Regulatory Systems on Ensuring Access to Quality Medicines

Country Reports

FY2023

Japan International Corporation of Welfare Services (JICWELS)

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1. Bangladesh

Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2023）

Name	:	Md. Aziulla
Country	:	Bangladesh
Organization/Department/Division	:	Directorate General of Drug Administration

Organizational Chart

Historical Background of DGDA

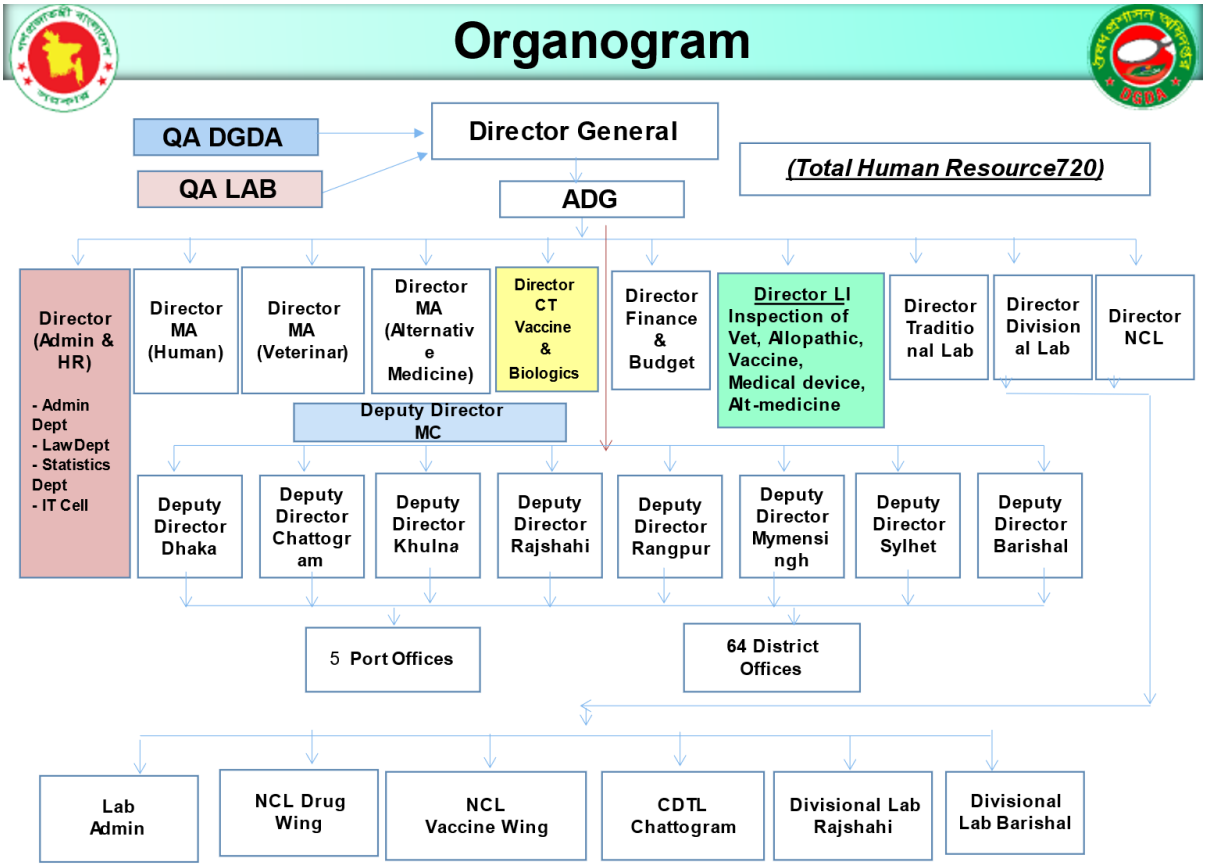
- In 1940, the Drug Acts (1940) was enacted, which was implemented by the then Directorate of health services of undivided India.
- Since 1947 it had been regulated by Directorate of health services, East Pakistan, until independence of Bangladesh in 1971.
- After liberation of Bangladesh, it was regulated by the Directorate of health services
- Formation of Directorate of Drug Administration under Ministry of Health and Family Welfare in 1974.
- In 10th January, 2010 it was upgraded to Directorate General of Drug Administration (DGDA).

Vision of DGDA

We strive to ensure quality and safe medicines for all

Mission of DGDA

To safeguard the health of humans and animals by ensuring safety, efficacy and quality of medicines, alternative medicines and medical devices.
2. To ensure availability, accessibility and affordability of essential medicines.
3. To implement GMP compliance in production and quality control of health products to ensure consumer safety as well as to facilitate export.



Management Infrastructure

- Ministry of Health and Family Welfare approved new organogram of DGDA with the total manpower 720.
- DGDA have two Quality Assurance department, who directly report to DG.
- Quality Assurance – NRA (DGDA),
- Quality Assurance – NCL (Laboratory)
- In DGDA organogram there are 1 ADG, 10 Directors and 31 Deputy Directors including Deputy Chief who are responsible for the below departments:
- Admin & HRM: Admin, HRM, Law, Statistics department and IT Cell. There are another Admin department for the laboratories.

Legislation on pharmaceutical administration

Legal Framework of DGDA

Legislation:

- The Drugs Act 1940
- The Drug Rules 1945
- The Bengal Drug Rules 1946
- The Drug (Control) Ordinance 1982
- Proposed Drug and Cosmetic Act 2023

Gazette Notification:

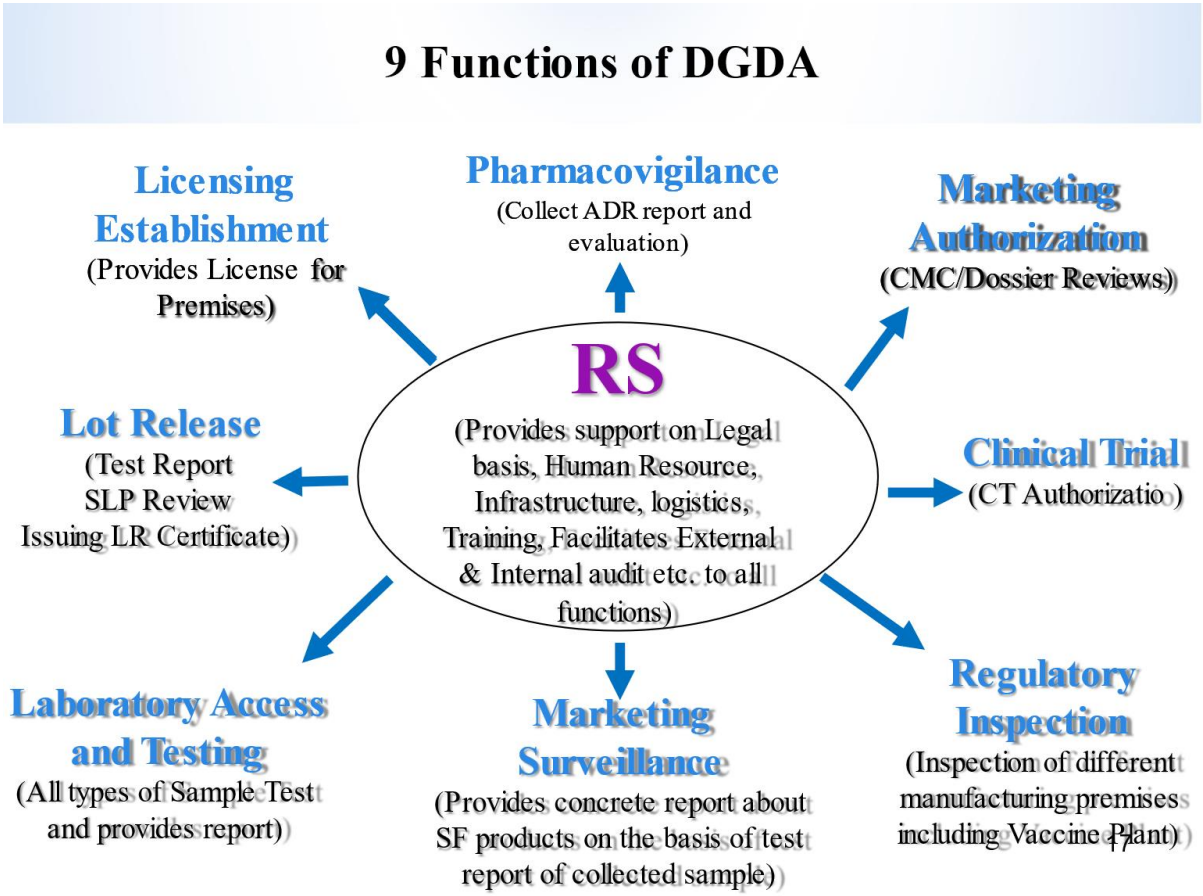
- Bangladesh Gazette Notification dated 17 May, 2020, Mandating DGDA to issue EUA / NOC in public health emergency.
- Govt. Notification No. 45.00.0000.182.89.001.21.93, dated: 24 April, 2021, mandated DGDA to consider Covid-19 vaccine for EUA considering EUA of country of origin and satisfactory clinical study data.
- Bangladesh Gazette Notification dated 28 June 2021, Mandating DGDA to perform CT, PV and Lot release function.
- Previously we were performing these functions according to guidelines for PV and CT and Ministry Orders.

Regulations and mandate:

- The National Drug Policy 2016
- Guidelines
- Standard Operating Procedures (SOPs)
- A number of manuals, forms, checklists and other documents.

Regulatory /Administrative Services

Directorate General of Drug Administration (DGDA) is the NRA of Bangladesh. It's a government organization under the Ministry of Health and Family Welfare, Bangladesh.Director General (DG) is the Head of NRA and also the Licensing Authority for Drugs. Enforce all prevailing drug laws and regulations and supervises all activities of DGDA. National Regulatory Authorities (NRA) are mandated to ensure Quality, Safety and Efficacy of the medical products to protect public health. Regulates and monitors all activities of the pharmaceuticals, medical devices and traditional medicines of the country. A number of Committees, composed of experts and representatives of different associations advise the Director General on matters related to his responsibilities.



Drug Pricing

Government of Bangladesh control the price of Primary Health Care Products (117 products). For the rest of the product DGDA give the price certificate only to the manufacturers as per their application for pay the VAT and Tax to the Government.

Statistic Data

Bangladesh is almost self-sufficient in manufacturing of different pharmaceuticals products. Around 98% of the country's needs met by domestic manufacturers and the rest of the 2% is import dependent. Current domestic pharmaceutical market is estimated 3 billion USD. At present, local pharma companies of Bangladesh produce 31908 brands and about 1610 generics drugs (Allopathic) and there are 206 functional allopathic medicine manufacturers in Bangladesh. There are around 248 Unani Medicine manufacturers, 162 Ayurvedic Medicines manufacturers, 50 Homeopathic Manufacturers and 34 Herbal Manufacturers in Bangladesh.

We are exporting finished pharmaceutical products to around 157 countries with a substantial growth every year. In the year of 2020 total export value was around 500 million USD.

Bangladesh imports 95% of Active Pharmaceutical Ingredients (APIs, key raw materials for Pharmaceutical Industries) and total value is approximately around $1 billion. Currently there are 20 API manufacturers in Bangladesh.

We import around 97% medical devices. Demand for medical equipment is being driven by the development of healthcare facilities.

The pharmaceutical sector has been among the highest priority sectors of Bangladesh's export policy since 2006. Highest priority sectors are entitled to income tax exemption for export earnings, export credit at reduced rates, assistance in marketing in overseas markets through participating in export fairs, and
so on.
There are 161000 registered retail Pharmacy outlet in Bangladesh. Most of the cases manufacturers distribute their medicines through their own distribution channel. In that case they need the whole sale drug license.

In Bangladesh there are 18921 registered A grade Pharmacists, 5731 registered diploma pharmacists, 148202 registered Pharmacy Technician,

Information on hospital pharmacy

In the public hospital Government appointed the Diploma Pharmacists for the management of the hospital pharmacy. The pharmacy is regulated by the DGDA but the hospital is regulated by DGHS. In the private hospital there is the hospital pharmacy run by the A grade pharmacist/Diploma Pharmacist/Pharmacy Technicians. Besides the hospital pharmacy and retail pharmacy there are model pharmacy nationwide which are supervise by the A grade registered pharmacists.

Education and License of Pharmacists

In Bangladesh there are 3 categories pharmacists like Category A, Category B and Category C. Category A are Bachelor of Pharmacy (4 years Honors), Category B is 3 years diploma and Category C (Pharmacy Technician) is 6 months short training course.

In Bangladesh Pharmacy Education is regulated by Pharmacy council of Bangladesh. In 13 public universities and 30 private universities have the pharmacy education. For Diploma Pharmacist there are 16 registered institute.

To get the registration from pharmacy council need to complete the degree from the Universities/Institution and apply to the council. After checking all the documents, they provide the registration for 5 years.

ADR (Adverse Drug Reaction) report

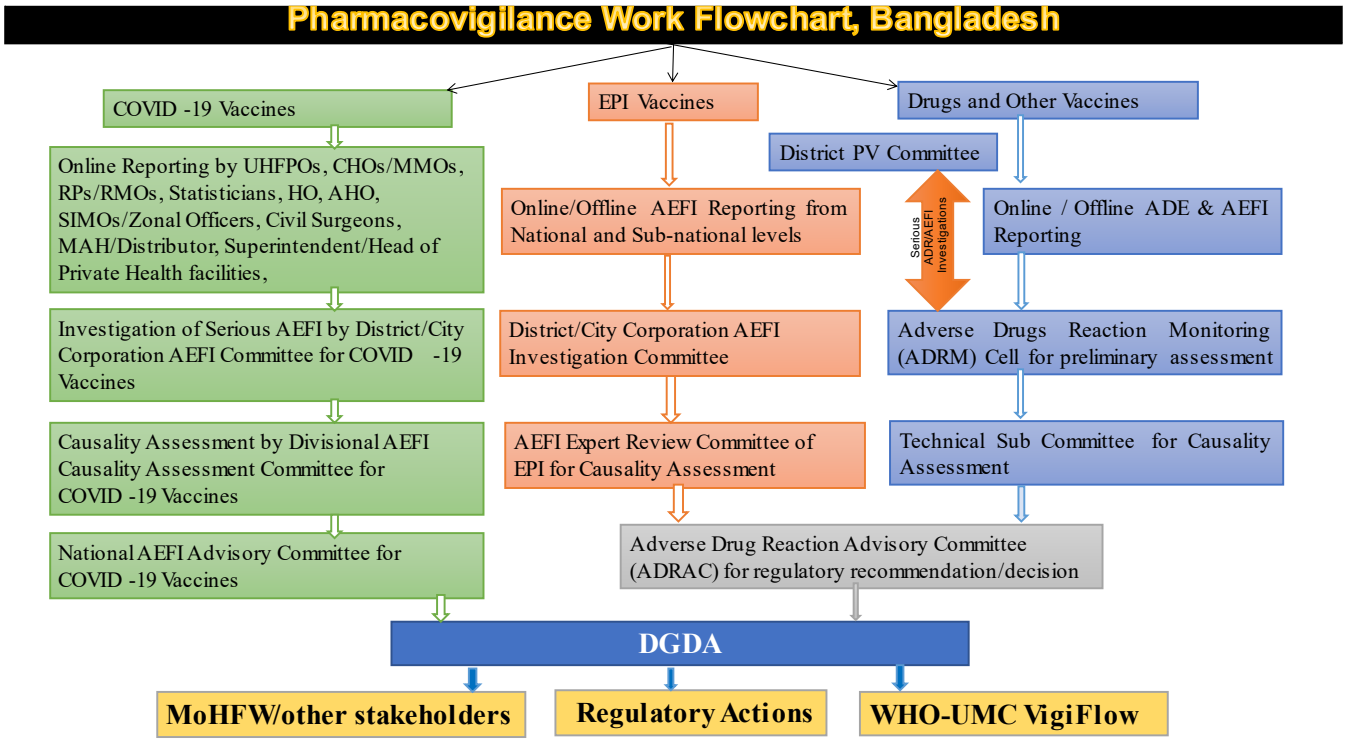
Pharmacovigilance (PV) is defined by the World Health Organization (WHO) as –

"The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem".

- *PV ensures Rational and Safe use of Medicines & Vaccines*

Minimum Information requirements for AE report

- **Identifiable Patient** – Age and Gender with other information (weight, pregnancy, contact number etc.)
- **Suspected Drugs-** Indication, generic name, daily dose with other information (Brand name, Dosage form etc.)
- **Adverse Events-** Brief description of the event, seriousness, start date, steps taken after event, outcome etc.
- **Identifiable Reporter-** Name, profession, address & contact.



Directorate General of Drug Administration (DGDA)

Bangladesh

Presented By
Md. Aziulla
Assistant Director, DGDA

1. Introduction of the work

Directorate General of Drug Administration (DGDA) is the NRA of Bangladesh. Director General (DG) is the Head of NRA and also the Licensing Authority for Drugs. Regulates and monitors all activities of the pharmaceuticals, vaccines, biotech industries medical devices and traditional medicines of the country.

I work with the Directorate General of Drug Administration since February 2013. Among the 9 functions of DGDA, I work with the Marketing Authorization Department.

Introduction of the work

- As a member of Marketing Authorization Department I engage with the following activities:
- Dossier evaluation of Vaccines and Biological products for new registration and Marketing Authorization (MA).
- Document evaluation of Vaccines and Biological products for renew registration and marketing authorization (MA).
- Review and Evaluation of Variation Application for Vaccines and Biological products
- Inspect the manufacturer facilities regularly.
- Any other activities instructed by the Head of the Organization

Introduction of the work

Roles and Position of Pharmacists in Bangladesh

- As per the Drug Acts and policy Appointment of registered Pharmacists is mandatory in the Pharmaceutical manufacturing facility.
- Registered Pharmacist works at the hospital pharmacy/Model Pharmacy as a hospital pharmacist/clinical pharmacist.
- In the retail pharmacy registered A grade/B Grade/ Pharmacy Technician works
- Registered Pharmacists works with the various Development Partners/Health Related NGOs.

2. Good Practice

- DGDA, Bangladesh is going to face the final audit of WHO ML-3 assessment in terms of vaccines.
- Dossier evaluated according to the CTD guideline
- GMP Inspection to manufacturers according to the WHO GMP.
- Contribute to the SOP and Guideline Preparations
- Risk Assessment, CAPA Management

3. Difficulties/Lessons Learned from Past Experience

- Issuance Deficiency letter to Manufacturers during Dossier Evaluation
- Implementation of Online Application system.
- Implementation of online database
- Emergency Use Authorization

4. My Interests

- ✓QMS aspects of regulatory systems
- ✓eCTD Dossier Evaluation
- ✓Emergency Use Authorization

2. Brazil

Regulatory Systems on Ensuring Access to Quality Medicines

(*JFY 2023*) *(202208270J001)*

Name: Lara Paro Dias
Country: Brazil
Organization/Department/Division:
Unicamp / Hospital das Clínicas / Pharmacy Service

① Organizational Chart

Health in Brazil is divided today into public and supplementary. Public health is structured within the Unified Health System (SUS), while supplementary health refers to private healthcare. Data from 2022 showed that 75% of Brazilians rely exclusively on SUS, while the remaining population utilizes private healthcare.

The SUS is one of the largest and most complex public healthcare systems in the world, encompassing everything from basic primary care to highly complex procedures like organ transplants. It ensures comprehensive, universal, and free access to healthcare for the entire population of the country, without discrimination based on social class or culture. Comprehensive healthcare, focusing on quality of life, prevention, and health promotion, has become a right for all Brazilians from conception throughout their lives.

The management of healthcare actions and services should be collaborative and participatory among the three levels of government: the federal government, states, and municipalities. The SUS network is extensive and includes both healthcare actions and services. It encompasses primary, medium, and high-complexity care, emergency services, hospital care, epidemiological, sanitary and environmental surveillance actions and services, as well as pharmaceutical assistance.

According to the Federal Constitution of 1988, "Health is the right of all and the duty of the State." Therefore, SUS consists of the Ministry of Health, states, and municipalities, as determined by the Federal Constitution. Each level of government has its own responsibilities:

1. MINISTRY OF HEALTH (MS) - National Level

As the national manager of the SUS, the Ministry of Health formulates, regulates, supervises, monitors, and evaluates policies and actions in coordination with the National Health Council.

2. STATE HEALTH SECRETARIAT (SES) - State Level

The State Health Secretariat participates in the formulation of health policies and actions, provides support to municipalities in coordination with the state council, and participates in the Bipartite

Intermanagement Committee to approve and implement the state health plan. Each Brazilian state has a Health Secretariat responsible for coordinating and implementing health policies at the state level. Within the State Health Secretariat, there may be a specific structure for pharmaceutical administration, such as the State Pharmaceutical Assistance Coordination, which is responsible for coordinating and implementing pharmaceutical assistance policies in the state, including medication distribution and management of related health programs.

3. MUNICIPAL HEALTH SECRETARIAT (SMS) - Local Level

The Municipal Health Secretariat plans, organizes, controls, evaluates, and executes health actions and services in coordination with the municipal council and the state level to approve and implement the municipal health plan.

In each Brazilian municipality, there is a Health Secretariat responsible for implementing health policies at the local level. Within the Municipal Health Secretariat, there may be a structure dedicated to pharmaceutical administration, such as the Regional Health Department, which is responsible for coordinating and implementing activities related to pharmaceutical assistance in the municipality, including medication stock management, dispensing of medications, and supervision of municipal pharmacies.
Therefore, each level mentioned above is involved in ensuring accessibility to medications for the SUS population.
The National Commission for the Incorporation of Technologies in the Unified Health System (Conitec) was created by Law No. 12,401 on April 28, 2011, and it deals with therapeutic assistance and the incorporation of health technologies within the SUS scope. Its objective is to advise the Ministry of Health on matters related to the incorporation, exclusion, or alteration of health technologies by the SUS, as well as the establishment or modification of clinical protocols or therapeutic guidelines. Thus, the medications available free of charge to the population have guidelines and protocols defined by Conitec/MS, with the action plan for accessibility being the responsibility of the State Health Secretariats, and the distribution plan being the responsibility of the municipal health secretariats.

From a sanitary standpoint, the regulation of medications in Brazil is governed by the National Health Surveillance Agency (ANVISA), which is responsible for:

- Regulating and controlling the manufacturing, distribution, commercialization, and use of medications;
- Approving the registration of medications, authorizing their commercialization in Brazil;
- Establishing norms and regulations related to the quality, safety, and efficacy of pharmaceutical products;
- inspecting and monitoring pharmaceutical companies to ensure compliance with good manufacturing practices.

The pharmaceutical professional not only plays a fundamental role in all the aforementioned

instances but is also essential in healthcare institutions. Their work encompasses various areas, contributing to health promotion, disease prevention, and the safe and effective use of medications. Here are some positions and roles performed by pharmacists in healthcare establishments:

1. Hospital Pharmacy

- Provides Pharmaceutical Care to inpatients and outpatients, aiming for the rational use of medications;
- Works in pharmaceutical logistics, with medication being the most important input;
- Represents the pharmacy in hospital committees, serving as the decision-maker in all matters related to medication;
- Acts as the legal responsible pharmacist for the medication flow within the hospital unit;
- Develops norms and controls that ensure the qualification of suppliers;
- Is responsible for medication dispensing through systems that allow for rational flows and minimize errors;
- Analyzes and compares costs and consequences of medication therapies for patients;
- Compounds magistral, officinal, and parenteral formulations according to the principles of good pharmacy manipulation practices;
- Is responsible for activities related to quality control of received inputs;
- Conducts pharmacovigilance actions within the hospital pharmacy;
- Actively participates in hospital committees such as the "Hospital Infection Control Committee" and the "Pharmacy and Therapeutics Committee”.;
- Prepares procurement bids and technical specifications for medications and related products.

2. Clinical Pharmacy

- Provides patient-centered care;
- Participates in the planning and evaluation of pharmacotherapy;
- Performs pharmaceutical interventions and provides pharmaceutical opinions to other members of the healthcare team, aiming to assist in the selection, addition, substitution, adjustment, or discontinuation of patient pharmacotherapy;
- Provides pharmaceutical consultations in a pharmaceutical office or other appropriate

environment that guarantees the privacy of the consultation;

- Performs pharmaceutical progress notes and documents them in the patient's medical record;
- Participates in and promotes integrated clinical case discussions with other healthcare team members;
- Orders laboratory tests within their professional competence to monitor the results of pharmacotherapy;
- Evaluates clinical and laboratory test results of the patient as a tool for individualizing pharmacotherapy;
- Monitors therapeutic levels of medications through clinical pharmacokinetic data;
- Develops the patient's pharmaceutical care plan;

3. Community Pharmacy and Primary Care

- In community pharmacies, pharmacists play an important role in providing guidance and correct dispensing of medications;
- They perform pharmacotherapeutic monitoring, identifying possible problems and drug interactions;
- They promote health education, guiding patients on the proper use of medications and the importance of treatment adherence;
- They participate in health campaigns such as vaccination and disease prevention.

The practice of the pharmaceutical profession is regulated by the "Federal Council of Pharmacy" (CFF) and "Regional Councils of Pharmacy" (CRF), which are also responsible for overseeing the practice of the pharmaceutical profession throughout the country:

- Monitor compliance with ethical and legal standards by pharmaceutical professionals;
- Promote educational and training initiatives for pharmacists;
- Contribute to the definition of policies related to pharmaceutical care.

② Legislation on pharmaceutical administration

The Health Surveillance agency is responsible for promoting, protecting, and controlling the health of the population, acting in the prevention of risks and damages to health arising from the use of products and services. It contributes to pharmaceutical management through:

- Licensing and Authorization: The Health Surveillance agency is responsible for licensing and authorizing health establishments and services, such as pharmacies, hospitals, clinics, laboratories, pharmaceutical industries, among others. It verifies if these places comply with health requirements and are in suitable conditions for operation;
- Quality Control: The Health Surveillance agency performs analysis and quality control of health-related products and services. This includes the evaluation of laboratory tests, labeling analysis, verification of good manufacturing practices, storage and distribution of medicines, food, and other products;
- Investigation of Health Risks: The Health Surveillance agency works in the identification and investigation of disease outbreaks, food poisoning incidents, adverse events related to medicines, and other public health issues. It collects information, conducts epidemiological analyses, and takes measures to control and prevent the spread of diseases and health risks.

Here are some of the main legislations related to pharmaceutical services in healthcare establishments and accessibility to medication in the unified health system:

◆ National Level

• Law No. 12,401/2011 - Provides for therapeutic assistance and the incorporation of health technology within the scope of the Unified Health System (SUS).

• Law No. 13,021/2014 - Deals with the exercise and supervision of pharmaceutical activities.

• Portaria 344/98 (and updates) - Approves the Technical Regulation on substances and medicines subject to special control.

• Portaria 3,916/1998 - Approves the National Drug Policy (PNM).

• Portaria 1,017/2002 - Establishes that Hospital Pharmacies and/or medication dispensaries in hospitals that are part of the Unified Health System must operate under the Technical Responsibility of a duly registered Pharmaceutical Professional in the respective Regional Pharmacy Council.

• Resolution 338/2004 - Approves the National Pharmaceutical Assistance Policy (PNAF).

• Resolution CFF 577/2013 - Deals with the technical management or technical responsibility of companies or establishments that dispense, sell, supply, and distribute pharmaceutical products, cosmetics, and health products.

• Resolution CFF 585/2013 - Regulates the clinical attributions of the pharmacist and provides for other provisions.

• Resolution CFF 596/2014 - Deals with the Pharmaceutical Code of Ethics, the Ethical Process Code, and establishes infractions and rules for the application of disciplinary sanctions.

• Resolution CFF 675/2019 - Regulates the attributions of the clinical pharmacist in intensive care units and provides for other provisions.

• Resolution CFF 735/2022 - Deals with the attributions of the pharmacist in the Pharmacy and Therapeutics Committee.

• Resolution CFF 746/2023 - Defines, regulates, and establishes the attributions and competencies of the pharmacist in the manipulation of medicines and health products.

• RDC 45/2003 - Provides for the Technical Regulation on Good Practices for the Use of Parenteral Solutions. • RDC 220/2004 - Provides for the operation of Antineoplastic Therapy Services.

• RDC 67/2007 - Deals with the fractionation of medicines in pharmacies and drugstores.

• RDC 38/2008 - Provides for the installation and operation of "in vivo" Nuclear Medicine Services.
• RDC 44/2009 (as it applies to Hospital Pharmacies) - Provides for Good Pharmaceutical Practices for the sanitary control of the operation, dispensing, and commercialization of products and the provision of pharmaceutical services.
• RDC 63/2011 - Good Functioning Practices for Healthcare Services.
• RDC 36/2013 - Establishes actions for patient safety in healthcare services and provides for other provisions.

◆ **Local Level.**

• Resolution SMS No. 01/2017 - Provides guidelines for the renewal of the Operating License for domestic health establishments in the municipality of Campinas

③ Regulatory /Administrative Services

◆ **Pharmaceutical Manufacturing**

RDC No. 301, dated August 21, 2019 - Provides guidelines for Good Manufacturing Practices for Medicines. It applies to all stages of medicine manufacturing, from the receipt of raw materials to the storage and distribution of finished products:

1. Quality system: Medicine manufacturers must implement a comprehensive quality system that includes appropriate procedures, controls, and documentation to ensure the quality of the manufacturing process.
2. Facilities and equipment: Requirements are established for the physical facilities, equipment, and utensils used in medicine manufacturing, aiming to ensure proper cleanliness, safety, and prevention of contamination.
3. Control of raw materials and packaging materials: Guidelines are defined for the control and qualification of raw materials and packaging materials used in medicine manufacturing, including requirements for identification, storage, traceability, and quality control.
4. Process and production control: Guidelines are established for the control of medicine manufacturing processes, including process validation, monitoring, quality control at all stages, and proper record-keeping.
5. Finished product quality control: Criteria and procedures are defined for the quality control of finished products, including laboratory testing, sampling, analysis, and release of medicines to the market.
6. Documentation system: The resolution sets detailed requirements for documentation related to medicine manufacturing, including standard operating procedures, manufacturing records, change control, among others.

◆Drug Import/Export

RDC 81/2018 - Provides for the Technical Regulation of Imported Goods and Products for Sanitary Surveillance. It applies to all imported products that are subject to sanitary surveillance, including medicines, food, cosmetics, health products, personal hygiene products, among others:

1. Importer's responsibility: The importer is responsible for ensuring that the imported products

comply with Brazil's legal and regulatory requirements, including registration or notification with ANVISA, when applicable.
2. Documentation and information: The importer must provide detailed information to ANVISA regarding the imported product, such as technical data, composition, manufacturer information, analysis certificates, among others.
3. Inspection and laboratory analysis: ANVISA may conduct inspections and collect samples of imported products for laboratory analysis to verify their compliance with sanitary requirements.
4. Customs control: The resolution establishes customs control procedures for imported products, including document verification and physical inspection of the products.
5. Rejection and return of products: If any non-compliance or health risks are identified, ANVISA may reject the importation of the product and determine its return or destruction, in accordance with applicable legislation.

RDC 203/2017 - Provides for the criteria and procedures for the exceptional importation of products subject to sanitary surveillance without registration with ANVISA.

1. Definition of exceptional importation: The resolution establishes that exceptional importation is a temporary measure that allows the importation of products without registration with ANVISA when there is a specific situation of public interest, such as cases of shortage, public health emergencies, clinical trials, among others.
2. Requirements and procedures: The interested party in importing a product exceptionally must submit a request to ANVISA, providing detailed information about the product, its purpose, justification for importation without registration, among other details.
3. ANVISA's analysis and decision: ANVISA will evaluate the request for exceptional importation, taking into consideration aspects such as the quality, efficacy, and safety of the product, the availability of registered alternatives, the evidence of the need for exceptional importation, and other criteria.
4. Conditions and responsibilities: If exceptional importation is authorized, the applicant must comply with the conditions established by ANVISA, including obtaining additional documents, implementing control and monitoring measures, and assuming responsibility for any adverse events related to the use of the imported product.

◆Marketing Authorization

Instruction Normative (IN) No. 9/2009 establishes rules and guidelines regarding the list of products permitted for dispensing and commercialization in pharmacies and drugstores. This normative defines which products can be sold in these establishments, taking into consideration aspects related to safety, quality, and current legislation. IN No. 9/2009 aims to ensure that only appropriate and authorized products are made available in pharmacies and drugstores, protecting the health and well-being of consumers.

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

RDC No. 304, dated September 17, 2019, and its updates - establishes Good Distribution Practices, Storage, and Transportation of Medicines.

1. Scope: The resolution applies to all companies and professionals involved in the distribution, storage, and transportation of medicines, including distributors, storages, transporters, pharmacies, among others.
2. Infrastructure and facilities: Requirements are established for physical facilities, equipment, and resources necessary to ensure proper storage and distribution of medicines, including temperature and humidity control, security, organization, cleanliness, and suitable conditions for product preservation.
3. Quality control: Guidelines are defined for quality control of medicines during distribution, storage, and transportation, including temperature control, batch traceability, assurance of packaging integrity, and prevention of contamination or adulteration.
4. Documentation and records: The resolution establishes the need for adequate documentation, including records of receipt, storage, transportation, and distribution of medicines. These records must be maintained in compliance with regulatory requirements and be available for inspection by ANVISA.
5. Training and qualification: RDC 304/2019 mandates appropriate training for professionals involved in the distribution, storage, and transportation of medicines, ensuring knowledge of good practices, procedures, and responsibilities.
6. Traceability: The resolution emphasizes the importance of traceability of medicines throughout the distribution chain, enabling precise identification of batches, their origin and destination, facilitating recall or withdrawal actions when necessary.

◆Medicine Safety (post-marketing)

It is the responsibility of pharmacovigilance to identify, evaluate, and monitor the occurrence of adverse events related to medications used in the population after their registration, with the aim of ensuring that the benefits associated with the use of these products outweigh the risks they may pose. RDC No. 406/2020 establishes Good Pharmacovigilance Practices for Holders of Human-use Drug Registrations and provides other provisions:

1. Definitions and responsibilities: The resolution establishes important definitions related to pharmacovigilance and identifies key stakeholders involved, such as the registration holder, the responsible person, and the pharmacovigilance team.
2. Pharmacovigilance System: RDC 406/2020 defines the requirements for the establishment and maintenance of a robust pharmacovigilance system, including the appointment of a responsible person, the establishment of standard operating procedures, the maintenance of records, and the implementation of a risk management strategy.
3. Data collection and analysis: Requirements are set for the collection, analysis, and continuous evaluation of medication safety data, including reports of adverse events, which must be recorded and reported according to established standards.
4. Safety communication: The resolution provides guidelines for the communication of safety information related to medications, including the preparation of periodic safety reports, the communication of regulatory safety measures, and interaction with competent authorities.
5. Risk management: RDC 406/2020 emphasizes the importance of risk management for medications, including the identification, assessment, minimization, and communication of risks associated with product use.
6. Audit and inspection: The resolution includes provisions for internal audits and inspections by ANVISA to verify compliance with good pharmacovigilance practices and adherence to established standards

◆Relief System for Adverse Drug Reactions

ORDINANCE No. 529, OF APRIL 1, 2013 - Establishes the National Patient Safety Program (PNSP).

One of the goals of this ordinance is "Safe Medication," and the contribution of the clinical pharmacist is through the pharmaceutical evaluation of the medical prescription, where it is possible to detect and prevent any potential adverse event related to drug therapy. The main pharmaceutical interventions are related to drug interactions, dosage, route of administration, dilution and infusion time, medication allergies, and medication reconciliation.

④ Drug Pricing

The Chamber of Regulation of the Pharmaceutical Market (CMED) is the interministerial body responsible for the economic regulation of the pharmaceutical market in Brazil, and the Brazilian Health Regulatory Agency (Anvisa) serves as the Executive Secretariat of the Chamber. In the public sector of Brazil, price control and the pricing mechanism for medications are regulated to ensure equitable access to essential medications for the population.
CMED establishes price limits for medications, adopts rules that promote competition in the sector, monitors commercialization, and applies penalties when its rules are violated. It is also responsible for setting and monitoring the mandatory minimum discount for public procurement. In the public sector, the federal government, states, and municipalities carry out public procurement of medications through bidding processes and contracts, with electronic auctions being the most common modality. These processes aim to obtain more competitive prices, seeking the best cost-benefit ratio for the public administration. Purchases can be made directly from manufacturers or through authorized distributors.

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 _____(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)

Data not available or not found.

※About the Hospital pharmacy only, if possible;

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: 1
b. Number of deputy chiefs: 4

c. Number of managers: 0

（2） Number of staff

a. Number of pharmacists: 22

b. Number of clinical pharmacists: 0 (non-exclusive activity)

c. Number of technicians: 60

d. pharmacy college interns: 6

（3） Number of the kinds of drugs managed in your pharmacy or hospital (542)

a. Oral medicine: 270

b. Injections: 250

c. Medicines for external use: 22

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

a. For inpatients: 483

b. For outpatients: 294 (22 working days/month)

c. For Emergency: 116

d. Oncology outpatients: 55 (22 working days/month)

（5） Equipment of the pharmacy in your hospital

a. Does your hospital have a dispensary room?

If "Yes", how large is it?

Yes ~354 ㎡ / No

The pharmacy service of HC/Unicamp has independent physical spaces:
Central Pharmacy - 126 ㎡
Emergency Satellite - 22.80 m²
Surgery Satellite - 55 m²
Ambulatory - Chemotherapy - 32.20 m²
Ambulatory outpatients - 84.70 m²
Unit Dose - 32.95 m²

Note: The warehouse is outsourced, and therefore, they have their own space for the pharmaceutical supply chain logistics

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

Yes / No

If "Yes", please describe it in detail

Detail:

The chemotherapy pharmacy has a clean room where the Class II B2 biological safety

cabinet (vertical for antineoplastic drugs) is installed. The structure includes an anteroom for hand hygiene and gowning, a manipulation room with HEPA filters, and a waste room. These three spaces are designed to have a unidirectional flow of work, preventing cross-contamination.

c. Does the pharmacy have computers?

Yes / No

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

Purpose:

Computers are used for both administrative tasks and the dispensation of medications through the computerized electronic prescription system.

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

Yes / No

Currently, the monitoring of vancomycin levels is typically performed by the prescribing physician. Vancomycin is an antibiotic commonly used to treat serious bacterial infections, particularly those caused by methicillin-resistant Staphylococcus aureus (MRSA) and other Gram-positive bacteria

e. Do you prepare TPN (Total Parental Nutrition)

Yes / No

The supply service of Total Parenteral Nutrition (TPN) is outsourced and carried out by a specialized pharmacy that handles the compounding of parenteral nutrition solutions.

f. Can you use Internet at the pharmacy?

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

Yes / No

Purpose:

The internet is used to access the electronic medical prescription system and handle them through the pharmacy module, record medication dispensing (with barcode reader in the high-cost pharmacy), place stock replenishment orders for the pharmacy, perform administrative tasks for the department such as shift scheduling, development of institutional projects, instruction on medication procurement processes through bidding, consultation of medications in databases such as Micromedex, UpToDate, ANVISA, and others. They are also used to request parenteral nutrition from the contracted third-party company, provide inventory information and request medications from the responsible entities for free medication programs at the municipal and Ministry of Health levels.

※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 5 years
Secondary 4 years
High school 3 years

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

The data pertains to the "Faculty of Pharmaceutical Sciences of the State University of Campinas" - FCF/Unicamp:

University / college: 5 years (full time)
Professional education: - years
Practical training: at Faculty of Pharmaceutical Sciences (FCF/UNICAMP) students are enrolled in 7 internships ~ 850 hours

Duration of training by each facility: ~ 60 hours Hospital pharmacy: ~90 hours
Community pharmacy: ~120 hours
Pharmaceutical company: ~450 hours
Others: ~130 hours
Age at graduation: 22 years old

In Brazil, there are 1024 undergraduate pharmacy courses recognized by the Ministry of Education (MEC) that grant a bachelor's degree. These courses are offered by both public and private institutions, and the standard workload for the degree is 4,000 hours, although there may be variations among different higher education institutions.

The undergraduate pharmacy program, leading to a bachelor's degree, should be structured into three training areas, encompassing theoretical and practical activities, mandatory internships, a final course project, and complementary activities. The program aims to integrate academic education with professional practice in a contextualized and problem-based approach.

The practical training or internships are distributed throughout the course, and the start and end periods may vary depending on the educational institution. It is important to note that each institution has autonomy in structuring its curriculum for the pharmacy program. The information provided in the table above represents the "Faculty of Pharmaceutical Sciences" at UNICAMP.

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

Yes

Academic Exams - days

Clinical Exams - days

No

In Brazil, there is no mandatory national examination for obtaining the pharmacist diploma after completing higher education. However, there are examinations to obtain a specialist title in a specific area of interest. For example, in the hospital pharmacy field, there are specialists in:

- Hospital Pharmacy - examination administered by the "Brazilian Society of Hospital Pharmacy";
- Clinical Pharmacy - examination administered by the "Brazilian Society of Hospital Pharmacy"; Radiopharmacy - examination administered by the "Brazilian Society of Hospital Pharmacy";
- Oncology - examination administered by the "Brazilian Society of Pharmacists in Oncology".

（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.

To obtain the diploma, it is necessary to complete all the theoretical and practical disciplines specified in the undergraduate pharmacy program and achieve the minimum satisfactory grade determined by the educational institution.
Internships must correspond to a minimum of 20% of the total workload of the undergraduate pharmacy program and should be developed in the following areas:
I - Drugs, Cosmetics, Medicines, and Pharmaceutical Assistance: 60%;
II - Clinical, Genetic, and Toxicological Analysis and Food: 30%;
III - Institutional and Regional Specificities: 10%.

The mandatory internships mentioned above should include practice settings within the Unified Health System (SUS) at different levels of complexity.
As mentioned earlier, the duration of practical training/internship may vary throughout the course, depending on the autonomy of each educational institution.

（5）Number of pharmaceutical university or college graduates:

people / per year

The alumni's placement rate (%)

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

These data are not publicly available. However, the Federal Pharmacy Council (CFF) is the regulatory body responsible for the registration of professionals, regulation of pharmacy practice and duties, and oversight. It is recommended for pharmacists to be registered with the CFF in order to work in healthcare establishments, and it is mandatory for Technical Managers and Substitute Technical Managers. Therefore, the CFF has the data on the number of registered professionals, and currently, there are 9960 registered pharmacists in the year 2023.

⑧ ADR(Adverse Drug Reaction) report

Cases of adverse drug reactions (ADR) are reported to ANVISA through a dedicated portal called VigMed. VigMed is the system for reporting adverse events related to medications and vaccines. It is available for healthcare professionals without institutional affiliation or from healthcare establishments that are not yet registered in VigMed. It is also accessible for healthcare services (sentinel networks, hospitals, outpatient clinics, and vaccination clinics) and for drug registration holders.

In the case of adverse events (adverse reactions, ineffectiveness, or medication errors), it is recommended by the responsible agencies to report primarily severe reactions that result in death, risk of death, hospitalization, prolonged hospitalization, congenital anomalies, or persistent or permanent disability. Additionally, reactions not described in the medication's package insert should be reported.

Any healthcare professional can make a notification, but healthcare establishments often undergo a prior institutional registration, and the notifier becomes linked to that healthcare service.

With the publication of Ordinance No. 529/2013, the National Patient Safety Program (PNSP) was established, and since then, healthcare services are required to have a Patient Safety Center. This center is a partner in developing patient safety policies in the hospital environment, and one of its activities involves reporting adverse events related to medications. When a hospital submits a notification to local or state authorities (ANVISA), an investigation group is formed. The patient's history, information about the suspected medication/product such as batch, expiration date, manufacturer, and registration holder's data are gathered.

9 Referências Bibliográficas

Lei Nº 8.666, de 21 de junho de 1993 - institui normas para licitações e contratos da Administração Pública e dá outras providências.

PORTARIA Nº 4.279, DE 30 DE DEZEMBRO DE 2010 - Estabelece diretrizes para a organização da Rede de Atenção à Saúde no âmbito do Sistema Único de Saúde (SUS).

RESOLUÇÃO No 6, DE 19 DE OUTUBRO DE 2017 - Institui as Diretrizes Curriculares Nacionais do Curso de Graduação em Farmácia e dá outras providências.

RDC N203, DE 26 DE DEZEMBRO DE 2017 - Dispõe sobre os critérios e procedimentos para importação, em caráter de excepcionalidade, de produtos sujeitos à vigilância sanitária sem registro

na Anvisa.
RDC No 81, DE 5 DE NOVEMBRO DE 2008. Dispõe sobre o Regulamento Técnico de Bens e Produtos Importados para fins de Vigilância Sanitária.
RDC No 301, DE 21 DE AGOSTO DE 2019 Dispõe sobre as Diretrizes Gerais de Boas Práticas de Fabricação de Medicamentos.
RESOLUÇÃO No 730, DE 28 DE JULHO DE 2022 - Regulamenta o exercício profissional nas farmácias das unidades de saúde em quaisquer níveis de atenção, seja, primária, secundária e terciária, e em outros serviços de saúde de natureza pública ou privada.

https://www.gov.br/conitec/pt-br/assuntos/a-comissao/conheca-a-conitec
https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed
https://site.cff.org.br/estatistica
http://sbrafh.tecnologia.ws/titulo-de-especialista/
https://sobrafo.org.br/titulo-de-especialista/
https://emec.mec.gov.br/emec/nova
https://www.gov.br/saude/pt-br/assuntos/saude-de-a-a-z/s/sus
https://www.ibge.gov.br/estatisticas/sociais/saude.html

Lara
Pharmacist

Hospital of Clinics
University of Campinas

Brazil

独立行政法人 国際協力機構

1. Introduction of the work

(1) HC/Unicamp - Pharmacy Service (Coordinator)

(2) 12 years (3.5y as a pharmaceutical manager)

(3) Regulatory services that I'm engaged in:

a) selection and technical analysis of drugs
b) Pharmacovigilance

position of pharmacists in Brazil

1. Health Units
   a. Hospital Pharmacist and Community Care
   b. Clinical Pharmacist
   c. Radiopharmacy

1. Industry and Regulatoy System

1. Clinical Analysis and Toxicology

1. Teaching and Research

2. Good Practice

✓Achievements + On-going projects to deal with current problems

- Implementation of electronic prescription system integrated with pharmacy
  – approximation between pharmacist and prescriber in drug safety

2. Good Practice

✓Successful countermeasures against problems

- Contingency plan for worldwide shortage of iodate contrast
  - fractionation of doses
  - import
  - protocol review

4

3. Difficulties/Lessons Learned from Past Experience

✓ Failed countermeasures to deal with the problems

- The only manufacturer of Immuno BCG had its factory interdicted by VISA - drug shortage
  - alternative: import
  - Problem With COA

5

3. Difficulties/Lessons Learned from Past Experience

✓ Emerging or Re-emerging Problems

- Twice Contaminated chlorhexidine (same manufacturer)
  - (Burkholderia P. - oral solution)

4. Your interests

(1) Learn about health systems and drug regulation of other countries and exchange experiences

(2) Improve technical qualification in the selection of medicines in public procurement, both domestic and imported drugs

Thank you!

Morro dois Irmãos - Rio de Janeiro/Brasil

3. Egypt

Part I: INFORMATION SHEET

Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2023）

Name: Mohamed Fadel Mohamed

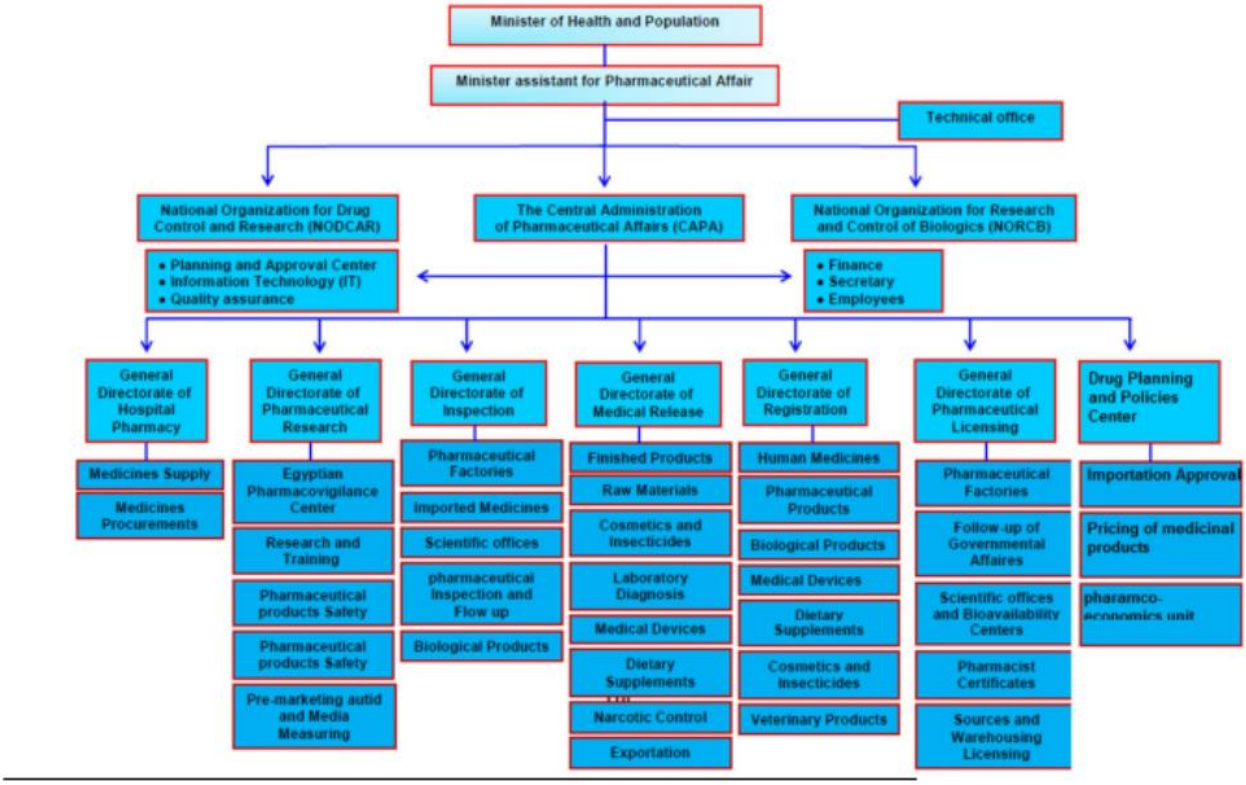
Country:Egypt

Organization/Department/Division: Central administration for pharmaceutical affairs (CAPA)

Ⓒ Organizational Chart

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

Figure 3: Central Administration of Pharmaceutical Affairs (CAPA) organization chart



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

※About the Hospital pharmacy only, if possible;

−Please briefly describe the position and role of pharmacist in the medical institution and the medical care system in your country.

Under the provisions of the law 127 for the year 1955, practicing the profession of pharmacy is considered to be the preparation, composition or retailing of any medicine, drug, medicinal plant or pharmaceutical substance that is used internally, externally or by injection to prevent humans or animals from diseases or treat them from them or is described as having these advantages.

Medicines in Egypt are government-regulated and its price is controlled by law and ministerial decrees.

Patients have to pay out-of-pocket (OOP) for their medicines. The public health insurance covers only 58% of the population. Public hospitals adhere to a list of standard medicines that are publicly tendered and procured centrally. Patients have to purchase their medicines if not on the list of the public tender medicines. Private pharmacies are licensed by the MOH 3 and considered as the main legal outlet to sell medicines (i.e.: medicines are not sold in groceries or any commercial store other than the pharmacy)

Ⓒ Legislation on pharmaceutical administration

−Please briefly bulletined major laws/acts

◆National Level

Law 127 for the year 1955

◆International Level:

The involvement of multiple committees and application reviews prior to MA is granted. Egypt's public pharmaceuticals registration process on transparency score is 6.03 using the WHO methodology for measuring transparency (WHO, 2015). According to the report, low scores are related to problems of transparency in registration and pricing

Ⓒ Regulatory /Administrative 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

- Administered by good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice

◆ Drug Import/Export

Article (65):

It is not allowed to enter private pharmaceutical preparations into Egypt, even if they are free medical samples, nor to release them unless the following conditions are met and after the approval of the Technical Committee for Drug Control:

(1) To be registered in the books of the Ministry of Public Health in accordance with Article (59) of this law.

(2) To have the same name by which it is known in its country of origin.

(3) It shall be brought in hermetically sealed envelopes, and it shall not be brought loose or unpacked.

(4) To mention on their labels the data stipulated in Article (57), and it is not permissible in any case to import the empty containers of these preparations or their packaging free of medicines or their labels, or to make anything of that except after obtaining the approval of the Ministry of Public Health.

◆ Marketing Authorization

Regulated by ministerial decrees numbers 425

For the year 2015, 645/2016 and 180/2019

◆ Medicine Safety (post-marketing)

The structures and the processes of pharmacovigilance in Egypt has to be implemented following the Good Pharmacovigilance practice. They can be achieved by having well-functioning pharmacovigilance system and a quality system for the pharmacovigilance, which are described in details in EMA GVP module I- Pharmacovigilance systems and their quality systems "I.B. Structures and processes''. This topic explains multiple items that shall be considered in implementation, such as Quality cycles, overall quality objectives for PV, principles for GVP, responsibilities for the quality system within an organization, training of personnel for PV, facilities and equipment for pharmacovigilance, specific quality system procedures and processes, including compliance managements by MAHs and EDA. In addition to record control, documentation of quality systems by MAHs and EDA, monitoring of the performance and the effectiveness of the PV system and its quality systems, and preparedness planning for PV in public health emergencies

④ **Drug Pricing**

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

With inadequate insurance coverage and high out-of-pocket health expenditure, income level becomes a major determinant of access to medication. Rural areas are at higher risk of facing inadequate access to healthcare due to their higher percentage of poverty. Adult literacy rate is 61%; illiteracy is particularly high in rural areas (WHO, 2005). Lack of health awareness, negligence and reluctance to seek medical advice indirectly influence access to healthcare services and, accordingly, Pricing is controlled through decrees

Resolution (373 of 2009) regarding drug pricing, issued by the Minister of Health, distinguishes in the pricing process between two types of drugs: the original drug, and the identical or generic drug. The original medicine is the medicine that contains a new active substance, while the generic medicine is the medicine that matches the original medicine in terms of effectiveness, but is cheaper.

According to the new decision, the original drug sale price will be determined on the basis of the lowest selling price to the public in the countries in which it is traded, after deducting 10% from this price.

Attached to the decision is an indicative list of 36 countries that the Ministry of Health will contact to confirm the price of the drug in them

The selling price of a similar drug is often determined on the basis of the original drug price after deducting fixed percentages from it. The decision defines three classes of generics based on the quality approvals obtained by the manufacturer. The first category of similar medicines is priced at 30% less than the price of the original medicine if that preparation is manufactured in one of the factories licensed by the Ministry of Health with the approval of the factory from one of the foreign or international bodies that the decision considered as a quality standard. The second category of similar medicines is priced at 40% less than the price of the original product for the rest of the factories licensed by the Ministry of Health - bearing in mind that this category exists only until 2020, which is the end date of the period granted by the Ministry to factories to obtain quality approvals or face closure.

Finally, the third category of similar medicines is priced at 60% less than the price of the original product, for the preparations of companies that do not own factories and manufacture with third parties.

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 310000(2023)
2. Number of GMP inspector (National & Local) 2000(2022)
3. Number of pharmaceutical manufacturers / manufacturing sites 180(2020)
4. Number of traditional medicine manufacturers / manufacturing sites (year)
5. Number of pharmaceutical importers (year)
6. Number of pharmaceutical wholesalers (year)

※About the Hospital pharmacy only, if possible;

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.

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

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

Primary 5years

Secondary 3years

High school 3years

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

University / college: 6years

Professional education: 5years

Practical training: 1years

Duration of training by each facility: years

Hospital pharmacy: weeks

Community pharmacy: 1000 hours

Pharmaceutical company: weeks

Others: weeks

Age at graduation: 23-24years 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

_____

* 1000 hours of retail experience

_____

（5）Number of pharmaceutical university or college graduates:

20000 people / per year

The alumni's placement rate (%)

a. Hospital: 10 %

b. Community Pharmacy: 50 %

c. Government Organization: 20 %

d. Enterprise: 10 %

e. Others: 10 %

⑧ **ADR(Adverse Drug Reaction) report**

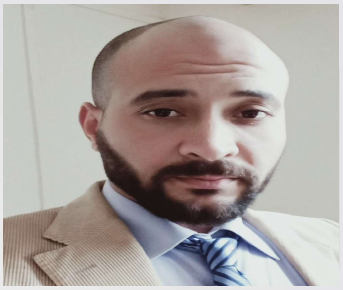
Please describe the flow of reporting system (from a medical institution to an administrative agency), when a severe ADR is detected in a medical institution. Describe specifically the rule and responsibility of each organization (an administrative agency / a medical institution), and their collaboration/cooperation.

The Egyptian Pharmaceutical Vigilance Center (EPVC) has been established at the Central Administration for Pharmaceutical Affairs (CAPA) - Ministry Of Health & Population in December 2009.

The center is responsible for the collection, evaluation and assessment of information about the safety of pharmaceutical products and Medical Devices marketed in Egypt.

The center is divided to Pharmacovigilance Department, Medical Device Safety Department & Biocidal Vigilance Department. Cosmetics & Veterinary Vigilance Departments are under construction.

Regional centers have been established in Alexandria, Cairo and Sohag.



Egypt

Central administration for pharmaceutical affairs

Mohamed Fadel Mohamed Diab

1. Introduction of the work

(1) I belong to the central administration for pharmaceutical affairs(CAPA) which is a section of the Egyptian ministry of health concerned with safe and efficient drug administration within Egyptian territories

(2) Working in CAPA for about 12 years now

(3) I am engaged in governmental audit and training

(4) Pharmacists work in drug dispensing in community pharmacies, clinical pharmacy in hospitals, regulatory work, food audit, pharmaceutical training and teaching

2. Good Practice

- I set the checklist for custom precautionary clearance of medical devices in the Egyptian ministry of health
- I pursued a big case as a junior drug inspector where I found a large amount of counterfeit albumin which I prevented from entering the Egyptian market(4 large containers)
- I introduced clinical nutrition course to Egyptian ministry of health

3. Difficulties/Lessons Learned from Past Experience

- A big problem which faces my work is financial needs and small investment in facilities and personnel and this is a chronic problem
- we do not apply real risk management
- I tried in the past to introduce drug tracking and tracing software but not yet

4. Your interests

(1)Regulation of drugs and medical devices in Japan

(2)How is regulatory work implemented in such a successful experience

(3)What can we implement and benefit from in Egypt

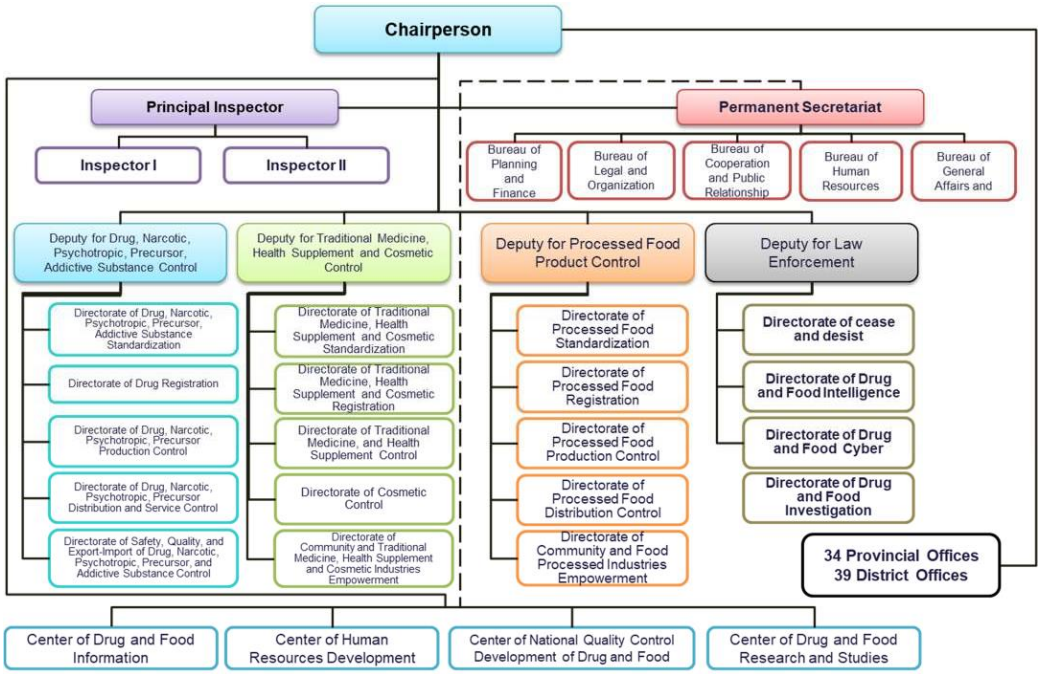
4. Indonesia

Part I: INFORMATION SHEET

Regulatory Systems on Ensuring Access to Quality Medicines
(JFY 2023)

Name	:	Fauziah Ridho
Country	:	Indonesia
Organization	:	Indonesian Food and Drug Authority (Badan POM)
Departement/ Division	:	Directorate of Drugs, Narcotics, Psychotropics, Precursors, Addictive Substances Standardization

1. Organization Chart



The Indonesian FDA (Badan POM) organizational chart at national & provincial/district levels

The Indonesian FDA is assigned and functions as a national regulatory authority on pharmaceutical administration in Indonesia. Indonesian FDA is a National Regulatory Authority (NRA) on Drugs and Food in Indonesia that administers government affairs in the sectors of a drug, traditional medicine, health supplement, cosmetic, and processed food control, which is responsible directly to the President.

To address the current challenges in drug control, the President of the Republic of Indonesia released the legal basis to strengthen medicine control, which has effectively empowered the Indonesian FDA, particularly in law enforcement and improving drug and food control effectiveness.

There are 3 Deputies under the Indonesian FDA Chairperson responsible for specific products and 1 Deputy for Law Enforcement. Concerning Indonesia's large territory, the Indonesian FDA has extensive coverage; thus, we are supported by 34 regional offices at the provincial level and 39 district offices in smaller cities. The total number of staff is approximately 5.000 across the country, and the number is increasing gradually with the commitment of the Indonesian Government to strengthen drug and food control in Indonesia continuously.

Vission:

Drugs and food are safe, quality, and competitive to realize a sovereign developed Indonesia independent and have a personality based on cooperation.

Mission:

1. Build excellent human resources related to drugs and food by developing partnerships with all components of the nation to improve the quality of Indonesian people.
2. Facilitating the acceleration of the development of the drug and food business world by taking sides with MSMEs to build a productive and competitive economic structure for the nation's independence.
3. Increase the effectiveness of drug and food control and law enforcement of drug and food crimes through the synergy of the central and regional governments within the framework of the Unitary State to protect the whole nation and provide a sense of security to all citizens.
4. Clean, effective, and reliable government management to provide excellent public services in drugs and food.

2. Legislation on Pharmaceutical administration

At the national level, legislation on pharmaceutical administration is conducted by the Indonesian FDA under the Deputy for Drug, Narcotic, Psychotropic, Precursor, and Addictive Substance Control. The technical implementation of drug control locally is conducted by provincial/district offices in 34 provinces.

a. National Level
   - Presidential Decree No. 80/2017 regarding BPOM (INDONESIAN FDA) to strengthen regulatory function on law enforcement administered by President
   - Presidential Instruction No. 3/2017 regarding the Drug and Food Control Effectiveness Improvement administered by President

b. Local Level
   - Regulation of The Indonesian FDA No. 21/2020 on Organization in the Indonesian FDA administered by The Chairperson of The Indonesian FDA
   - Regulation of The Indonesian FDA No. 23/2021 on the amendment to Regulation of The Indonesian FDA No. 22/2020 regarding the Organization Technical Unit In the Indonesian FDA administered by The Chairperson of The Indonesian FDA

c. International Level:
   - PIC/s member No.41, on 1st July 2012
   - ICH observer
   - ASEAN Consultative Committee on Standards and Quality ACCSQ-PPWG member
   - APEC-LSIF RHSC member since 2013
   - South East Asia Regulatory Network (SEARN) member
   - International Pharmaceutical Regulators Programme (IPRP) member since May 2020

3. Regulatory/Administrative Services

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

a. Pharmaceutical Manufacturing

Standard	:	Regulation of the Chairperson of The Indonesian FDA on Indonesian GMP Guideline, 2018 edition
Administered by	:	Directorate of Drug, Narcotic, Psychotropic, Precursor Production Control

b. Drug Import/Export

Standard : Regulation of the Minister of Health and Regulation of the Chairperson of The Indonesian FDA on Export and Import of Drug, Narcotic, Psychotropic, and Precursor

Administered by : Directorate of Safety, Quality, and Export-Import Control of Drug, Narcotic, Psychotropic, Precursor, and Addictive Substance

c. Marketing Authorization

Standard : Regulation of the Minister of Health on Drug Registration, Regulation of the Chairperson of The Indonesian FDA on Criteria and Procedure of Drug Registration

Administered by : Directorate of Drug Registration

d. Drug Distribution

Standard : Regulation of the Chairperson of The Indonesian FDA on Indonesian GDP Guideline, 2020 edition

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

e. Medicine Safety (post-marketing)

Standard :
a. Regulation of the Minister of Health on Pharmaceutical Industries,
b. Regulation of the Minister of Health on Standard of Pharmaceutical Service in Hospitals,
c. Regulation of the Minister of Health on Standard of Pharmaceutical Service in Public Health Centers,
d. Regulation of the Minister of Health on Standard of Pharmaceutical Service in Pharmacy,
e. Regulation of the Chairperson of The Indonesian FDA on the Implementation of Pharmacovigilance for Pharmaceutical Industry.

Administered by : Directorate of Safety, Quality, and Export-Import Control of Drug, Narcotic, Psychotropic, Precursor, and Addictive Substance

f. Relief System for Adverse Drug Reactions

Only for COVID-19 Vaccine and administered by the Ministry of Health and Social Security Health Agency

Standard : Regulation of the Minister of Health on Implementation of Vaccination in order to Countermeasures COVID-19 Pandemic

4. <u>Drug Pricing</u>

Drug pricing policy is regulated and controlled by Ministry of Health.

5. <u>Statistic Data</u>

1	Number of pharmacists	:	± 77.000 – 82.000
2	Number of GMP inspector (National & Local)	:	± 165
3	Number of pharmaceutical manufacturers / manufacturing sites	:	± 240
4	Number of traditional medicine manufacturers / manufacturing sites	:	± 130
5	Number of pharmaceutical importers	:	± 85

6 Number of pharmaceutical wholesalers : ± 2.200

6. Education and License of Pharmacist 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	:	4 years
Professional education	:	1 years (including practical training in national regulatory authority, 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, Indonesian Pharmaceutical Competency Exam) and practical exam (1 day, Objective Structured Clinical Examination)

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

5 Number of pharmaceutical university or college graduates
± 2.000 - 2.500 people/per year

7. ADR (Adverse Drug Reaction) Report

The monitoring system of ADR report conducted by The Indonesian FDA (Badan POM) consists of:

a. Spontaneous reporting from health care professionals using Yellow Form (post mail to Badan POM), email to pv-center@pom.go.id or online reporting (http://e-meso.pom.go.id).
b. Reporting from pharmaceutical industries, consists of:
   i. Spontaneous reporting, using post mail to Badan POM, email to pv-center@pom.go.id or online reporting (http://e-meso.pom.go.id);
   ii. Periodic safety update report;
   iii. Reporting of post marketing safety study;
   iv. Reporting of scientific publications/literature;
   v. Reporting of NRA regulatory action in other country;
   vi. Reporting of Marketing Authorization Holder action in other country;
   vii. Reporting of the risk management plan.

   Reporting for points (b) to (g), using post mail to Badan POM or email to: pv-center@pom.go.id.

The rule and responsibility for ADR report as follows:

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

Inception Report

Fauziah Ridho, S.Farm, M.Si.

Directorate of Drugs, Narcotics, Psychotropics, Precursors, Addictive Substances Standardization

The Indonesian FDA

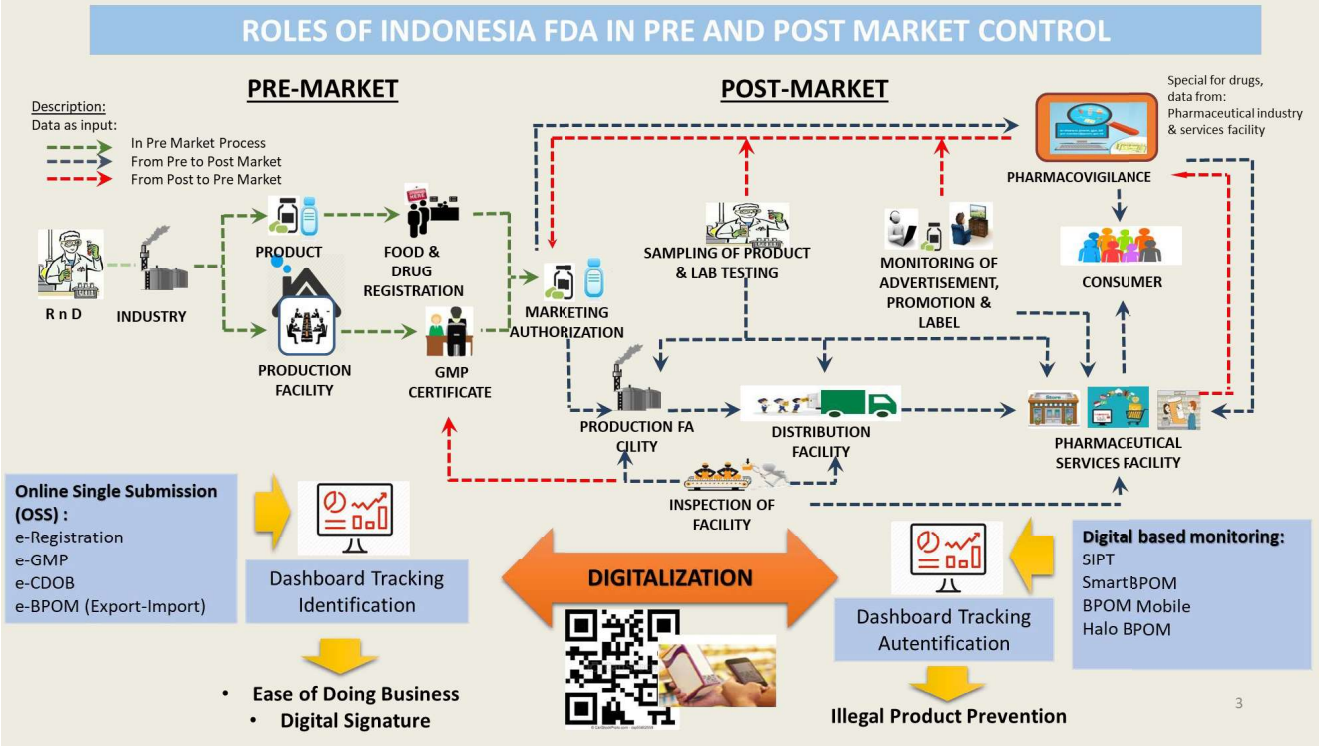
JICA Knowledge Co-Creation Program

Regulatory System on Ensuring Access to Quality Medicines
Japan, July 6 – August 11, 2023

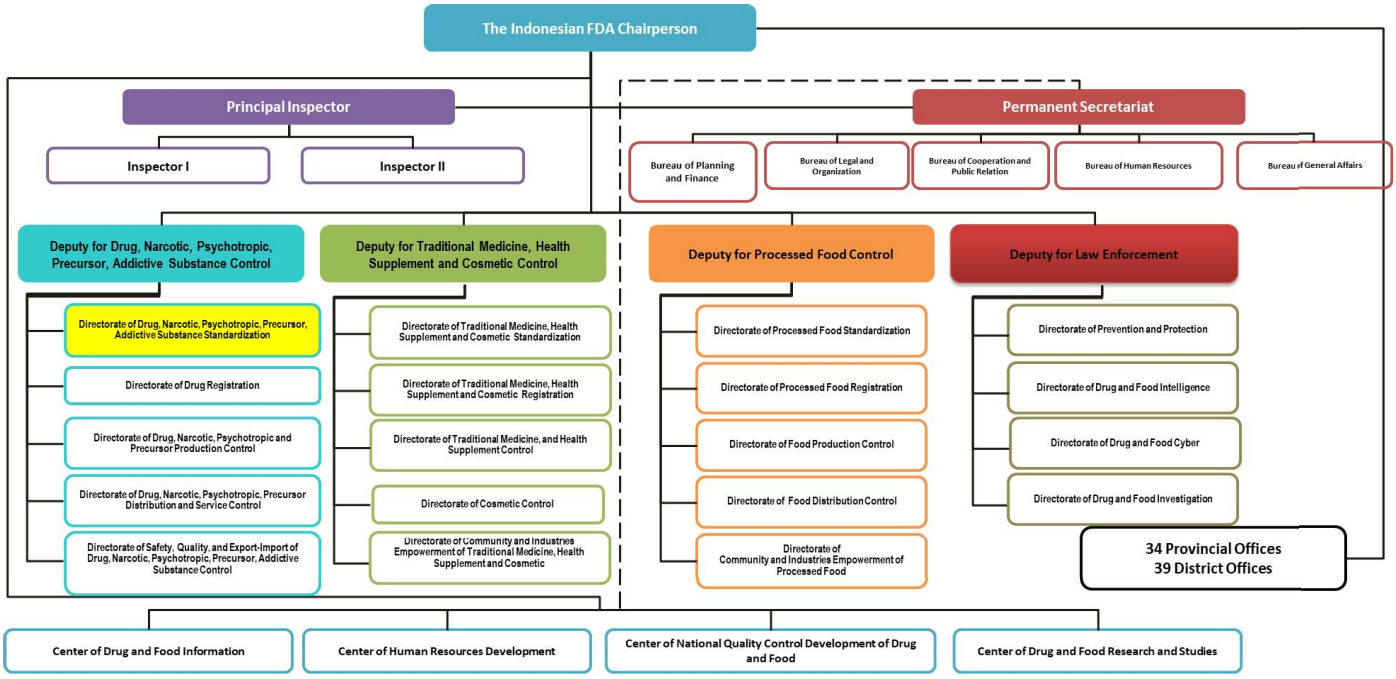
Outline

- Introduction
- Good Practice
- Difficulties/Lessons Learned from Past Experience
- Interests

1. INTRODUCTION



The Indonesian FDA Profile



Directorate of Drugs, Narcotics, Psychotropics, Precursors, Addictive Substances Standardization

The Directorate of Drugs, Narcotics, Psychotropics, Precursors, Addictive Substances Standardization consists of 4 (four) teams, namely:

- Directore of Drugs, Narcotics, Psychotropics, Precursors, Addictive Substances Standardization
  - Team for Preparation and Dissemination of Quality Standardization of Medicines, Drug Materials, and NPP
  - Team for Preparation and Dissemination of Standardization of Efficacy and Safety of Drugs
  - Team for Preparation and Dissemination of Standardization of ONPP Production, Distribution and Materials and Information on Tobacco Products
  - Team for Compilation of Quality of Drug Control Policy and Strategic Studies in the Drug Sector of Narcotics

Job Tenure and Regulatory Services 2019 - Now

1. Preparation of materials and implementation of policies
2. Preparation of norms, standards, procedures, criteria
3. Implementation of technical guidance and supervision
4. Monitoring, evaluation, and reporting of implementation of Standardization Quality of Drugs, NPP

Analytical method for the COVID-19 vaccine

Guidelines for radiopharmaceutical quality assessment

Roles and Position of Pharmacists in Indonesia

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

Undertaking pharmaceutical work in production of pharmaceutical preparations → ensuring compliance with the GMP (responsible person in production, QC, and QA Departement)

Undertaking pharmaceutical work in distribution of pharmaceutical preparations → ensuring compliance with the GDP (responsible person in drug distribution facility)

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)

International Organization for Standardization ISO 9001:2015

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

2. GOOD PRACTICE: REGULATION MAKING

Drafting
Identification of legislative needs, prepare materials for regulation

Discussion
Discussion of regulatory content with internal or related stakeholders

Public Consultation
Public consultations are conducted to solicit input from stakeholders on the draft regulation that has been prepared

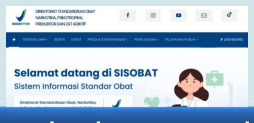
Harmonization
To harmonize and not overlap with other regulations

Socialization
Publication and dissemination of regulation

jdih.pom.go.id

standarobat.pom.go.id

3. DIFFICULTIES/LESSONS LEARNED FROM PAST EXPERIENCE

Unavailable regulations for health emergencies	• **Needs making regulations for health emergencies** • Emergency Use Authorization (EUA) • Analytical method for the COVID-19 drugs and vaccines • Guideline for Lot release vaccine
There are issues related to cases of acute kidney failure in children, which are thought to be caused by cough syrup contaminated with EG and DEG from drug solvents.	• Pharmacovigilance system strengthening • Strengthening Quality Control in the Pharmaceutical Industry • Strengthening Pre-Post Market Supervision and Enforcement • Regulatory strengthening
The lack of equal understanding on drug legislation	• **Launching information system application**  standarobat.pom.go.id

INTEREST

The regulatory management in Japan for access to quality medicines, including the regulatory system, as well as trends of international collaboration among regulatory authorities

Quality control of medicines and medicinal substances in Japan, especially for drugs such as radiopharmaceuticals, stem cells, and biosimilars

The process of drafting drug regulations in Japan and Japanese collaboration with stakeholders

TERIMA KASIH
THANK YOU
ありがとうございます

5. Laos

COUNTRY REPORT

FOR

Regulatory Systems on Ensuring Access to Quality Medicine

(JFY 2023)

(July 6 – August 11, 2023)

Tokyo, JAPAN

Mrs. Soutthida VONGSAVATH

Technical officer

Ministry of Health – Lao P.D.R

Drug and Medical Device Control Division, Food and Drug Department

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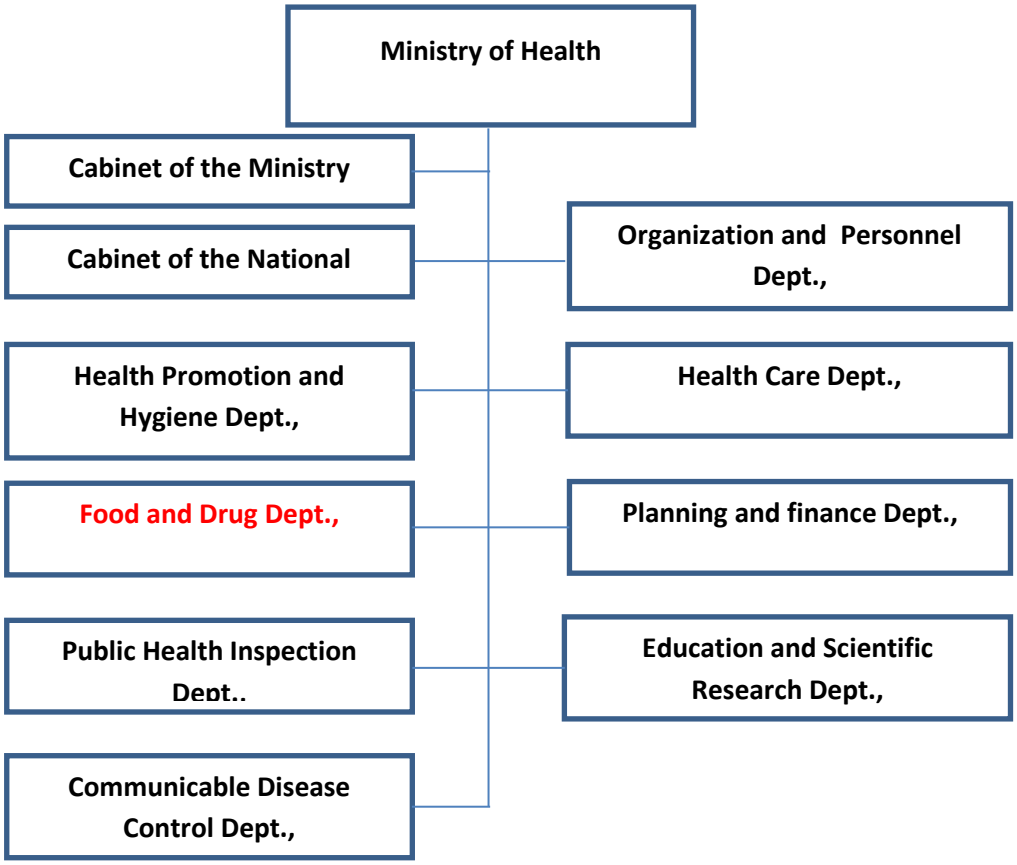
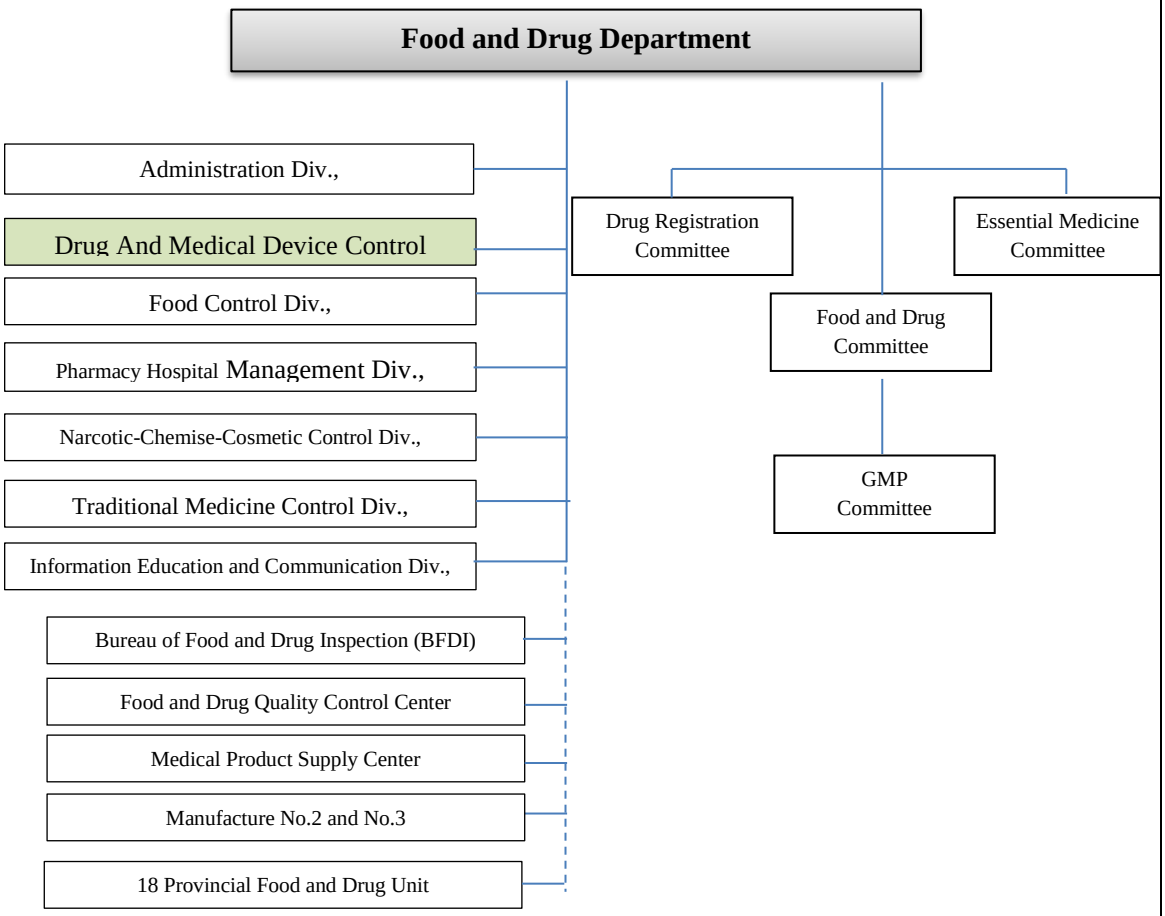
1. Organizational Chart



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

Food and Drug Organization Chart



◆ **Vision:**

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

◆ **Mission:**

- Develop and implementing strategy and Policy

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

The Food and Drug has responsibility for consumer protection on food and drug based on the Forth MoH's action plan, In the Organizational structure of the food and drug Department there are seven divisions in the organization chart, for the Drug Control Division is a one in Charge of the Pharmaceutical Regulatory Systems on Ensuring Access to Quality Medicine and for the Pharmacy Hospital Management Division Ensuring access the Essential medicines, Rational use of medicines and Pharmacovigillance in Health facility.

2. Legislation on Pharmaceutical administration

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

1. Revised National Drug Policies, dated on 13/8/2003
2. Revised Drug and Medical Product law issued in 21 December 2011
3. Degree for National Health Insurance No. 470/Gov., dated 17 Oct 2012
4. Degree for Traditional Medicine No. 155, dated 30 Sep 2003
5. Regulation for Drug registration No. 1441, dated 13 Aug 2003
6. Regulation Establish Factory and Company No. 1820, dated 25 Aug 2017
7. Regulation for Pharmacy No. 2922, dated 21 Sep 2016
8. Regulation for good manufacturing practice and quality control of drugs No. 1021, dated 11 Aug 1999
9. Regulation on Good Manufacturing Practice No. 937/MOH, 12/07/2004

10. Regulation for disposal of medicines including vaccines No. 1862, dated 05 Aug 2016
11. Decision/Approval based on National medicine policy main goal and related components
12. Regulation of Donation of Drugs and Medical Product No.2579/MoH dated 12th Nov 2003 concerning Drug and Medical Equipment Donation.
13. Regulation on the banned drug in Lao No.1018/MOH in 2003
14. Regulation on specific controlled medicine and uncontrolled and OTC Drug No.2580/MOH, on 25/11/2002
15. Regulation on concerning Food, Drug and Medical Equipment Advertisement No. 2581/MOH in 2003
16. Revolving Drug Fund Guideline
17. Lao Pharmacovigillance Guideline
18. Good Manufacturing Practice Guideline
19. The ASEAN common technical dossier (ACTD) for the registration of the pharmaceuticals for the human use.
20. SOP for recall Drug and medical Product
21. SOP for fast track registration
22. Quality Management System (QMS) Manual
23. Good Regulatory Practice (GRP) Guideline
24. Draft revised Drug regulation
25. Draft Medical device regulation

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

3. Regulatory Services

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

◆ **Pharmaceutical Manufacturing**

- **Licensing of manufacturing site:**

Licensing and Registration is a pre-marketing authorization activity with belong to the responsibility of Drug business Control Division. Within this Division, the licensing for manufacturing site and the qualification of the product activities are under to control of the Licensing Unit.

- **Licensing pharmaceutical Company and pharmacy:**

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

- **Drug Registration System:**

According to the regulation No. 1441, on August 13, 2003 covering drug registration in Lao PDR, every drug before marketing must be registered. The drug selection for registration is mainly based on National Essential Medicine List and needs of hospitals.
Now the drug products has registered about 2 372 items (June,2023), there are the import products 1 935 items and the local production 437 items and traditional medicines and Health supplement registered more 600 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 as following detail:

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

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

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

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

◆Marketing Authorization

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

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

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

This Committee consists of Food and Drug Department, Finance Department, Cabinet, Department Health Care and Rehabilitation, Department of Health Education and research, Department of Planning and Cooperation, and other related Ministry. Under Food and Drug Department, the Medical Product Supply Center is appointed as a

coordination agency for facilitating procurement process of medicines and medical products.

In the past, decentralized system was use for procurement of medicines and medical products, but now the food and Drug department and the Medical Product Supply Center started central tendering procurement for the 5 central hospital and 17 provinces.

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

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

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

1. Order in the Pharmacy
2. Banned drug
3. Availability of ED with INN + clear label
4. Quality of Drug + Expiry date
5. The correct bill
6. Drug dispensing
7. Knowledge of drugs sellers
8. Prescription for antibiotics drug
9. Essential equipment and documents
10. Presence of technical staff

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

4. Drug Pricing

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

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

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

5. Statistic Data

a/. Number of Pharmacists

(Average number of Pharmacists)

Data 3812

Years 2023

b/. Number of GMP inspection

Data 27 (only Drug Product Manufacturer Committee)

Years 2023

c/. Number of Pharmaceutical manufacturers/ manufacturing sites

Data 13

Years 2023

d/. Number of traditional medicine manufacturers/ manufacturing sites

Data 5

Years 2023

e/. Number of traditional medicine household

Data 35

Years 2023

f/.Number of pharmaceutical importers

Data 104

Years 2023

g/. Number of pharmaceutical wholesalers

Data 12

Years 2023

6. Information on your hospital pharmacy

N/A

7. Education and License of Pharmacists in your country

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

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

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

Items	Number
University / college:	5 years
Professional education:	2 years
Practical training:	2 years
Duration of training by each facility:	0.3 year
Hospital pharmacy:	4 weeks
Community pharmacy:	4 weeks
Pharmaceutical company:	4 weeks
Others:	4 weeks
Age at graduation:	25 years old

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

Items	Number
Academic Exams	2 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	15 %
Community Pharmacy	40 %
Government Organization	30 %
Enterprise	15 %
Others	5 %

References:

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

LAO PDR

Food and Drug Department

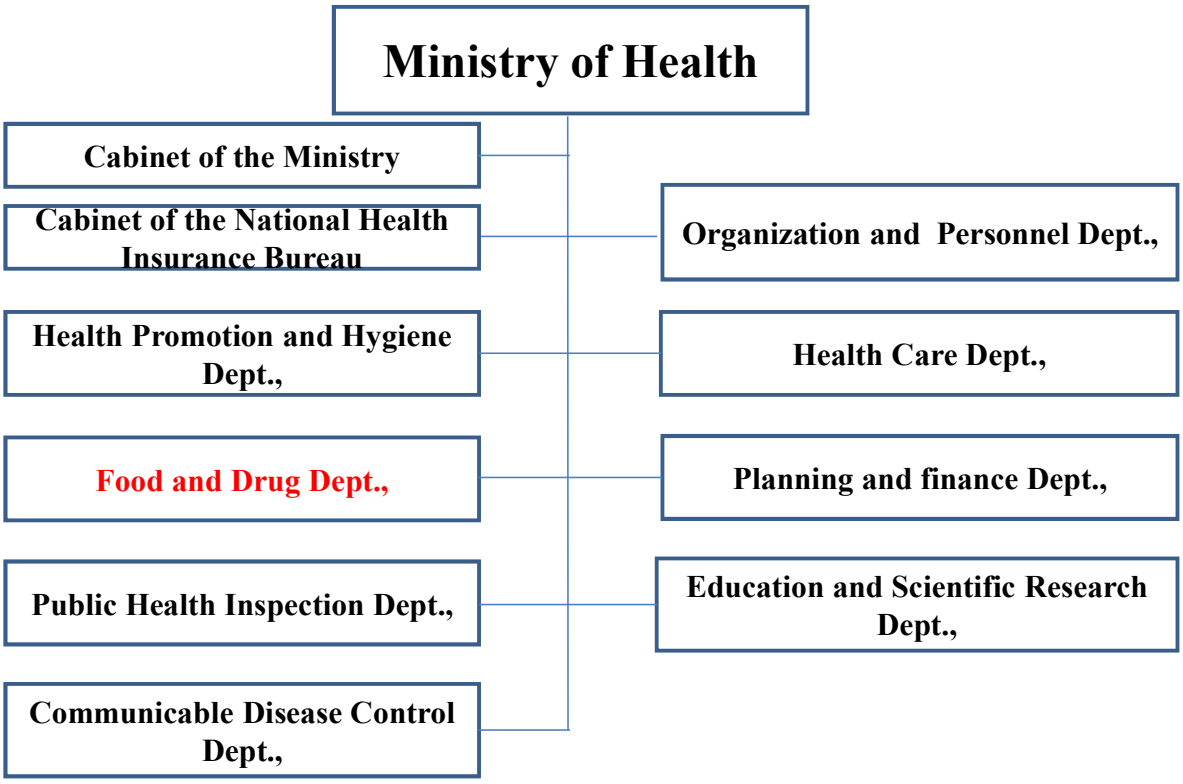
Ministry of Health

Mrs Soutthida VONGSAVATH

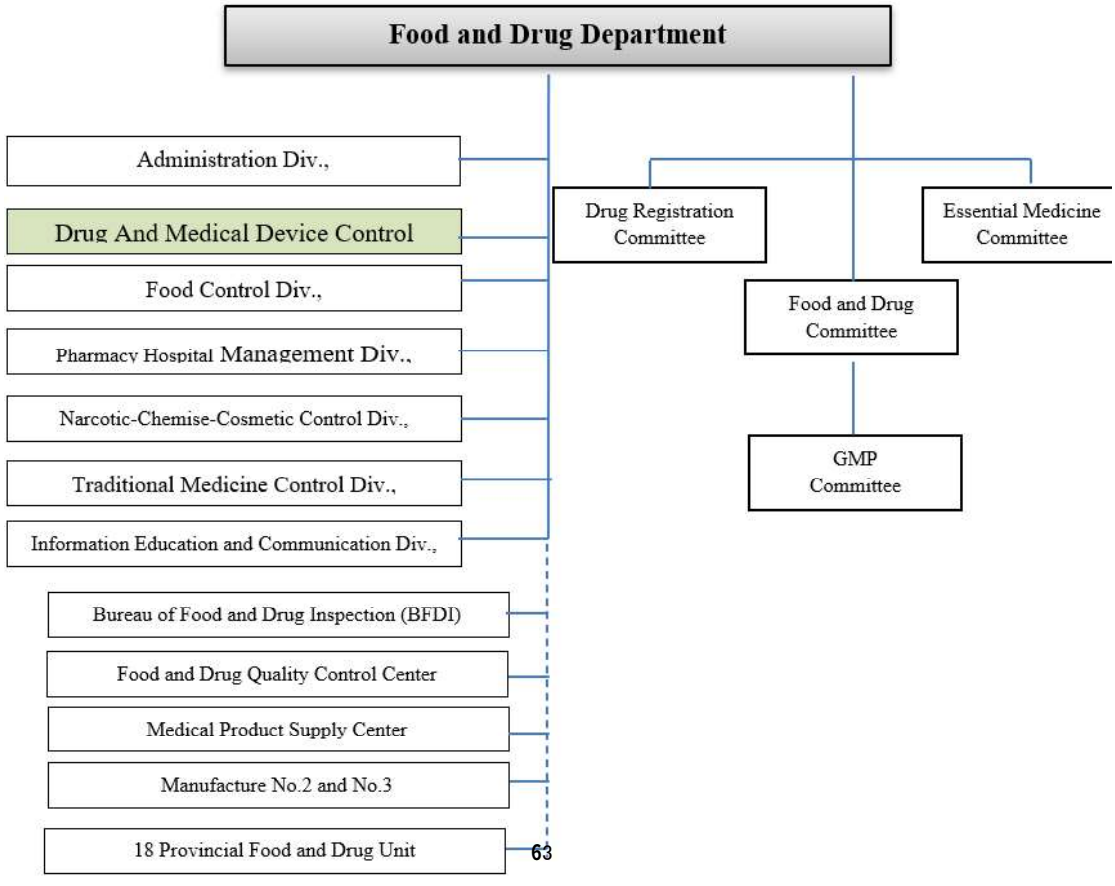
Outline

I. MoH and FDD Organization chart
II. Regulatory services that engaged in
III. roles and position of pharmacists in my country
IV. Achievements
V. Difficulties/Lessons Learned from Past Experience
VI. Challenge
VII. My interests

Organization Chart of MoH



Organization Chart of FDD



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.

Policy, Law, Regulation, SOP and Guideline

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

Policy, Law, Regulation, SOP and Guideline

- Regulation on the banned drug in Lao No.1018/MoH in 2003.
- Regulation of Donation of Drugs and Medical Product No.2579/MoH dated 12th Nov 2003.
- Regulation on specific controlled medicine and uncontrolled and OTC Drug No.2580/MOH, on 25/11/2002
- Regulation on concerning Food, Drug and Medical Equipment Advertisement No. 2581/MOH in 2003
- Revised Drug regulation 2023
- Regulation on the medical device registration 2023
- Regulation on Price control 2023

I Introduction of the work

Job tenure: 8 years

Engaged Regulatory services in:

- Evaluation on Import Permit of Drug and medical devices
- Evaluation and Monitoring of Good Pharmacy Practice of Private Pharmacy
- Evaluation on Application of Drug destruction

II. **Roles and position of pharmacists in Laos**

1.**Pharmacists in hospitals**
- Validate prescription and drug dispensation.
- Manage the supply chain of drug store

2. **Pharmacists in Research**

-Carrying out in analytical research of drugs and clinical trial

3. **QA,QC and Production staff, pharmacist license holder** in pharmaceutical factories

4. **Academic pharmacists** (Faculty of pharmacy, UHS)

5. **Sale, pharmacist license holder** in pharmaceutical companies

6. In-charge in **private pharmacies**

-Manage GPP and GSP of pharmacies

7. **Technical officer at Ministry of Health**

8. **GMP inspector**

III. Good Practice

❑Achievements

- Revised Drug regulation, 2023
- Regulation on the medical device registration, 2023
- Regulation on Price control, 2023
- Revised indicator of GPP inspection
- GPP training to 108 pharmacies in 5 provinces (VTE, Vientiane, LPB, CPS, SVK)
- Completed monitoring GPP implementation after training

IV. Difficulties/Lessons learned

- Limited Knowledge of GPP
- Insufficient budget to improve the premise for the Owner
- GPP inspection
- Unregister medicines circulated in both public and private sector
- Drug Price in whole country is very different
- Review of Biological products and New Drug
- Availability Essential Medicine in some health facility under 85%

V. Challenge

- Limited resource
- Insufficiency of English skills
- Limited expertise on review biological product
- Lack of experience to implement the price control
- Preparedness to new Online registration of drug products

VI. My interests

- The implementation of Price control
- Risk management plan
- Drug licensing and approval system
- Countermeasure against Counterfeit

Thank you

ຂອບໃຈ

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6. Timor-Leste

PowerPoint Material only

Ministry of Health Timor-Leste

Delfim Da C.X.Ferreira
National Director of Pharmacies and Medicines
Head of NRA (Regulatory System)

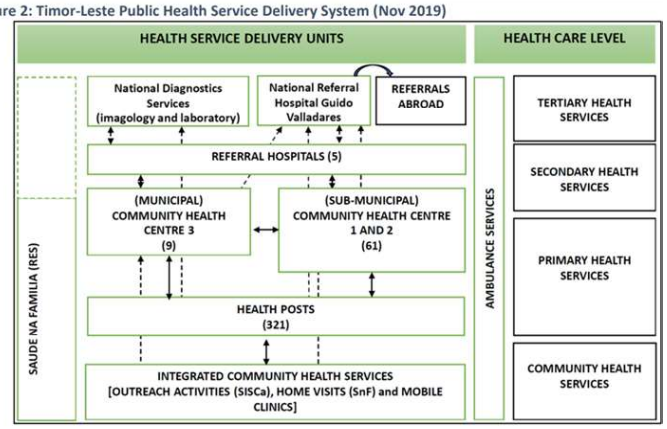
1.Introduction

- ✓ 1.364,242 habitants (2022)
- ✓ Life expectancy at Birth (2022) was total 71.5 years (M) 70 (F) 72.4.
- ✓ 13 Municipalities
- ✓ 1 Autonomy region (RAEOA-Oecusse)

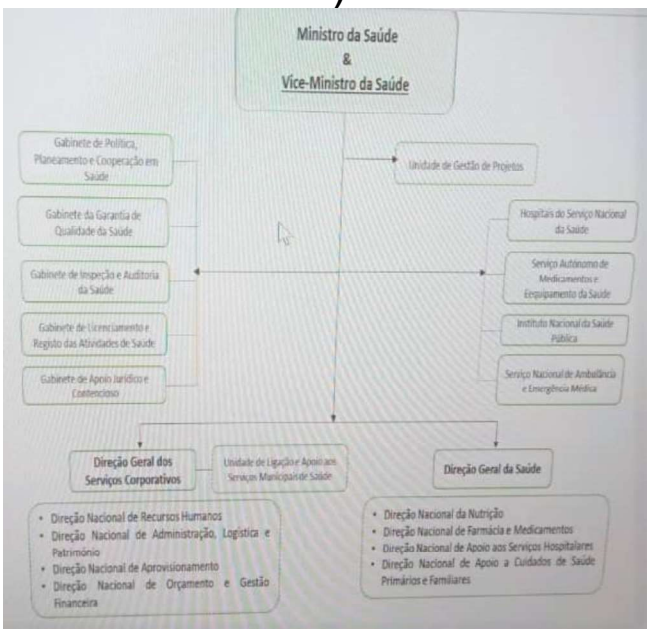
The National Health System and Organic law of MoH Timor-Leste

(8th Government Constitutional)

Figure 2: Timor-Leste Public Health Service Delivery System (Nov 2019)



[20] https://hamutuk.tl/en/profiles/organisation/CCT/



- ✓ Guarantee the availability of the medicines and others pharmaceuticals products for the country needs.
- ✓ Planning and controlling the use of medicines (quality-safety-efficacy) and others pharmaceuticals products for the country.

2.Good Practices and Ongoing Projects

- ✓ TLEML (Essential Medicines List) and STGs implemented
- ✓ International collaborations (TGA Australia, WHO and others SEARN countries)
- ✓ Pre-benchmarking Assessment of WHO experts (ML 1)
- ✓ Timor-Leste Electronic Single Window piloted
- ✓ Attending International and regional training workshop
- ✓ Priority adoption of the NMP appears crucial to improve the regulation of medical products in Timor-Leste.

3. Difficulties/Lessons Learned from Past Experience

Cross-Cutting challenges

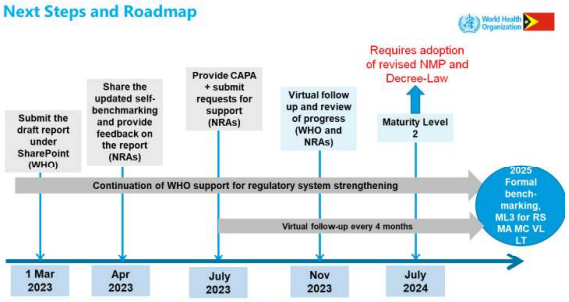
- Examples
  - ✓ Current legal framework outdated
  - ✓ **Stock out of the medicines (frequently)**
  - ✓ **Fragmented organization and duplication of work**
  - ✓ **Inefficient communication within and between the NRAs**
  - ✓ **Absence of Quality Management System**
  - ✓ **Inadequate facilities and IT infrastructure**
  - ✓ Insufficient resources to effectively regulate

4. Your interests

(1) To gain Good Understanding how to developsthe Registration and Marketing Authorization systm

(2) To have Understanding on how to Develops procedures and guideline of maket surveylance and control

(3) Well Understanding on regulatory inspections procedures



独立行政法人 国際協力機構


THANK YOU
OBRIGADO

出典：2023 年度 JICA 課題別研修「適正な医薬品の供給・品質管理・使用に向けた薬事行政」
カントリーレポート

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 contributing 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 フェローの受け入れ、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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