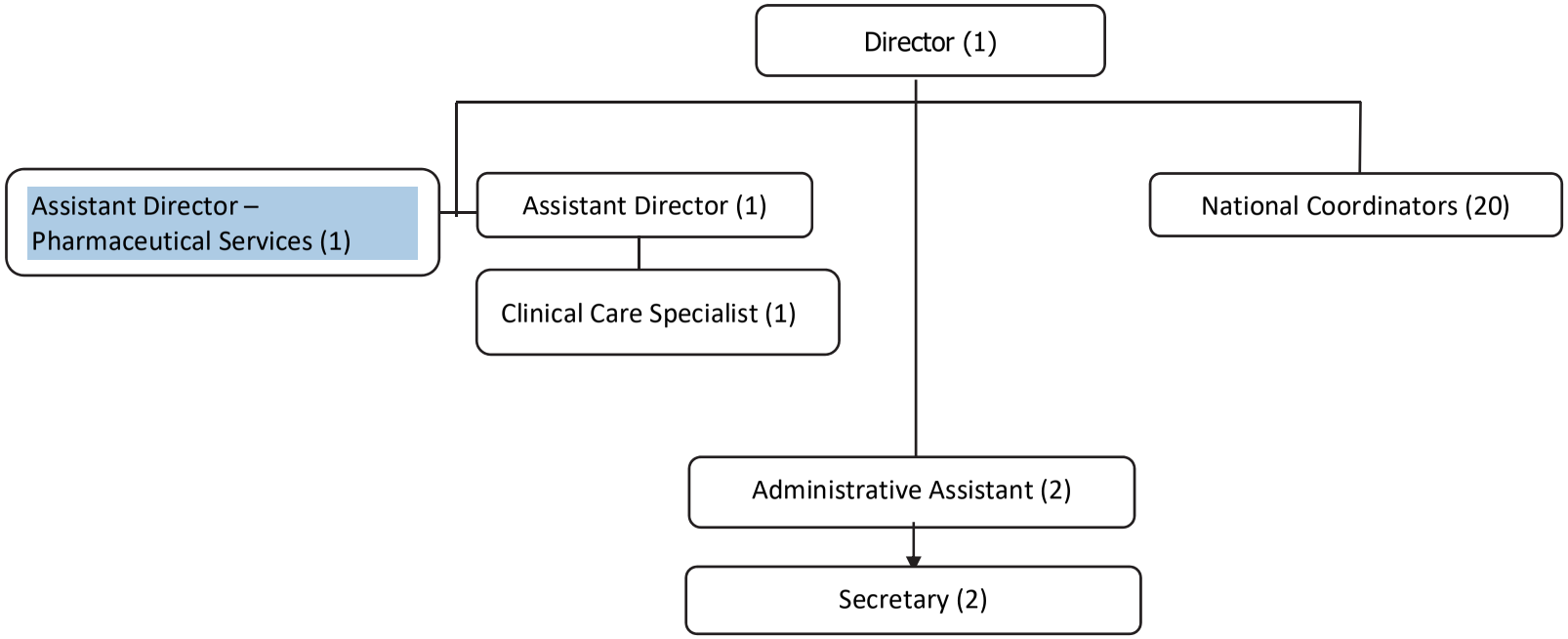
The other important legislations and statutes include: the Dangerous Drugs Act, Narcotic and Psychotropic Substances Act, Regulations on Pharmaceutical Licences, Regulations on Wholesale Dealing, Regulations on Health Shops, Regulations on Agrovet Shops, and Statutory Instrument (No. 38) on Fees.

1. ORGANISATIONAL CHART

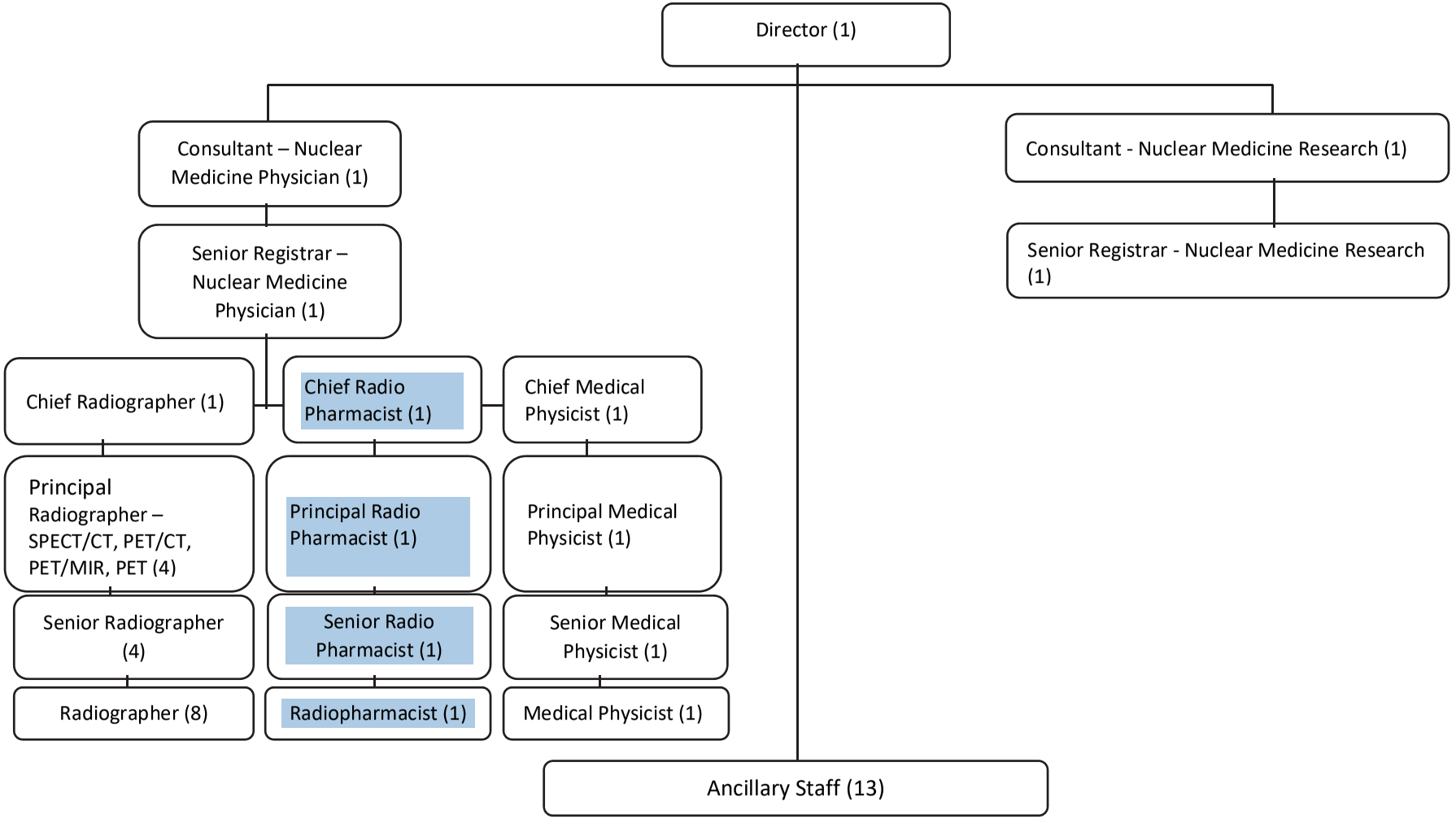
The organisational chart for pharmaceutical administration in Zambia is given below:



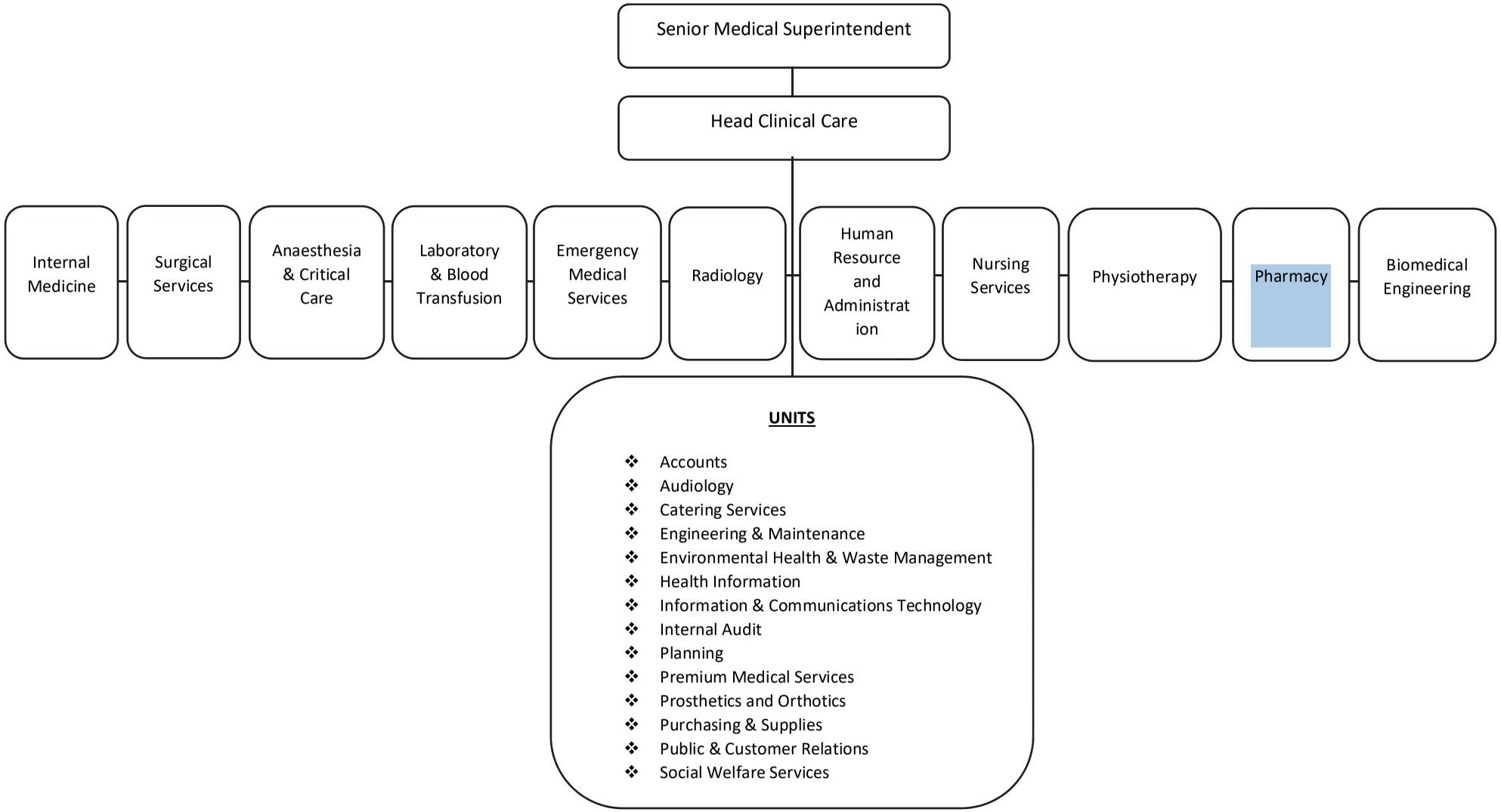
DEPARTMENT OF CLINICAL CARE & DIAGNOSTIC SERVICES



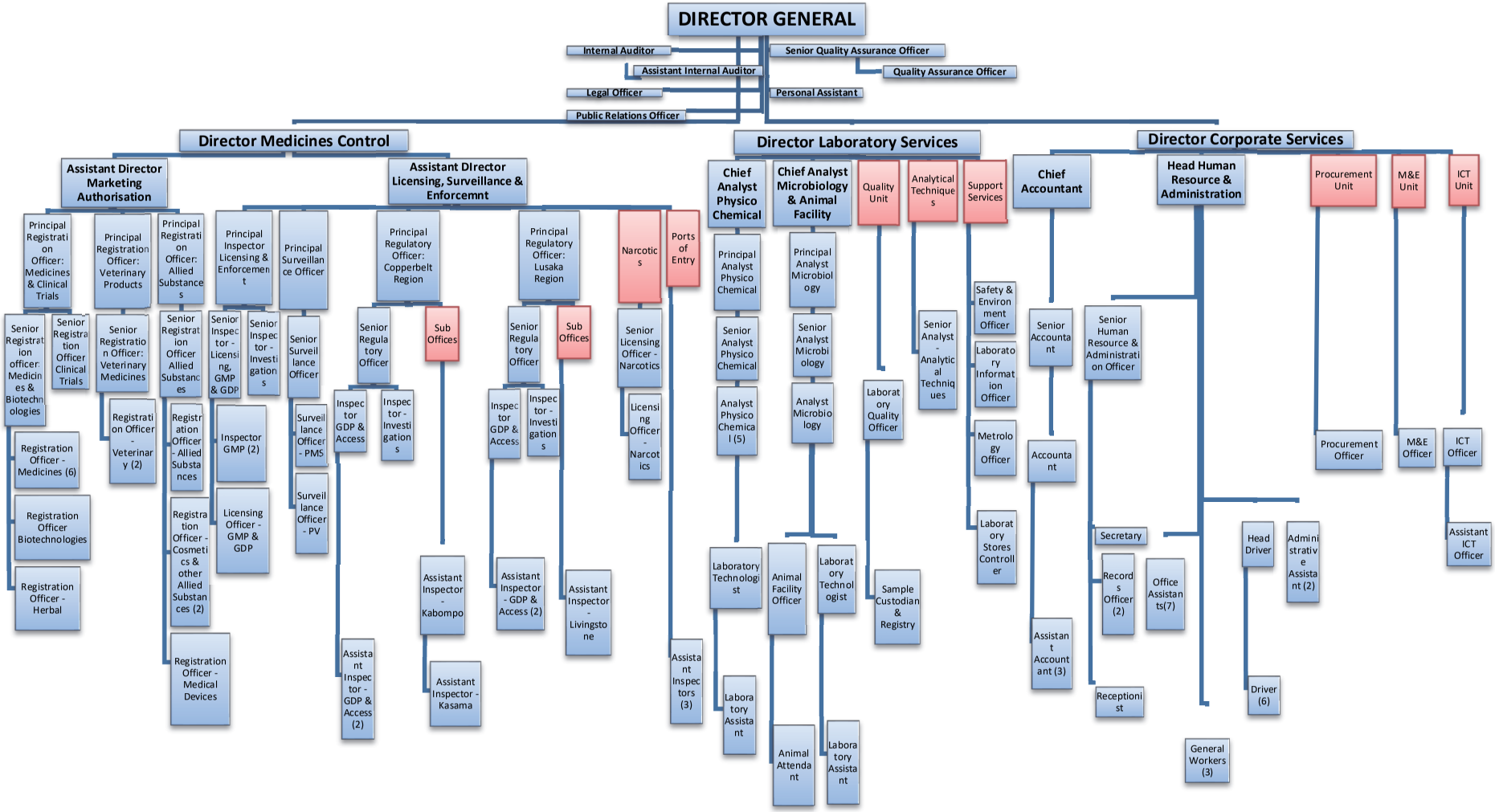
NUCLEAR MEDICINE & RESEARCH DEPARTMENT



UNIVERSITY TEACHING HOSPITAL – ADULT HOSPITAL



ORGANISATIONAL STRUCTURE – ZAMBIA MEDICINES REGULATORY AUTHORITY



The roles and responsibilities for pharmacists working at the following levels in the Ministry of Health are summarised below:

a) **Ministry of Health**:
   - provides policy direction, resources including medicines and other health technologies;
   - ensure access to quality healthcare services and commodities at all times;
   - lead the process of quantification and procurement of medicines and health commodities for the public sector;
   - storage and distribution of medicines and other health commodities (Medical Stores Limited, MSL);
   - MSL has central and regional warehouses for effective storage and distribution of medicines and other health commodities.
   - identification of training needs for personnel.

b) **Ministry of Health** (Provincial and District levels)
   - implement policy and manage resources, including medicines and other health technologies;
   - ensure access to quality healthcare services and commodities at all times;
   - participate in the process of quantification of medicines and health commodities for the public sector;

c) **Hospital level**
   - quantification of medicines requirements;
   - participate in ward rounds as part of clinical care team to develop pharmaceutical care plans;
   - undertaking monthly orders of medicines;
   - generating various monthly departmental reports, including stock-outs, needs assessments, trainings conducted and medicines safety issues;
   - dispensing of medicines and counselling patients;
   - ordering medicines from main stores to dispensary;

d) **Zambia Medicines Regulatory Authority**
   - undertake registration of medicines;
   - undertake inspection and licensing of premises used for distribution, sale and manufacture of medicines;
   - undertake quality control testing of products on the Zambian market;
   - undertake authorisation of conduct of clinical trials;
   - undertake post-marketing surveillance and pharmacovigilance activities.

2. LEGISLATION ON PHARMACEUTICAL ADMINISTRATION

◆National Level

- Medicines and Allied Substances Act (No. 3) of 2013 administered by the Zambia Medicines Regulatory Authority (ZAMRA)
- Dangerous Drugs Act administered by the Zambia Medicines Regulatory Authority (ZAMRA)
- Narcotic and Psychotropic Substances Act administered by the Zambia Medicines Regulatory Authority (ZAMRA) and the Drug Enforcement Commission (DEC)
- Public Health Act administered by the Ministry of Health and Zambia Medicines Regulatory Authority (ZAMRA)
- Food and Drug Act administered by the Ministry of Health and Food and Drug Laboratory

◆Local Level

- above laws apply at all levels

◆PIC/S

Yes ___ OR No ✓

If yes, joined when

Zambia is not a member of PIC/s but would like to join in the near future.

3. REGULATORY SERVICES

The Medicines and Allied Substances Act (No. 3) of 2013 is the overarching law that provides for various regulatory services, including the following:

◆Pharmaceutical Manufacturing

- Regulations on Pharmaceutical Licences (for manufacturers) administered by ZAMRA
- WHO Good Manufacturing Practice (GMP) guidelines administered by ZAMRA
- WHO Good Laboratory Practice (GLP) guidelines administered by ZAMRA
- WHO Good Clinical Practice (GCP) guidelines administered by ZAMRA

Most of the guidelines used by the Authority are WHO guidelines.

◆Drug Import/Export

・Statutory Instrument (No. 38) on Fees administered by ZAMRA

・Customs and Exercise Duty Act administered by Zambia Revenue Authority (ZRA)

・Dangerous Drugs Act (for Narcotics and Psychotropic Substances) administered by ZAMRA. In addition, Zambia abides with the conventions under the International Narcotics Convention Board (INCB) specifically for controlled substances

◆Marketing Authorization

・Guidelines on preparation and submission of dossiers in CTD format administered by ZAMRA

・Guidelines on grant of marketing authorisation for human medicines administered by ZAMRA

・Guidelines on grant of marketing authorisation for veterinary medicines administered by ZAMRA

・Guidelines on grant of marketing authorisation for biological products administered by ZAMRA

・WHO Guidelines on assessment of biosimilar products administered by ZAMRA

・Guidelines on grant of marketing authorisation for nutritional supplements administered by ZAMRA

・Guidelines on grant of marketing authorisation for human medicines administered by ZAMRA

・Guidelines on grant of marketing authorisation for herbal medicines administered by ZAMRA

・Guidelines on bioavailability or bioequivalence administered by ZAMRA

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

・Guidelines on good distribution practices (GDP) administered by ZAMRA

・Regulations on Wholesale Dealing administered by ZAMRA

◆Medicine Safety (post-marketing)

・Regulations on Wholesale Dealing administered by ZAMRA

・Guidelines on pharmacovigilance administered by ZAMRA

◆Relief System for Adverse Drug Reactions

・Guidelines on pharmacovigilance administered by ZAMRA

4. Drug Pricing

◆Since 1991 when the Zambian government introduced liberalisation policy of the Economy, there is no price control of pharmaceutical products or any other commodities. Thus, market forces determine what prices businesses charge for their good and services.

5. Statistic data

a) Number of pharmacists: **630** (2017)

b) Number of GMP inspectors: **6** (2018)

c) Number of pharmaceutical manufacturers/ manufacturing sites: **7** (2018)

d) Number of traditional medicine manufacturers/ manufacturing sites: unknown (not regulated)

e) Number of pharmaceutical importers: **117 wholesalers** (2017) (but other players including Ministry of Health, cooperating partners, non-governmental organisations, private companies and donors also import medicines)

f) Number of pharmaceutical importers: **117** (2017)

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

① Education and License of Pharmacists in your country

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

Primary (Grade 1 to 7)	**7** years
Secondary (Grade 8 to 9)	**2** years
High school (Grade 10 to 12)	**3** years

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

University / college:	**5** years
Professional education:	**2** years
Practical training:	**2** years
Duration of training by each facility:	**5** years
Hospital pharmacy:	**52** weeks
Community pharmacy:	weeks (Not applicable)
Pharmaceutical company:	weeks (Not applicable)
Others:	weeks (Not applicable)
Age at graduation:	24 years old (average)

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

Yes

Academic Exams	5 days
Clinical Exams	1 days

No

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

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

Practical training in dispensing medicines at a public hospital and clinical pharmacy practice, including participating in clinical care team on wards.

（５） Number of pharmaceutical university or college graduates:

≈100 people / per year

The alumni's placement rate (%)

a. Hospital: **80** %
b. Community Pharmacy: **5** %
c. Government Organization: **10** %
d. Enterprise: **3** %
e. Others: **2** % (e.g. academia)

② Side effect report

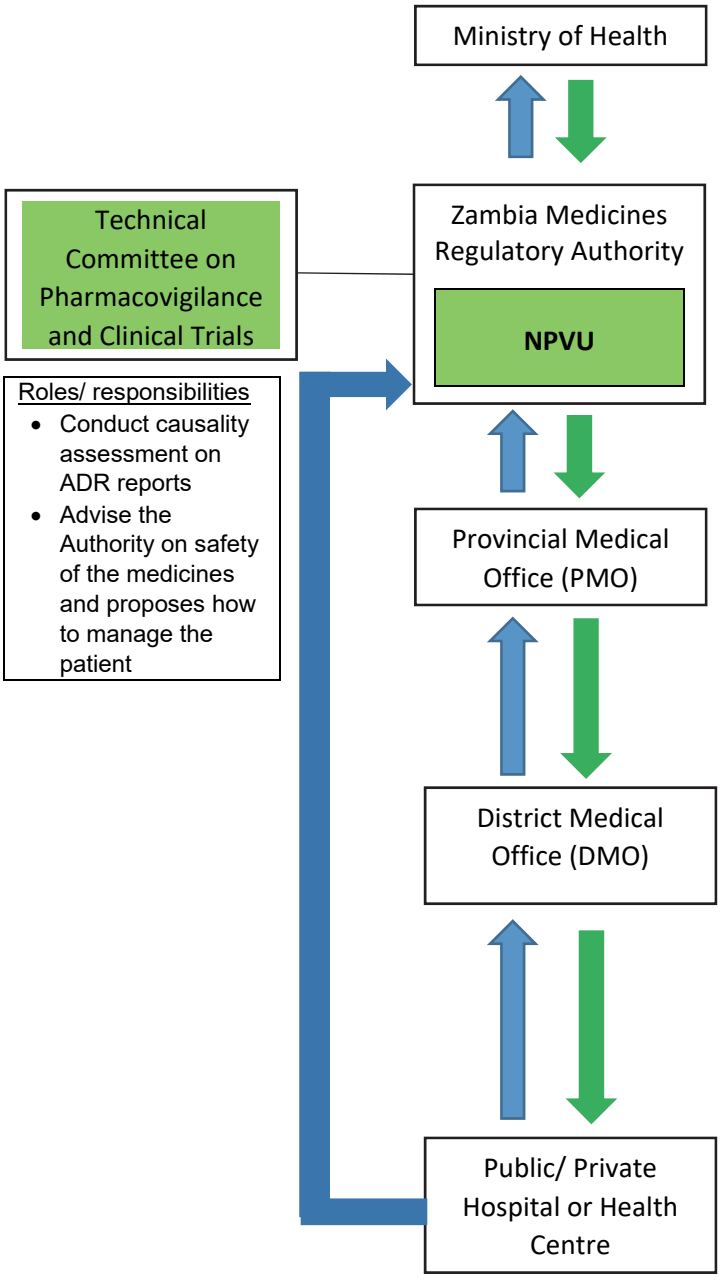
Please describe the flow of reporting system (from a medical institution to an administrative agency), when a severe side effect case is occurred in a medical institution. Describe specifically the rule and responsibility of each organization (an administrative agency / a medical institution), and their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

The Medicines and Allied Substances Act (No. 3) of 2013 gives mandate to ZAMRA to undertake pharmacovigilance activities. The reports on suspected adverse drug reactions (ADRs) or suspected medicine quality defects (MQDs) are sent directly to the Authority (ZAMRA) using any of the following mechanisms:

- Electronic submission using ADRA* mobile application or directly on ZAMRA website (www.zamra.co.zm);
  (*The ADRA app requires one time registration)
- Completed hard copy of adverse drug reaction (ADR) report form (for health care professionals, members of public) or adverse event following immunisation (AEFI) form;
- Calling ZAMRA directly on +260211220429. Reports received by phone are transcribed on the reporting form;

All received reports are forwarded to the *National Pharmacovigilance Unit* (NPVU), within ZAMRA, which records the received reports, prepares summaries for consideration by the Technical Committee on Pharmacovigilance and Clinical Trials, and uploads the reports on VIGIFLOW when the committee establishes causal-relationship with the medicinal product.

The chart below summarises the flow of reports and information from hospitals and the roles/functions of organisations involved in management of reports at this level:



Roles/ responsibilities

- Conduct causality assessment on ADR reports
- Advise the Authority on safety of the medicines and proposes how to manage the patient

Roles/ responsibilities

- Provides policy direction
- Guides on all matters of public health

- recruits and trains staff for the Unit;
- providing ADR reporting forms/tools;
- develop manuals and guidelines for health facilities and laboratories;
- train health care workers in the use of report forms;
- collecting data;
- manage a coding and archive system for data entry and retrieval; and
- provides feedback to reporters on the ADRs.

- Collaborate/ cooperate with DMOs and their health facilities;
- providing administrative, technical and logistical support to MDOs and hospitals;
- provide feedback to and from ZAMRA;
- distribute blank ADR forms;
- collect and forward completed forms; and
- verifies/ investigates ADRs, when needed.

- supervise the collection of reports from sites within their jurisdiction;
- distribute blank ADRs reporting forms;
- collect and forward completed forms;
- verify/ investigate ADR, if required;
- provide administrative, technical and logistical support to health centres, laboratories, and (in some cases) hospitals; and
- provide feedback from PMO and ZAMRA.

- record and report ADRs;
- forwarding completed forms directly to ZAMRA and to the District Medical Office; and
- provide feedback to the patient.

KEY

Submit report/ information

Receive feedback

Regulatory Systems
on Ensuring Access to Quality Medicines

LAOS

Regulatory System

(Regulation of Drug Law to Medicine)

By: Ms. Vongviengsa SITHIDETH
Drug Control Division
Food and Drug Department, MoH
Lao PDR.

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.

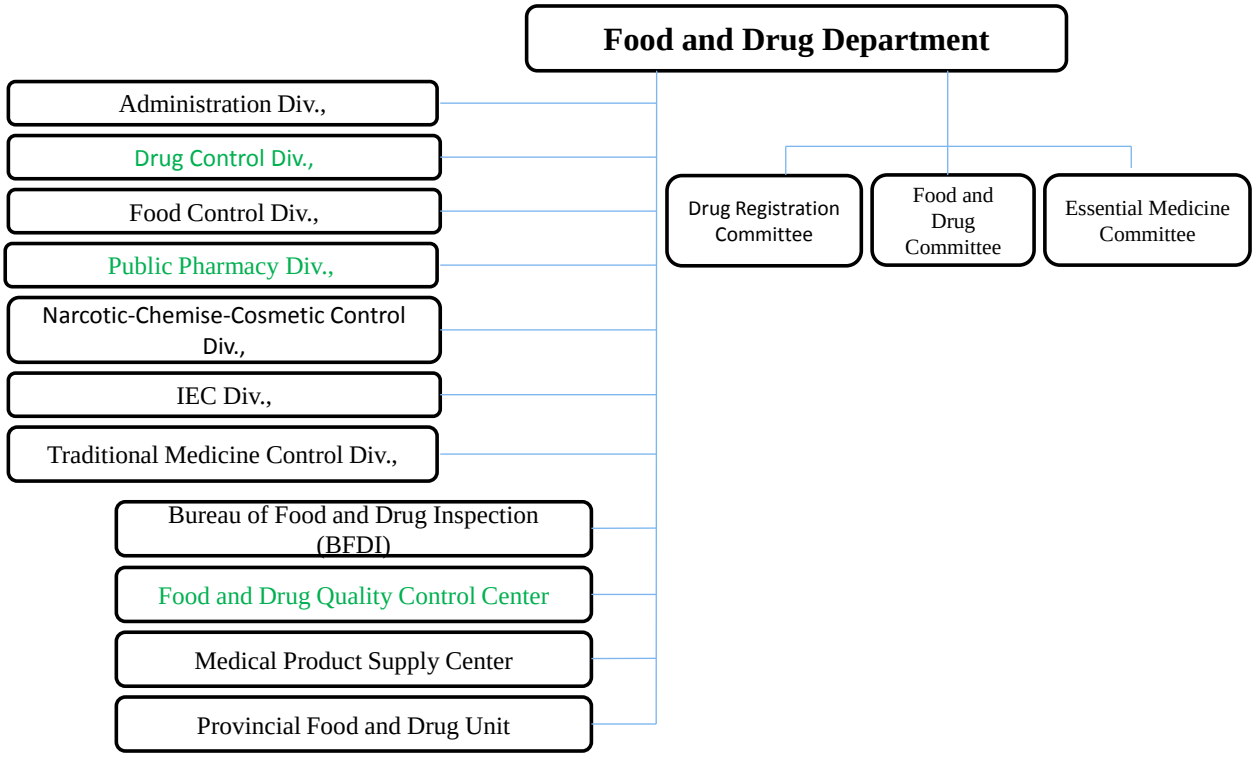
•Pre-marketing and Post-marketing surveillance of drugs, medical devices and cosmetic product.

•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.

Food and Drug Organization Chart



Law and regulation

- Law on Drug and Medical Products No: 07/NA , date: 21 December 2011.
- 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.
- Regulation of Donation of Drugs and Medical Product No.2579/MoH dated 12th Nov 2003.
- Regulation on the banned drug in Lao No.1018/MoH in 2003.

Good Practices

Administered pharmaceuticals and medical products such as:

- The pharmaceutical business unit is growing as a pillar to supply medicine and medical products to the public health sector across the country.
- Has Issued the License for the pharmaceutical professionals to pharmaceutical and medical products.
- Has issued Certificate of medicines are now available to 1865 items.
- Has issued a Certificate of Good Manufacturing Practice (GMP) to four factories: Factory No. 3, Codupha Factoty, CBF Factory, Tungmeng Factory.

Good Practices (Con't)

- The value of domestic production has increased, generating an average of US $ 11,799,756 per year, accounting for 50% of the total drug.
- Has developed and strengthened its ongoing Food and Drug Research work, which has provided ISO / IEC17025 ISO / IEC17025 Certificates of Vietnam VILAS in Vietnam in 2017.
- Establish a system of tracking the impact of drug use, monitoring the effects of drug use, deepening monitoring, reporting on antiretroviral (AEFI) antiretroviral screening system, expanding 7 provinces and 5 central hospitals.

Good Practices (Con't)

Implementation of drug procurement:

• Strengthening the procurement work together with the hospitals and centers, which now a days together with 5 central hospitals and 3 Centers for special healthcare services.

• Jointly organized for 4 provinces in southern Laos (Champasak, Saravane, Sekong and Attapeu) and expanded to jointly operate in Khammouane, Savannakhet and Houaphanh Province.

• Implementing Joint Drug Management Operations of 05 central hospitals and 10 provinces, which can address the problem of drug quality and drug prices at state-run facilities. In the two provinces, the procurement of pharmaceuticals was organized.

Good Practices(Con't)

Follow-up of drug use:

•The hospital management work has been well-developed, especially in promoting basic medicines, using rational drugs and tracking the consequences of drug use.

•Has established a system of tracking the impact of the World Health Organization's drug treatment, which began with ARV treatment at 5 HIV treatment centers and expanded to nine centers nationwide in collaboration with the Department of Health, the Center for AIDS, Pathology and related provinces.

•As a result of this work, Lao PDR has become a Official member of the World Health Organization (WHO) on the consequences of drug use (WHO-UMC) as the 122th country in 2015.

Good Practices(Con't)

Rational use of Medicine

•Follow up and promote the implementation of the Central and District Medical and Health Committee.

•Provide provincial and district training on rational use of drugs, follow up, encourage central hospitals - provincial hospitals - district hospitals and health clinics based on 10 indicators for the use of rational and 25 chronic diseases in accordance with the National Uniform Handbook.

Difficulties/Lessons learned

- Management of supply, supply and distribution of drugs at all levels from central to local levels is not uniform.
- Promoting the use of traditional medicine combined with traditional medicine, but the implementation policy has not yet been formulated.
- The use of medicine at the hospital at each level, especially at the central and provincial levels, is also good, there is a need for over-the-counter medication, expensive drugs, medicines, trade names and drugs that are not essential to basic medicines.
- Promoting Domestic Production to Achieve Good Manufacturing Standards GMP has not been actively implemented and there are no strictly planned and planned measures to comply with the requirements of ASEAN and the WTO.

The priority topic in this workshop

We were interested all topics from the course

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

•The lesson from the course, that we have learn it could be shared for better practice on health product management to increase accessibility of drug in reasonable price and enhancing regulatory system to reach the objective of Universal Health Coverage.

Challenges

- Assessment experiences are limited among staffs
- Insufficiency of English skills
- Learning from the ASEAN region on ACTD/ACTR implementation
- Not enough experiences on New drug review practices.

COUNTRY REPORT

FOR

Regulatory Systems on Ensuring Access to Quality Medicine

(JFY 2018)

(July 8 – August 11, 2018)

Tokyo, JAPAN

Mrs. Vongviengsa SITHIDETH

Technical officer

Ministry of Health – Lao P.D.R

Drug Control Division, Food and Drug Department

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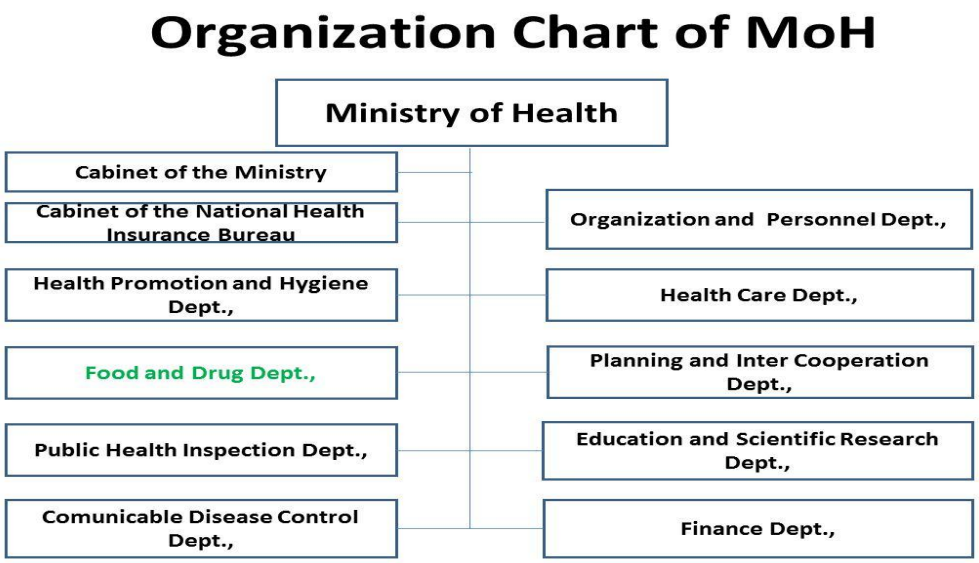
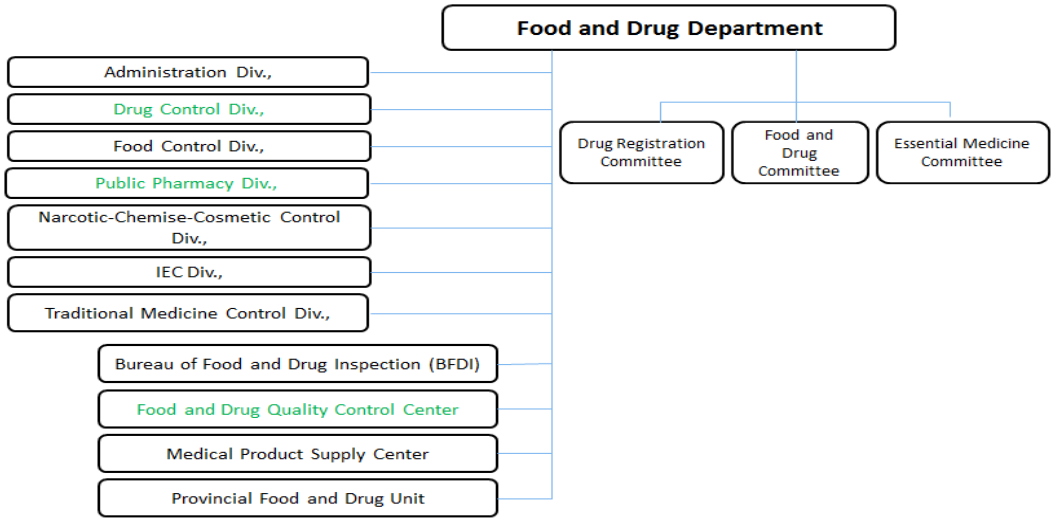
Website: www.fdd.gov.la

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 and the Drug Control Division is a one in Charge of the Pharmaceutical Regulatory Systems on Ensuring Access to Quality Medicine.

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. Regulation for Drug registration No. 1441, dated 13 Aug 2003
4. Regulation Establish Factory and Company No. 1820, dated 25 Aug 2017
5. Regulation for Pharmacy No. 2922, dated 21 Sep 2016
6. Regulation for good manufacturing practice and quality control of drugs No. 1021, dated 11 Aug 1999
7. Regulation on Good Manufacturing Practice No. 937/MOH, 12/07/2004
8. Regulation for disposal of medicines including vaccines No. 1862, dated 05 Aug 2016
9. Decision/Approval based on National medicine policy main goal and related components
10. Regulation of Donation of Drugs and Medical Product No.2579/MoH dated 12th Nov 2003 concerning Drug and Medical Equipment Donation.
11. Regulation on the banned drug in Lao No.1018/MOH in 2003
12. Regulation on specific controlled medicine and uncontrolled and OTC Drug No.2580/MOH, on 25/11/2002
13. Regulation on concerning Food, Drug and Medical Equipment Advertisement No. 2581/MOH in 2003

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 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 Drug List and needs of hospitals.

Now the drug products has registered about 1,865 items, there are the import production 1562 items, the local production 303 items and traditional medicines registered 281 items, 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,

the document that required are :

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

The application form is approved by the Food and Drug Department after 3 days, an import permit license will be issued by Director of FDD.

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

The Food and Drug Administration is an integral part of the Ministry of Public Health's Procurement and Supply Committee under the agreement of Ministry of Public Health No. 0150 / SAT on January 24, 2017 on the establishment of the Committee on Procurement of Drugs, Chemicals, Medical Equipment, Vehicles, Drug Supply Centers as a coordinating point with the Food and Drug Department and The Board of Directors of the Board of Directors, the Board of Directors, is also the chief contractor of the bidding process. It is a year since printing, auctioning, auctioning, auctioning, auctioning and technical research of each type of equipment in the procurement plan provided to 5 central hospital and 3 centers for special health services.

Technical meeting is essentially the procurement of medicine and there are regulations and steps of research starting from

- Compile all requirements
- Assess the qualifications of the factory and the company
- Academic research with representatives from each region (5 Central hospitals and 3 centers for special health services.
- Assessment by technical team is based on specifications, registrations, pricing and so on. It will be selected from 1 to 2 to 3 in order to present a committee to be a decision-making alternative.
- Subsequent to the bidding and execution of the contract.

◆ Medicine Safety (post-marketing)

The Food and Drug Department monitors quality assurance program of pharmaceutical products in the market by collaborative work with the Food and Drug Quality Control Center.

The Bureau of Food and Drug Inspection have been taking drugs samples from the

markets. The drug import companies submit document for importation must be refer to the list of drug which have been registered, and inspection activities should be done at the port of entry as well. Beside this, the indicators for the pharmaceutical inspection have been established to be guidance for inspectors on control and inspection of pharmacies.

The 10 indicators are as follows:

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 registration sample is selected by the company applying for registration, 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 2000, 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.

4. Drug Pricing

Price of drugs is decided in different stage if its distribution from local

manufacturers or importers to consumers. They depend also mainly of the competition between those sellers in actual free market. In public sector for ensuring that, with the budget provided by the government for drugs supply, how to obtain essential with adequate quality (efficacy and safety) but also quality more important too, manufactures are requested to produce drugs with less of sophistication for hospital utilization.

In the present, we are preparing the survey for regulation Pharmaceutical Price Control The price of drugs was indicated by increasing of 25% of the procurement price as mark up to be indicated; for the imported drugs have no price mechanism was indicated.

5. Statistic Data

a/. Number of Pharmacists

(Average number of Pharmacists by category (Data year 2016-2017)

Data 2684

Years 2017

b/. Number of GMP inspection

Data 13 (GPM Committee)

Years 2017

c/. Number of Pharmaceutical manufacturers/ manufacturing sites

Data 9

Years 2017

d/. Number of traditional medicine manufacturers/ manufacturing sites

Data 3

Years 2017

e/. Number of pharmaceutical importers

Data 66

Years 2017

f/. Number of pharmaceutical wholesalers

Data 2684

Years 2017

6. Information on your hospital pharmacy

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

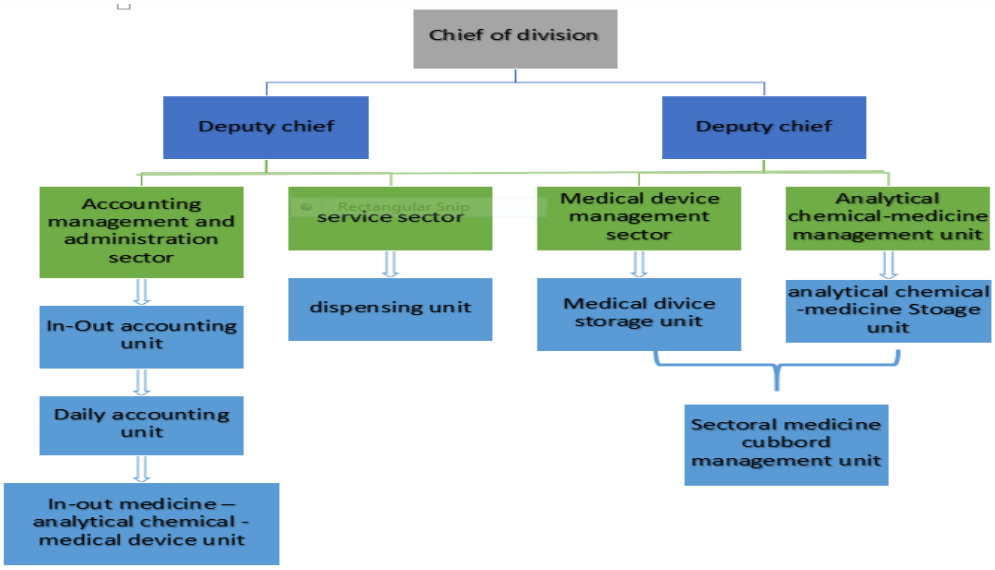
❄**Remark:** **This is a presentation information of only one hospital**

- **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 Mittaphab Hospital**



Drug division comprises 1 Chief , 2 Deputy chiefs, 1 Sectoral chief, 1 Sectoral Deputy Chief, 1 Head of unit and drug division comprises 3 main sectors, divided in 7 units :

4 main sectors:

- Accounting management and administration sector
- Analytical chemistry - Medicine sector

- Medical device management sector
- Dispensing sector

7 Units:

- In-Out accounting unit
- Daily accounting unit
- In-out medicine and medical device unit
- Daily dispensing unit
- Sectorial Medicine service unit
- Analytical chemistry-medicine management unit
- Medical device management unit

a/. Number of section chiefs:

Data 1

Years 2017

b/. Number of deputy chiefs

Data 2

Years 2017

c/. Number of managers:

Data 4

Years 2017

◆ **Number of staff**

a/. Number of pharmacists

Data 26 peoples, Female 22 peoples

Years 2017

b/. Number of clinical pharmacists

Data 21 peoples

Years 2017

c/. Number of technicians:

Data 15 peoples

Years 2017

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

Item	Number
Bag	**28**
Flacon	**61**
Ampoule	**113**
Tablet	**194**
Sachet	**14**
Tube	**20**
Total:	**430**

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

Item	Number
inpatients	**547**
outpatients	**129**

Equipment of the pharmacy in your hospital

At the hospital have a dispensary room and the room area about 70 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 use excel sheet system for the control and recode of medicine information.

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

Items	Number
University / college:	5-6 years

Professional education:	2 years
Practical training:	42 years
Duration of training by each facility:	6 years
Hospital pharmacy:	4 weeks
Community pharmacy:	4 weeks
Pharmaceutical company:	4 weeks
Others:	4 weeks
Age at graduation:	6 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)
- Medical Statistic Division, Budgeting and Planning Department (MOH).
- Administration and Statistic Division of Mitaphab Hospital
- Administration Division, The Pharmaceutical Development Center (PDC) Pharmaceutical Factory No: 3.
- Administration and Statistic Division of University of Health Science.

出典：平成 ３０年度 JICA 課題別研修カントリーレポート
- 平成 30 年度 JICA 課題別研修「水道管理行政（A）」
- 平成 30 年度 JICA 集団研修「水道管理行政（B）」
- 平成 30 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.

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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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