Regulatory Systems on Ensuring Access to Quality Medicines

Country Reports

FY2021

Japan International Corporation of Welfare Services (JICWELS)

Contents

1. Indonesia

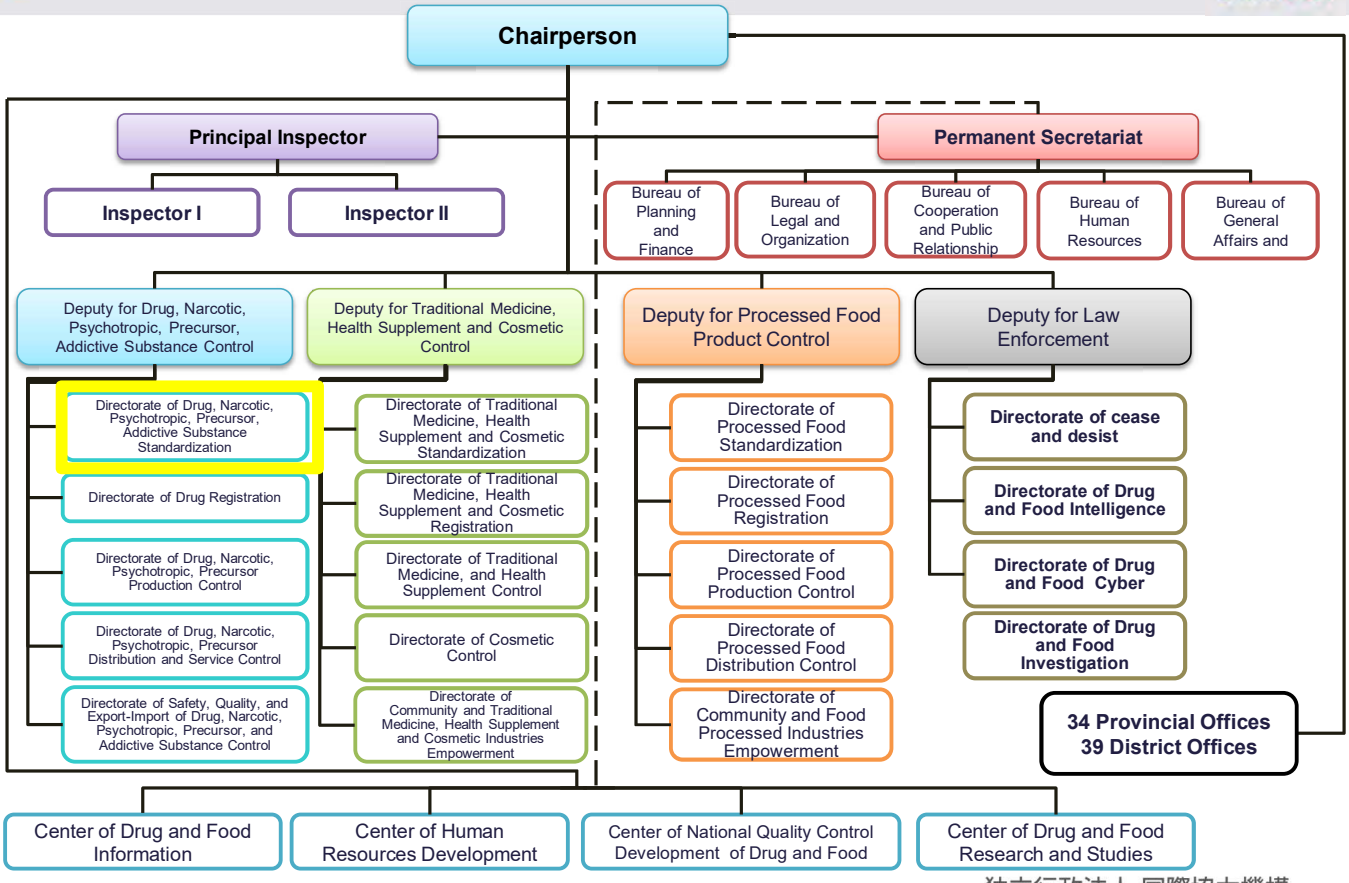
Indonesia

The Indonesian Food and Drug Authority (Badan POM)

Alsya Utami Rahayu

JICA Knowledge Co-Creation Program
Regulatory Systems on Ensuring Access to Quality Medicines
January 25th, 2022

The Indonesian FDA (Badan POM) Structure



Departement Structure

Directorate of Drug, Narcotic, Psychotropic, Precursor, Addictive Substance Standardization, Consist of 3 (three) substance:

- Standardization of Quality Drugs, Drug Ingredients, Narcotics, Psychotropics, and Precursors
- Standardization of Efficacy, Safety, and Information on Drug Products and Drug Ingredients
- Standardization of Production and Distribution of Drugs, Drug Ingredients, Narcotics, Psychotropics, Precursors, and Addictive Substance
- Standardization of Efficacy and Safety of Generic Drugs and Product Information of Addictive Substances
- Standardization of Efficacy and Safety of New Drugs, Biological Products, and New Development Drugs
- Operational Procedure

2019 - Now

Job Tenure and Regulatory Services

- Preparation of materials and implementation of policies
- Preparation of norms, standards, procedures, criteria
- Implementation of technical guidance and supervision
- Monitoring, evaluation, and reporting of implementation of Standardization of Efficacy and Safety of Generic Drugs and Product Information of Addictive Substances

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)

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

Good Practice: Regulation Making

Drafting — Identification of legislative needs, prepare materials for regulation

Discussion — Discussion of regulatory content with internal or related stakeholders

jdih.pom.go.id

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

standarobat.pom.go.id

Socialization — Publication and dissemination of regulation

Difficulties/Lessons Learned from Past Experience

Unavailable regulations for health emergencies

- Needs making regulations for health emergencies
  - *Emergency Use Authorization* (EUA)
  - *Expanded Access Program* (EAP)

The lack of equal understanding on drug legislation

- Launching information system (SISOBAT)

Interest

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

improve my knowledge in roles of Regulatory System on Ensuring Access to Quality Medicines.

Observe and identify process that can be improved in drug regulatory system

Thank You

Terima Kasih

ありがとうございます

Regulatory Systems on Ensuring Access to Quality Medicines (JFY 2021)

Name	:	1. Farida Ami Asviah 2. Alsya Utami Rahayu
Country	:	Indonesia
Organization/ Departement/ Division	:	Indonesian FDA (Badan POM)/ 1. Directorate of Safety, Quality, and Export-Import Control of Drug, Narcotic, Psychotropic, Precursor, and Addictive Substance/Subgroup of Quality Control of Drug, Narcotic, Psychotropic, and Precursor 2. Directorate of Standardization of Drug, Narcotic, Psychotropic, Precursor, and Addictive Substance/ Subgroup of Standardization of Efficacy and Safety of Generic Drugs and Product Information of Addictive Substances

① Organizational Chart

The organizational chart of Indonesian FDA (Badan POM) at national & provincial/district levels (Attachment 1).
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To address the current challenges in drug control, the President of Republic of Indonesia had released the legal basis to strengthen the medicine control which has effectively empowered the Indonesian FDA, particularly in the context of law enforcement and improving the drug and food control effectiveness.

There are 3 Deputies under the Chairperson of Indonesian FDA which responsible on specific products, and also 1 Deputy for Law Enforcement. With regard to Indonesia's large territory, Indonesian FDA has a large coverage thus we are supported by 34 regional offices in 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 continuously strengthen drug and food control in Indonesia.

Vission:

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

Mission:

1. Build excellent human resources related to drug 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 independence of the nation.
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 secure to all citizens.
4. Clean, effective, and reliable government management to provide excellent public services in the field of drug and food.

② Legislation on pharmaceutical administration

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

- 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
- Local Level
  - Regulation of The Indonesian FDA No. 21/2020 regarding Organization in Indonesian FDA administered by The Chairperson of The Indonesian FDA
  - Regulation of The Indonesian FDA No. 23/2021 about amendment to Regulation of The Indonesian FDA No. 22/2020 regarding Organization Techinal Unit In Indonesian FDA administered by The Chairperson of The Indonesian FDA
- 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 Badan POM, under the Deputy for Drug, Narcotic, Psychotropic, Precursor, Addictive Substance Control, which responsible for the administration of:

- Pharmaceutical Manufacturing

  Standard : Regulation of the Head of Badan POM on Indonesian GMP Guideline, 2018 edition

  Administered by : Directorate of Drug, Narcotic, Psychotropic, Precursor Production Control

- Drug Import/Export

  Standard : Regulation of the Minister of Health and Regulation of the Head of Badan POM 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 (Subdirectorate of Export and Import Control of Drug, Narcotic, Psychotropic, and Precursor)

- Marketing Authorization

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

  Administered by : Directorate of Drug Registration

- Drug Distribution

  Standard : Regulation of the Head of Badan POM on Indonesian GDP Guideline, 2020 edition

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

- Medicine Safety (post-marketing)

  Standard : Regulation of the Minister of Health on Pharmaceutical Industries,
  Regulation of the Minister of Health on Standard of Pharmaceutical Service in Hospitals,
  Regulation of the Minister of Health on Standard of Pharmaceutical Service in Public Health Centers,
  Regulation of the Minister of Health on Standard of Pharmaceutical Service in Pharmacy,
  Regulation of the Head of Badan POM 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 (Subdirectorate of Safety Control of Drug, Narcotic, Psychotropic, and Precursor)

- 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 Drug Pricing

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

⑤ Statistic Data

1.	Number of pharmacists:	± 75.000 – 80.000 (2021)
2.	Number of GMP inspector (National & Local):	± 153 (2021)
3.	Number of pharmaceutical manufacturers / manufacturing sites:	± 228 (2021)
4.	Number of traditional medicine manufacturers / manufacturing sites:	± 129 (2021)
5.	Number of pharmaceutical importers:	± 81 (2021)
6.	Number of pharmaceutical wholesalers:	± 2.146 (2021)

⑥ Education and License of Pharmacists in your country

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

Primary:	6 years
Secondary:	3 years
High school:	3 years

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

University / college:	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 Indonesian FDA (Badan POM) consists of:

1. 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).
2. Reporting from pharmaceutical industries, consists of:
   a. Spontaneous reporting, using post mail to Badan POM, email to pv-center@pom.go.id or online reporting (http://e-meso.pom.go.id);
   b. Periodic safety update report;
   c. Reporting of post marketing safety study;
   d. Reporting of scientific publications/literature;
   e. Reporting of NRA regulatory action in other country;
   f. Reporting of Marketing Authorization Holder action in other country;
   g. Reporting of the risk management plan.

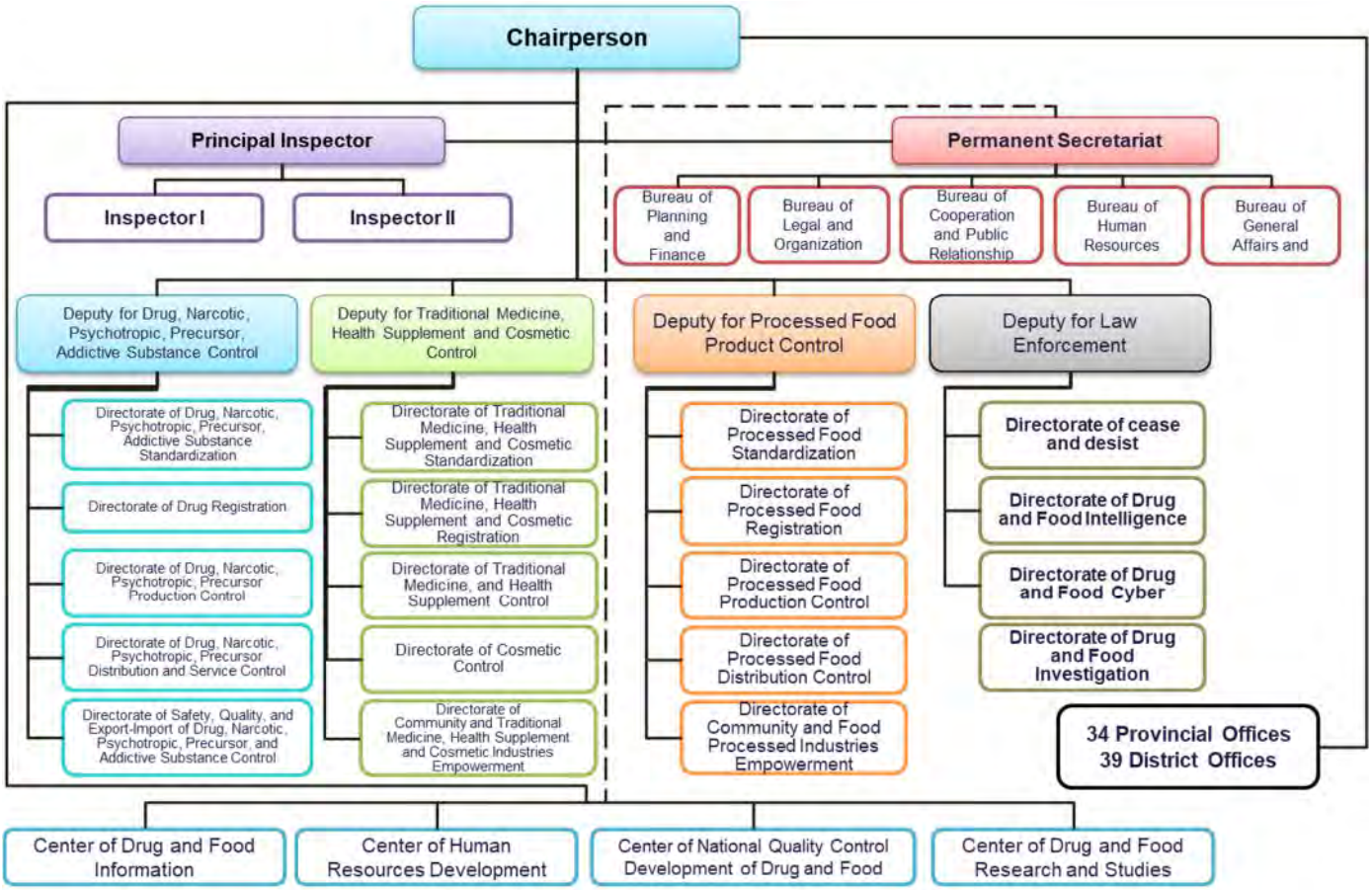
   Reporting for points (b) to (g), using post mail to Badan POM or email to pv-center@pom.go.id.

The rule and responsibility for ADR report as follows:

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

Attachment 1

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



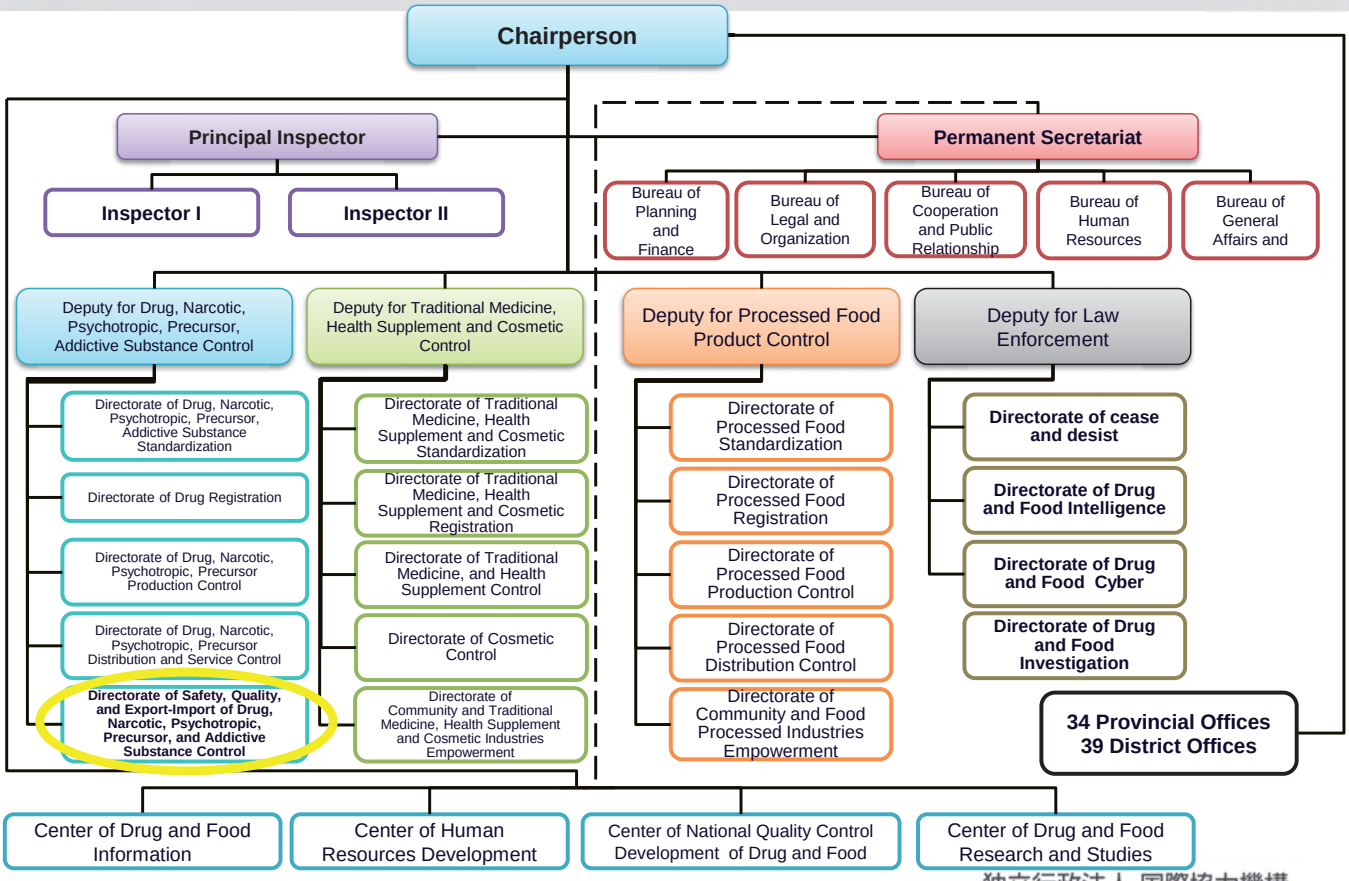
Indonesia

Indonesia FDA (Badan POM)

Farida Ami Asviah

JICA Knowledge Co-Creation Program
Regulatory Systems on Ensuring Access to Quality Medicines
January 25th, 2022

Indonesian FDA (Badan POM) Structure



Departement Structure

Directorate of Safety, Quality, and Export-Import Control of Drug, Narcotic, Psychotropic, Precursor, and Addictive Substance, consist of 4 group:

- Safety Control of Drug, Narcotic, Psychotropic, and Precursor
- **Quality and Product Information Control of Drug, Narcotic, Psychotropic, and Precursor**
  - **Quality Control of Drug, Narcotic, Psychotropic, and Precursor**
  - Product Information Control of Drug, Narcotic, Psychotropic, and Precursor
- Export and Import Control of Drug, Narcotic, Psychotropic, and Precursor
- Tobacco Product Information Control

- ❑ Preparing materials for policy-making and policy implementation in the field of quality control of drug.
- ❑ Preparing norms, standards, procedures, criteria, technical guidance and materials supervision in the field of quality control of drug.
- ❑ Preparing guidance of post market sampling of drug.
- ❑ Evaluating substandard drug reports and taking regulatory actions.
- ❑ Evaluating CAPA of substandard drug which submitted by pharmaceutical industry.
- ❑ Providing national report of quality control of drug.

Job Tenure and Regulatory Services

2010 – February 2018: Directorate of Production Control of Therapeutic Product and Household Medical Supplies

March 2018 – present: Directorate of Safety, Quality, and Export-Import of Drug, Narcotic, Psychotropic, Precursor, Addictive Substance Control

Evaluator of post marketing quality surveillance:

Evaluating substandard drug reports (from provincial/district offices, pharmaceutical industry, public, and other stakeholders).

Propose appropriate regulatory action against substandard drug based on evaluation results.

Roles and Position of Pharmacists in Indonesia

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

Good Practice: Post Market Quality Surveillance

- Combining targeted (risk based) and random sampling strategies

Sampling Policy and Planning

Laboratory Testing

- Regionalization concept to optimize laboratory testing → **on going,** handled by Center of National Quality Control Development of Drug and Food

Regulatory action against substandard drugs

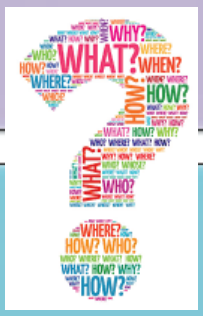
Availability of monographs/ analytical methods

- Updating regulation on the withdrawal and disposal of substandard drugs → **on going,** carried out together with related departments

- Coordinating with related departments for the development of analytical methods and updating of monographs on pharmacopoeia and relevant regulations → **on going**

Difficulties/Lessons Learned from Past Experience

Follow-up of new impurity compound OOS report (previously unknown)



- Needs to develop analytical methods for testing impurities and studies to determine the impurity threshold
- Needs adequate risk assessment to determine appropriate follow-up

Quality control of marketed COVID-19 vaccine with limited data/under research

- Needs intensive communication with the pharmaceutical industry (EUA holder) and related department regarding vaccine quality control

Interest

Regulatory system for post-marketing quality surveillance, including:

Regulation for post-marketing quality surveillance	Quality testing of drugs and vaccines	Regulatory action against substandard drugs

Thank You

Terima Kasih

ありがとうございます

独立行政法人 国際協力機構

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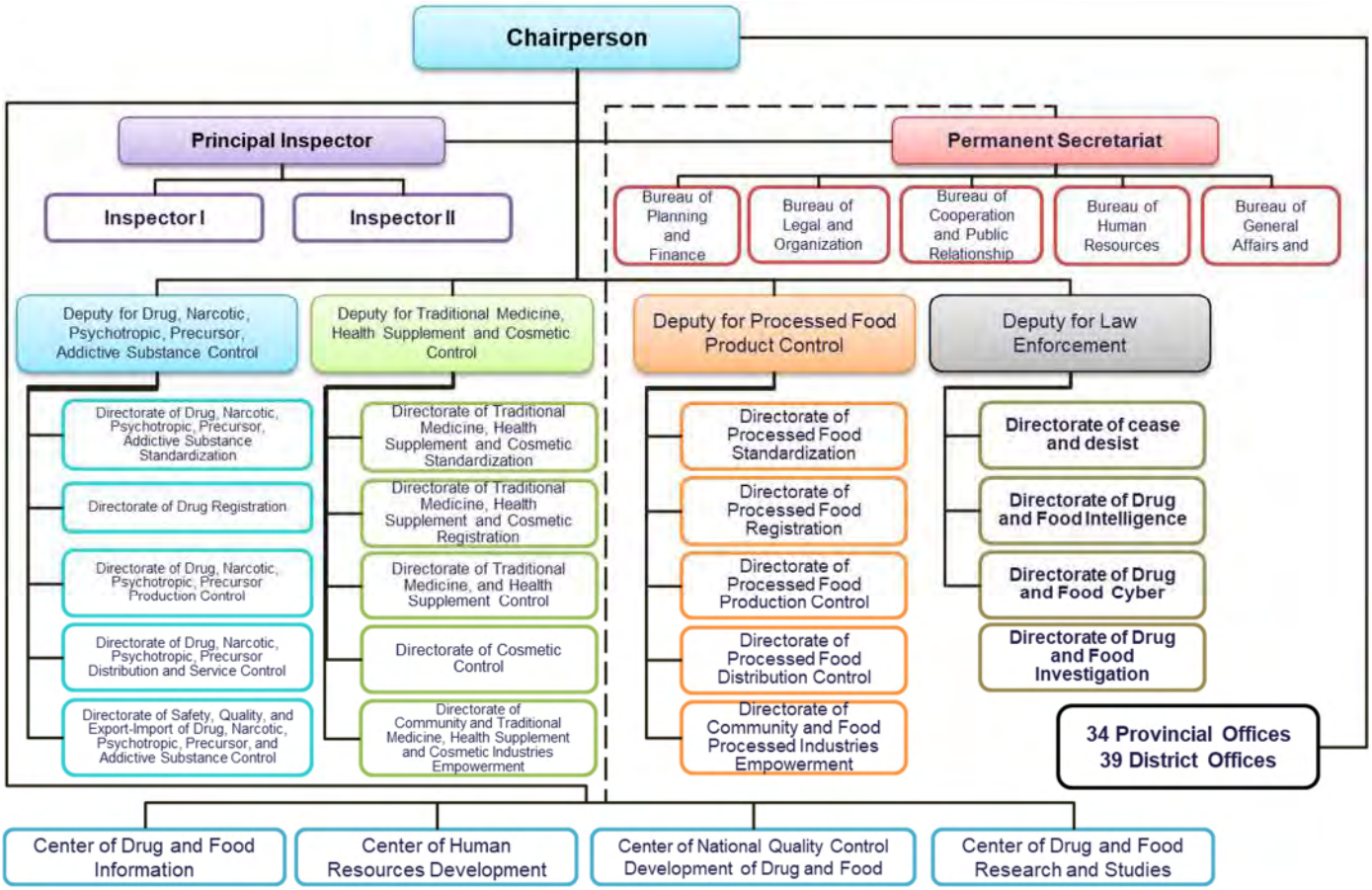
   b. Periodic safety update report;
   c. Reporting of post marketing safety study;
   d. Reporting of scientific publications/literature;
   e. Reporting of NRA regulatory action in other country;
   f. Reporting of Marketing Authorization Holder action in other country;
   g. Reporting of the risk management 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:

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

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



2. Lebanon

Lebanon

Ministry of Public Health

Randa S. Hamadeh

独立行政法人 国際協力機構

1. Introduction of the work

(1) Director of Primary Healthcare and Social Health department & National Essential Drugs Program(EDP) at the Ministry of Public Health(MoPH)

(2) Full time basis with MoPH Since 2001, was assigned as Director of PHC & EDP in 2008.

(3) **My role is more related to regulatory pharmaceutical issues related to PHC since PHC in Lebanon provides packages of healthcare services including acute and chronic drugs based on WHO essential drugs list.**

(4) Pharmacists are part of a multidisciplinary team of healthcare providers in the country. They could run their own pharmacies and they should belong to a national body which is the Order of Pharmacists.

2. Good Practice

- Examples
  - ✓ Achievements:Procurement of essential drugs and vaccines through UNICEF and WHO
  - ✓ Solutions for past problems: Guarantee to use allocated budget for the purpose of drugs procurement since it is earmarked UNICEF and WHO.
  - ✓ On-going projects to deal with current problems: channeling all funds related to PHC drugs through the existing system to prevent parallel system and to strengthen this procurement mechanism which guarantee transparency .
  - ✓ Successful countermeasures against problems:M&E system in place, decision making commitment.

3. Difficulties/Lessons Learned from Past Experience

- Examples
  - ✓ Problems that cannot be improved or solved: People's trust and acceptability toward generic drugs
  - ✓ Failed countermeasures to deal with the problems: Communication lines with the private pharmaceutical sector.
  - ✓ Emerging or Re-emerging Problems, if any

4. Your interests

(1) Share experiences with other countries on PHC generic medications.

(2) Help identify some gaps regarding healthcare providers capacities to advocate for generic drugs

Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2021）

Name: Randa S. Hamadeh/Myriam Watfa
Country: **Lebanon**
Organization/Department/Division: **Ministry of Public Health/ Pharmacy Service + Quality Assurance of Pharmaceutical Products Program**

① Organizational Chart

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

You may find the organizational chart of the different affiliated departments/services within the Ministry of Public Health (MoPH) in this link https://www.moph.gov.lb/en/Pages/9/1024/the-ministry . This chart includes the public pharmaceutical services however no organizational chart is available for private pharmaceutical entities.

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

The Pharmacy Service at MoPH is the national regulatory authority for pharmaceutical products. Under this Service, lies three departments: The import-export department, inspection department and narcotics department. There are other programs at MoPH which do not fall under the Pharmacy Service however have roles in the pharmaceutical administration such as the Expanded Program on Immunization, Primary Health Care (PHC) Department, Quality Assurance of Pharmaceutical Products Program (QAPP), and e-health program.

The Lebanese Order of Pharmacists' (OPL) mission is to raise the level of the profession. It also enforces the laws, defends the rights of pharmacists, and improves the level of practice and development of scientific competence. It is also aiming at providing the conditions for enhancing the patient's access to the appropriate medications and its safe use.

② Legislation on pharmaceutical administration

−Please briefly bulletined major laws/acts

◆National Level

- **https://www.moph.gov.lb/en/laws administered by Pharmacy Service at Ministry of Public Health**
- **https://www.opl.org.lb/# administered by the Bylaws of Order of Pharmacists of Lebanon**

◆Local Level

- **NA** administered by **NA**

◆International Level:

- PIC/S: Yes OR **No**
  If yes, joined when
- Others if any

by

③ 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

・Systems, Regulations, etc.

・Good Laboratory Practice: GLP Lebanon 2017, self-assessment & evaluation of GLP Implementation for Laboratories dated 2017 Director General Letter dated 2016 (available on https://www.moph.gov.lb/en/Pages/4/6642/quality-assurance-of-pharmaceutical-products) administered by the QAPP at MoPH.

・Good Manufacturing Practice: GMP Lebanon 2009, Minister Decision No.422/1 dated 2009, WHO Progress Report 2010, Country Case Study and Best Practice (available on https://www.moph.gov.lb/en/Pages/4/6642/quality-assurance-of-pharmaceutical-products#/en/view/6645/good-manufacturing-practice) administered by the Pharmacy Service at the MoPH.

・Good Clinical Practice: Minister Decree No.1159/1 Date 23/6/2014 Concerning Clinical Trial Regulations , IRB regulations, IRB Evaluation Report and Lebanon Clinical Trial Registry (LBCTR) (available on https://www.moph.gov.lb/en/DynamicPages/index/3/4760/clinical-trial-regulations) administered by the Quality Assurance of Pharmaceutical Products Program

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

◆Drug Import/Export

・Systems, Regulations, etc.

・Regulations and requirements available on https://www.moph.gov.lb/en/AdministrativeServices/index/1 administered by Import/Export Department at MoPH.

◆Marketing Authorization

・Systems, Regulations, etc.

・Regulations and requirements available under "Registration of Pharmaceutical & Other Products" available on https://www.moph.gov.lb/en/AdministrativeServices/index/1 administered by Import/Export Department at MoPH.

・Guidelines for the Drug Technical Submission available on https://www.moph.gov.lb/en/Pages/4/6642/quality-assurance-of-pharmaceutical-products administered by the QAPP at MoPH.

※Example: Good Quality Practice

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

・Systems, Regulations, etc.

・Good Storage and Distribution Practices for food supplement and pharmaceutical products available on https://www.moph.gov.lb/en/Pages/4/6642/quality-assurance-of-pharmaceutical-products administered by Quality Assurance of Pharmaceutical Products Program

◆Medicine Safety (post-marketing)

・Systems, Regulations, etc.

・Regulations: **Ministerial Decree No.13370 (2004), Ministerial Resolution No. 1636 (2013), Collaborative Agreement (2016), PV Strategic Plan and Operational Plan (2020-2025), Ministerial Resolution No. 1438/1 (2019), Ministerial Resolution No. 427/1 (2020), Ministerial Resolution No. 556/1 (2020), Minister's Decision No.180/1 (2021), Minister's Decision No.181/1 (2021), Memorandum No.8 (2021) available on** https://www.moph.gov.lb/en/Pages/4/44742/pharmacovigilance-system-lebanon **administered by the QAPP at the MoPH**

・ **Adverse Event Reporting Forms: available on https://www.moph.gov.lb/en/Pages/4/44742/pharmacovigilance-system-lebanon administered by the Quality Assurance of Pharmaceutical Products Program**

※Example: Good Pharmacovigilance Practice

◆Relief System for Adverse Drug Reactions

・Systems, Regulations, etc.

NA

④ Drug Pricing

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

Public price is determined by an External reference pricing (ERP). It is one of the pricing policies adopted by Lebanon, with different baskets of reference countries. This pricing policy is used to price originator brands and thereafter for most of the newly launched on-patent medicines in the country. The basket of countries to which the prices in each country are benchmarked varies. In Lebanon, prices are benchmarked against three sets of prices with the lowest price adopted: ex-factory and patient selling price of medicines in the country of origin; basket 1 which is composed of seven European countries; and basket 2 comprised of neighboring Arab countries. Regardless of the landed price at registration and the pricing strategy used to set a registration price for a pharmaceutical, mark-ups are applied with different schemes along the pharmaceutical supply chain in both countries. A decree detailing all the different mark-up schemes is available to the public in Lebanon. In Lebanon, the MoPH decision 306/1 of 2005 was continuously reviewed with the latest update being Ministerial Decision 119/1 in 2020, adopting the lowest price out of any of the price comparisons considered for registration. The different CIF and free-on-board (FOB) tranches were lately updated as well in decisions. The mark-up in Lebanon is variable and regressive depending on the CIF or FOB price and whether the medicine is exempted from taxes or not. Mark-up includes custom duties, distributors and pharmacists' margin. The public price is the one sold within community pharmacies. As for Lebanon where the market for generics is active, the price of generic medicines is at least 30% less than their comparative originator. If no originator brand is registered, the price of generics is reviewed once three generics are available in the market and average price is adopted. Generally, the price of generic brands is pegged to the originator; this results in price review for both originator and generic brands every 5 years. Hence, any change in the OB price is translated in a change of the generic brand at a rate that equals half that of the originator. The MOPH in Lebanon is also promoting the use of generics by supporting the local packaging and manufacturing of pharmaceutical as expressed by a higher profit margin (higher mark-up schemes) applied to local manufactured generics. All

regulations related to pricing are available on https://www.moph.gov.lb/en/Laws/index/10#/Laws/view/75 under تسعير الأدوية

Purchase and prices of medicines that are bought by governmental institutions (MoPH, army etc.) fall under other schemes and procedures.

−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	**8855 (2019)**
2.	Number of GMP inspector (National & Local)	**NA**
3.	Number of pharmaceutical manufacturers / manufacturing sites	**12 (2022)**
4.	Number of traditional medicine manufacturers / manufacturing sites	**NA**
5.	Number of pharmaceutical importers	**120 (2022)**
6.	Number of pharmaceutical wholesalers	**10 to 15 (2022)**

⑤ Education and License of Pharmacists in your country

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

Primary	**9 years**
Secondary	**4 years**
High school	**2 years**

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

University / college:	**5 to 6 years (depending on the university)**
Professional education:	
Practical training:	**4 to 5 years (practical trainings start after the 1st year of Pharmacy school during summers and academic years)**
Duration of training by each facility:	
Hospital pharmacy:	**6 weeks**
Community pharmacy:	**6 months**
Pharmaceutical company:	**Not required**
Others:	**Laboratory training (8 weeks)**
Age at graduation:	**22 to 23 years old**

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

Yes

Academic Exams	**2 days**
Clinical Exams	**NA**

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.

* If practical training is optional, give the reasons.

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

Training is mandatory to graduate from university and also necessary to prepare for the national examination

（５） Number of pharmaceutical university or college graduates: **6 pharmaceutical universities**

The alumni's placement rate (%)

a. Hospital: **5% (2019)**
b. Community Pharmacy: **63.4% (2019)**
c. Government Organization: **3.7% (2019)**
d. Enterprise: **24% (2019)**
e. Others: **3.9% (2019)**

⑥ **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 Pharmacovigilance (PV) System in Lebanon includes many stakeholders:

- **The government is responsible for providing all the support needed for the national PV System through well-established national policy and action plan.**
- **The QAPPP at the MoPH, that is responsible for the implementation of quality standards related to the safety of pharmaceutical products, aimed at ensuring that medicines reach the patient in a safe, effective and acceptable manner. The QAPPP oversees the implementation of the PV System.**
- **The Lebanese National Pharmacovigilance Center (LNPVC) at the Faculty of Pharmacy - Lebanese University : http://phcvg-lebanon.com/index.php/en/phcvg-n/**
- **The WHO-PIDM which is the forum where member states can collaborate in PV. The PIDM is responsible for policy issues, while the other partner, the Uppsala Monitoring Center (UMC) conducts operations.**
- **Other parties (e.g., Marketing Authorization Holder, Health-Care Providers, Public Health Programs, Expanded Program for Immunization (EPI) and Primary Health Care Centers and patients/consumers) responsible for reporting AEs which collaborate as main stakeholder to the PV System through submitting Individual Case Study Reports (ICSRs) to the LNPVC.**

Each medical institution/administrative agency has a (PV) focal point. The role of the PV focal point is to make sure reporting forms are available in the respective medical setting, collect and centralize notifications, validate forms' content, send completed Adverse Event/Adverse Event Following Immunization (AE/AEFI) Reporting Forms to National PV Center; and promote PV trainings and education in respective medical setting. In all cases, AE/AEFIs reporting forms are available on the MoPH's Website. The means of reporting are the same for medicines and vaccines except for COVID-

19 vaccines which fall under other means of reporting.

For COVID-19 vaccines, vaccine recipients experiencing any AEFI or PV focal points/healthcare professional reporting on behalf of vaccine recipients can report through one of the following means: 1214 Hotline Call Center, IMPACT Platform established by MoPH, Vaccination Sites/Hospital Sites through "Kobo tool box: AEFIs Software for reporting" or by direct contact with the PV program, Preventive Medicine, Epidemiology Surveillance Program, Health Education and other departments from the MoPH. A case report refers to a report received by the PV Program which pertains to one individual vaccine recipient who reported at least one adverse event after receiving the COVID-19 vaccine (i.e., temporally associated with the vaccine). All case reports are screened and validated for data completion at the level of the PV Program. Incomplete or inconsistent case reports are followed-up directly with the initial reporter. The case reports are classified as serious or non-serious cases. The non-serious case reports are entered directly into the national web-based report management system, VigiFlow, while serious cases go through a follow–up/ investigation and causality assessment process before they are entered into VigiFlow.

As for the rest of vaccines and all medicines, patients experiencing any AE/AEFI can report through one of these means: National AE/AEFI reporting form to be sent by email, e-reporting, hotline, and XML file to be sent by email (only applicable to Marketing Authorization Holders). All case reports are screened and validated for data completion at the level of the PV Program. Incomplete or inconsistent case reports are followed-up directly with the initial reporter. The case reports are classified as serious or non-serious cases. The non-serious case reports are entered directly into VigiFlow, while serious cases go through a follow–up and causality assessment (without investigation) process before they are entered into VigiFlow.

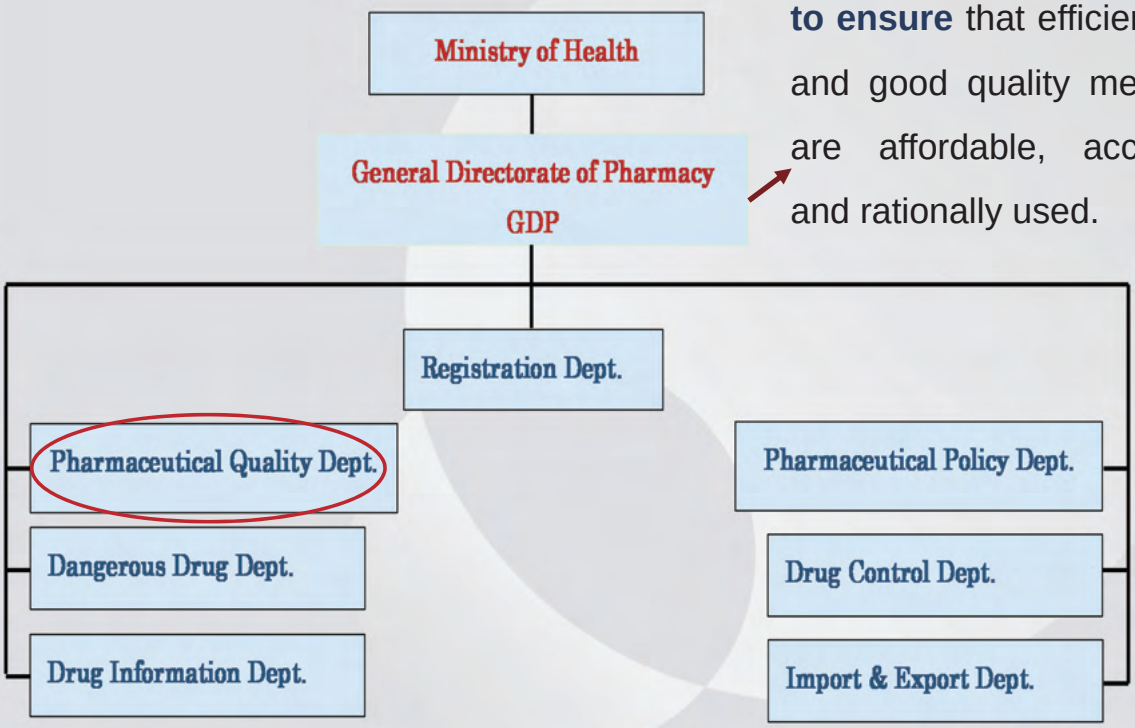
3. Palestine

State of Palestine

Ministry of Health

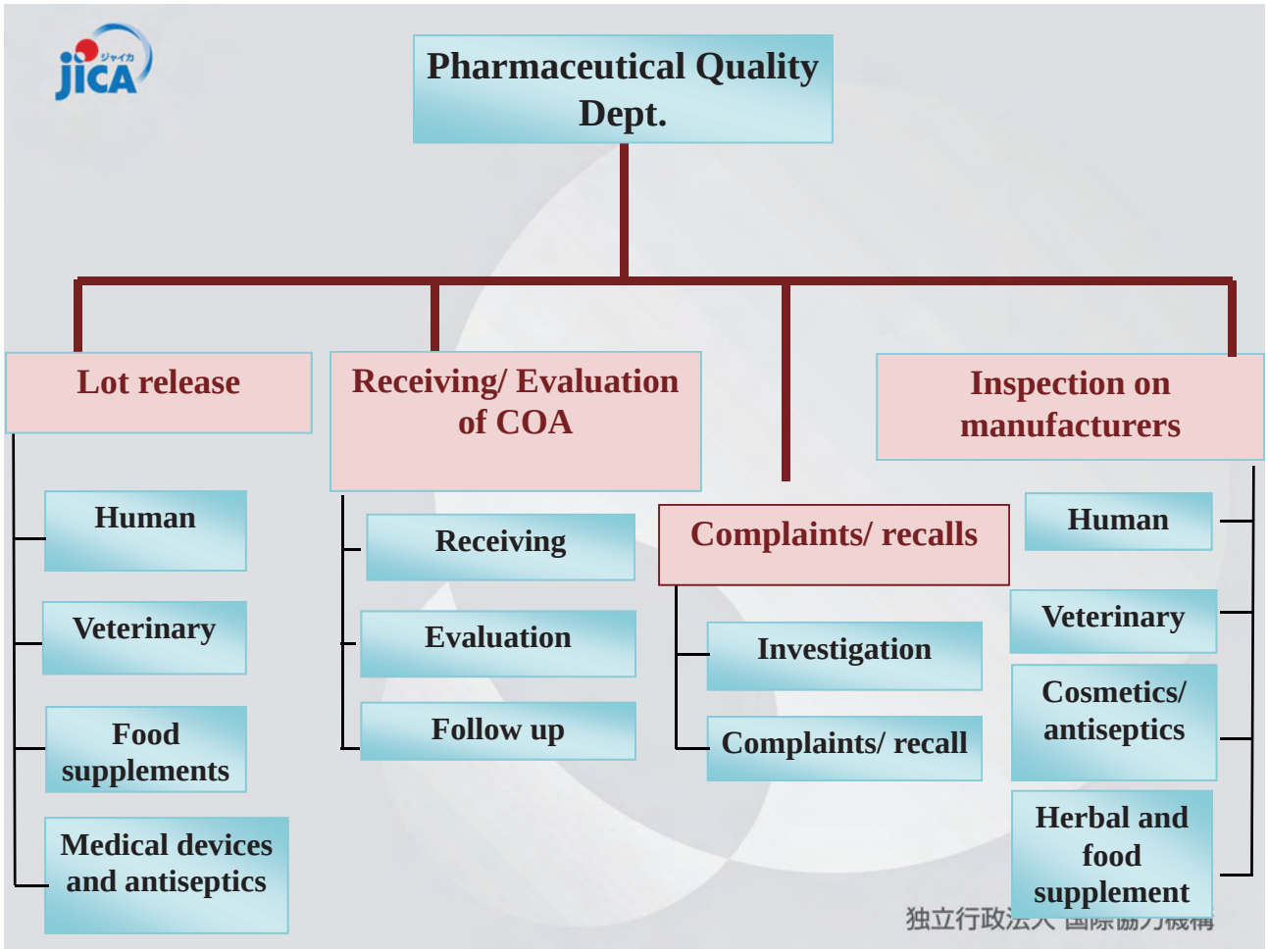
Reem Hijaz

独立行政法人 国際協力機構



to ensure that efficient, safe and good quality medicines are affordable, accessible and rationally used.

独立行政法人 国際協力機構



Regulatory services engaged in……

- Preparing the structure, organogram and responsibilities, laws ……of the Palestinian Food and Drug safety Agency (**PFDA**).
- Writing the **SOP's** related to Pharmaceutical Quality control Department.
- Follow up **complaints** and **recalls**.
- **Releasing** the first three lots after registration.
- **Licencing and Conducting inspection** on pharmaceutical manufacturers.
- **Evaluating certificates of analysis** for pharmaceutical products and conducting **investigation** if needed.

Role of pharmacists in Palestine

Pharmacists

- GDP
- Primary Health Cares
- Pharmaceutical manufacturers and stores
- Hospitals
- Academic scheme
- Community pharmacy

*NGOs, Insurance companies….

Good Practices

Achievements

- A national **framework** for good governance for medicines (**GGM**), starting up **stage III**.
- GDP has adopted **ISO 9001:2015**
- Established instructions for **registration** pharmaceuticals and for **licensing** pharmaceutical manufacturers, research & development centers, Pharmaceutical laboratories, general guidelines and **law for bioequivalence** studies.
- Launching **pharmacovigilance** program activities.

Solutions for past problems

- **Developed SOPs** for most activities in GDP.
- **E- services**.

On-going projects to deal with current problems

- Working on establishing the **PFDA**.
- **Updating** Pharmacy Practice Ordinance and **EDL**.
- **Updating** most of work instruction and guidelines.
- **Establishing** a network that connect all inspectors.

Problems that cannot be improved or solved

- **Lack of control** over the crossings through borders and lack of control over the purchases via international mail.
- Palestine has **limited control on land** and borders due to occupation. Therefore, authorities in Palestine need more efforts to ensure quality and safety of medicines.
- **Lack of experts** in pharmaceutical field due to their immigration to other countries in search for better living conditions.

Challenges

- **Shortage** of medicines.
- Lack of a **national database**.
- Lack of **financial and technical** support to perform most of regulatory functions required.
- Lack of **Laws** to rely on.
- No **post marketing surveillance**.

Palestinian interests

- **Identifying gaps** in Palestinian regulations.
- Establishing a **regulatory information exchange**, collaboration and harmonization **networks** between members of this training.
- **Identifying areas** in need for external **technical support**.

独立行政法人 国際協力機構

Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2021）

Name: Reem N.M. Hijaz.

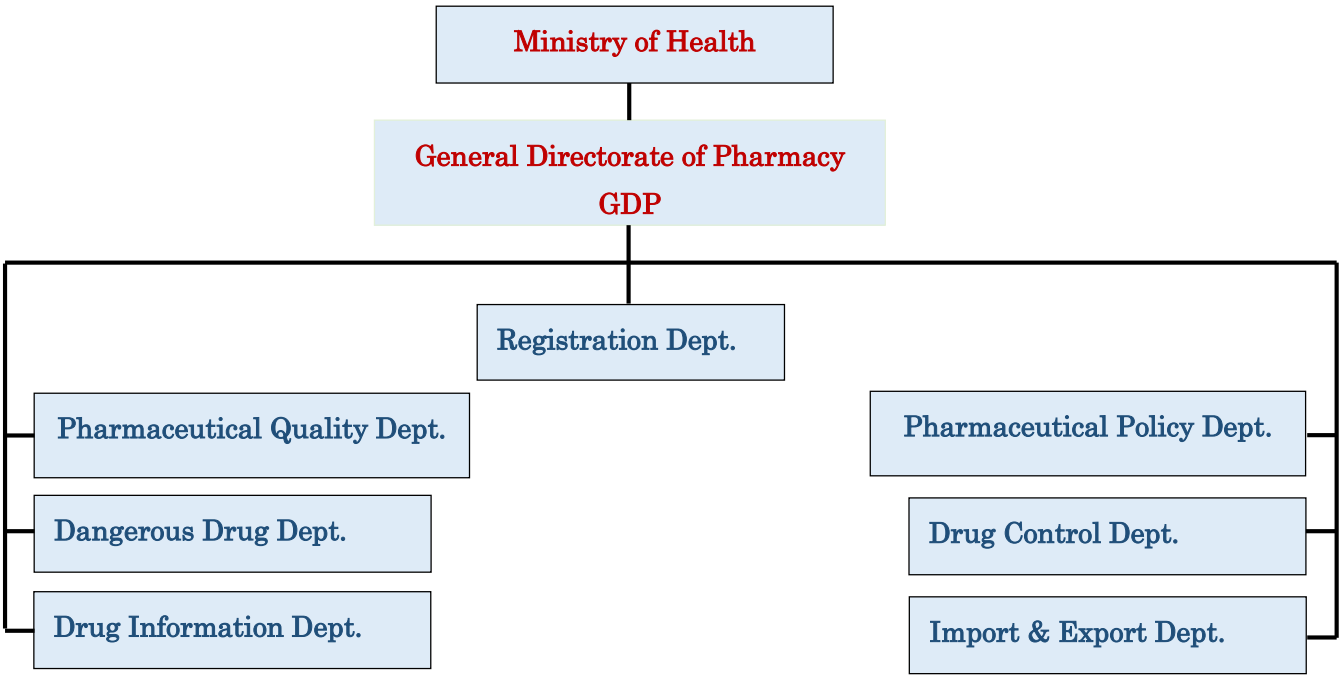
Country: Palestine.

Organization: Ministry of Health General Directorate of pharmacy

Pharmaceutical Quality Department Quality control division.

① Organizational Chart

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



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

The GDP is an active Directorate in the MOH composed of seven departments:

- Registration Department
- Pharmaceutical Quality Department
- Drug Control Department
- Pharmaceutical Policy Department
- Dangerous Drug Department (narcotics and psychotropic drugs)
- Drug Information Department
- Import & Export Department

The GDP is responsible for several activities concerning the whole pharmaceutical sector by coordinating with the Drug Technical Committee (DTC) and other subcommittees like: registration, pricing, drug and therapeutic medicine promotion/ advertising, and pharmacy profession licensing exam committees.

The GDP is concerned of all pharmaceutical sectors:

(i) **The public sector**: GDP, Central Medical Stores (CMS), all hospitals and Primary Health Care (PHC) pharmacies.

(ii) **The private sector**: private pharmacies, wholesalers which are importers of medical and pharmaceuticals goods, General drugstores which are the retailers to private pharmacies and pharmaceutical manufacturers.

(iii) **The nonprofit sector**, NGOs and especially UNRWA for the care to the refugees.

Main Responsibilities of each department in GDP:

1. Drug Registration Dept.: registration of pharmaceutical products
2. Pharmaceutical Quality Dept.: licensing and conducting GMP inspection on local pharmaceutical manufacturers, lot release and follow up complaints and issuing recalls.
3. Drug Policy Dept.: medicines pricing, follow up strategic plans and drug dispensing guidelines.
4. Drug Control Dept.: inspection on pharmacies, general drug stores, hospitals, importers.
5. Drug Information Dept.: PV activities and ADR reporting, regulating the promotion of pharmaceutical products, updating EDL and issuing national drug policy and treatment guidelines and protocols.
6. Export & Import Dept.: grant the permission for Export & Import processes of pharmaceutical products.
7. Dangerous Drug Dept.: grant the permission for purchasing narcotics and updating the lists of Narcotics & psychotropic.

※Hospital pharmacy only

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

The role of pharmacist in medical care system in Palestine can be summarized as follows.

- To ensure the quality of medicines supplied to patients.
- Ensuring that the supply of medicines is within the law.
- Ensuring that the medicines prescribed to patients are suitable to their needs.
- Advising patients about medicines, how to take them, reactions may occur and answering patients' questions.
- Supervise the medicines supply chain and ensure pharmacy premises and systems are fit for purpose.
- Advise healthcare professionals about safe and effective medicines use, and safe and secure supply of medicines.
- Receiving complaints related to medicines from related parties.
- The specialty of a pharm D or clinical pharmacist role in MOH centers is still underutilized due to lack of employment of clinical or Pharm-D pharmacists.

② Legislation on pharmaceutical administration

−Please briefly bulletined major laws/ acts

◆National Level

- Public Health Law 2014 administered by MOH.
- Pharmacy Practice Ordinance 2006 & Pharmacists Syndicate Law 2016administered by MOH & Pharmacists Syndicate.
- Decision by Law No. (26) of 2018, amending by Law No. (18) of 2015 regarding Combating narcotic drugs and psychotropic substances administered by GDP-MOH with related parties.
- Decision by Law No. 21 of 2016 regarding conducting pharmacological studies administered by GDP-MOH with related parties.

◆Local Level

◆International Level:

- PIC/S: No X
  If yes, joined when
- Others if any

by

③ 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

Systems, Regulations, etc.

- Good Manufacturing Practice Inspection guide (GMP).
- Instructions for licensing Cosmetic products.
- Instructions for licensing pharmaceutical laboratories.
- Instruction for licensing herbal and food supplement manufacturers.
- Instruction for licensing sterilizers/ disinfectants manufacturers.
- Instructions for licensing pharmaceutical research and development centers.

All Administered by Pharmaceutical Quality department.

◆Drug Import/ Export

Systems, Regulations, etc.

- Instructions for importing and exporting pharmaceutical products which is administered by drug import and export department.

◆Marketing Authorization

Systems, Regulations, etc.

- Instructions for the principles and requirements necessary for licensing agencies.
- Human Medicines Registration Instructions.
- Herbal products registration instructions.
- Biological products registration Instructions.
- Cosmetic products registration instructions.

- Medical devices and materials registration Instructions.
- Mandatory technical instructions 2017- 74 for cosmetics products.
- Instructions for civil responsibility insurance arising from conducting drug studies.
- Terms and conditions for commercial agencies.
- Instructions for variations to registered drugs 2018.
- Instructions for labeling products 2018.
- Instructions regarding Bioequivalence Studies in Palestine.
- Instructions for registering veterinary medicines.
- Mandatory technical instructions for nutritional supplements.
- Decision by Law No. 21 of 2016 regarding conducting pharmacological studies.
- Instructions for preparing patient leaflet for locally manufactured generic product.

All are administered by Registration department.

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

Systems, Regulations, etc.

- Pharmacy Practice Ordinance 2006 & Pharmacists Syndicate Law 2016/ Technical conditions for licensing a pharmacy/ a medicine store/ administered by Drug Control Dept. & Pharmacists Syndicate.
- Instructions for choosing a list of essential medicines/ updated EDL administered by Pharmaceutical Information Department.
- Medicine pricing instructions/ National drug policy/Updated instructions for dispensing essential medicines in pharmacies of primary care centers and hospitals administered by Drug Policy department.
- Instructions for handling dangerous drugs in hospitals and medical centers/ pharmaceutical institutions administered by Dangerous Drug department.
- Schedules of narcotic drugs and psychotropic substances administered by Dangerous drugs department.

◆Medicine Safety (post-marketing).

Systems, Regulations, etc.

- Pharmacovigilance guidelines administered by pharmaceutical information department.
- Medicine promotion and advertising committee which supervised by pharmaceutical information department.
- Instructions for medicine Promotion and advertising.
- List of OTC medicines.

◆Relief System for Adverse Drug Reactions

Systems, Regulations, etc.

Not Available.

④ **Drug Pricing**

- The pricing division at Drug Policy department is responsible for pricing the medicines according to medicine pricing instructions and publishing the prices on the website of the General Directorate of Pharmacy.

- During inspection, the price is controlled by checking the price on medicine and if it was different from the published lists, the medicine will be seized.

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	**nearly 5000**	**(2021)**
2.	Number of GMP inspector (National & Local)	**3**	(**2021**)
3.	Number of pharmaceutical manufacturers / **6** medicine / **31** cosmetic/ **7** veterinary		(**2021**)
4.	Number of traditional medicine manufacturers /	**3**	(**2021**)
5.	Number of pharmaceutical importers	**200**	(**2021**)
6.	Number of pharmaceutical wholesalers	**250**	(**2021**)

※Hospital pharmacy only

⑥ **Information on your hospital pharmacy**

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

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

（2） Number of staff

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

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

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

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

a. For inpatients:
b. For outpatients:

（5） Equipment of the pharmacy in your hospital

a. Does your hospital have a dispensary room?
If "Yes", how large is it?
Yes _____ m^2 No

b. Does the pharmacy have a clean room or laminar flow hood?
Yes / No
If "Yes", please describe it in detail
Detail: _____

c. Does the pharmacy have computers?

Yes / No

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

Purpose:

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

Yes / No

e. Do you prepare TPN (Total Parental Nutrition)

Yes / No

f. Can you use Internet at the pharmacy?

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

Yes / No

Purpose:

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

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

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

Primary	**10**	years
Secondary	**2**	years
High school		years

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

University / college:	**5**	years
Professional education:		years
Practical training:	**1440**	hours
Duration of training by each facility:		years
Hospital pharmacy:	about **one year** for pharm D.	
Community pharmacy:		weeks
Pharmaceutical company:		weeks
Others:		weeks
Age at graduation:	**23**	years old

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

Yes

Academic Exams	**2**	days
Clinical Exams		days

No

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

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

It is mandatory to have training on pharmacy practice pharmaceutical, legislations, pharmaceutical products that are available in Palestine.

The period of training is 1440 hours. After completing the training, the pharmacist should pass the national exam (that held in coordination between MOH & Pharmacist's Syndicate) in order to obtain the license.

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

（５）Number of pharmaceutical university or college graduates:

400 people / per year

The alumni's placement rate (%)

a. Hospital: **10%**
b. Community Pharmacy: **60 %**
c. Government Organization: **5 %**
d. Enterprise: **15 %**
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 reporter can inform the general directorate of pharmacy (GDP) about the side effects of medicines, herbal preparations or nutritional supplements, or any problems related to their use (lack of effectiveness, drug errors, drug interactions, etc.).

- Reporting should be by filling out the adverse reactions reporting form "yellow card" approved by GDP that is available in Arabic and English on GDP website (http://pharmacy.moh.ps/index/Forms/Language/ar).
- Healthcare professional (doctor/ pharmacist/ nurse) in the health institution should fill the form through the website and upload it then it should be approved by the director of the institution and then the general director, who in turn will send it to the GDP by person / via fax or/ by e-mail (gdp@moh.ps) if the institution is in the private sector.
- The form is reviewed and audited by pharmaceutical information department in GDP and recorded in the department's database.

- In the event that the number of reports increases a certain medicine, the director of the department instructs the head of the pharmacovigilance division to develop an action plan to evaluate the reports and make a study of them.
- The department may send a pharmacovigilance representative to the manufacturer or to the supplier of the medicine in order to follow up patients who have had side effects of the drug and to provide the department with follow-up reports.
- The head of the pharmacovigilance division submits the study and recommendations to the department director for review and approval.
- The department director, after studying, verifying and evaluating the reports, shall take a decision, including preventing circulation or banning the import, suspending registration or recall of the drug, or amending the internal leaflet or the method of dispensing the drug.
- The company must implement decisions of GDP, including, but not limited to:

1. An amendment to the internal leaflet or other safety measures in response to the new available drug safety information.
2. Withdrawal of the medicine
3. Restrictions on use…, etc.

- The company must inform health care providers and recipients of all measures and changes taken regarding the medicine.

Yellow Card

Report of Suspected Adverse drug reaction and pharmaceutical product related problems

Note: Identities of Reporter, Patient and Institution will remain confidential

Patient details	Initials:	Weight Kg	Height cm	Age Years
	Gender □ Male □Female	Is the patient Pregnant □ Yes □No if yes, which trimester: □1st □ 2nd □3rd		

Suspected pharmaceutical product (s)

Brand Name	Manufacturer & Batch no	Route of administration	Dosage	Indication	Date started	Date stopped

Suspected adverse reaction/Product related problem information (Low efficacy, manufacturing defects...)

Description of reaction (s) or problem		Date started		Date stopped	

Was Suspected Drugs (s) Discontinued	□ Yes □ No	Did reaction(s) disappear after discontinuation of suspected drugs(s)?	□Yes □No □Unknown	Did reactions(s) reappear after reintroduction of suspected drugs(s)?	□ Yes □ No □ Unknown

Do you consider the reactions to be serious?	□ Yes □ No	If yes, please indicate seriousness of reaction (tick all that apply):	□ Life threatening □ Involved or prolonged inpatient hospitalization □ Congenital abnormality □ Involved persistent or significant disability or incapacity □ Medically significant; please give details:	Outcome on the day of report	□ Recovered fully □ Recovered with reduced function □ Unknown consequence □ Full recovery is expected □ Death □ other (Specify .....)

Other concomitant drugs (including self-medication, complementary remedies, sold from internet)

Did the patient take any other medicines/vaccines/complementary remedies in the last 3 months prior to reaction?
□Yes □No
If yes, please give the following information if known:

Brand Name	Manufacturer & Batch no	Route of administration	Dosage	Date started	Date stopped	Indication

Additional relevant information e.g. medical history, test results, known allergies, re-challenge. For reactions relating to use of a medicine during pregnancy please state all other drugs taken during pregnancy, the last menstrual period, information on previous pregnancies, ultrasound scans, any delivery complications, birth defects or developmental concerns.

Reporter Details Name and Professional Address: Tel No: Email: Specialty: Date: Signature:	**Healthcare Professional (if not the reporter)** Name and Professional Address: Tel No: Email: Specialty: Date:

For General Directorate of pharmacy:
Date of receiving the report:
Program report No.:
Note: in case there is additional information you can attach extra form.

Palestinian Pharmacovigilance Division (PPVD),
Pharmaceutical Information Department,
General Directorate of Pharmacy, Ministry of Health - Nablus
Tel no: 09 -2384771-6 Fax no: 09-2386410
E-mail : pharmainfo@moh.ps
Website: http://pharmacy.moh.ps

4. South Africa

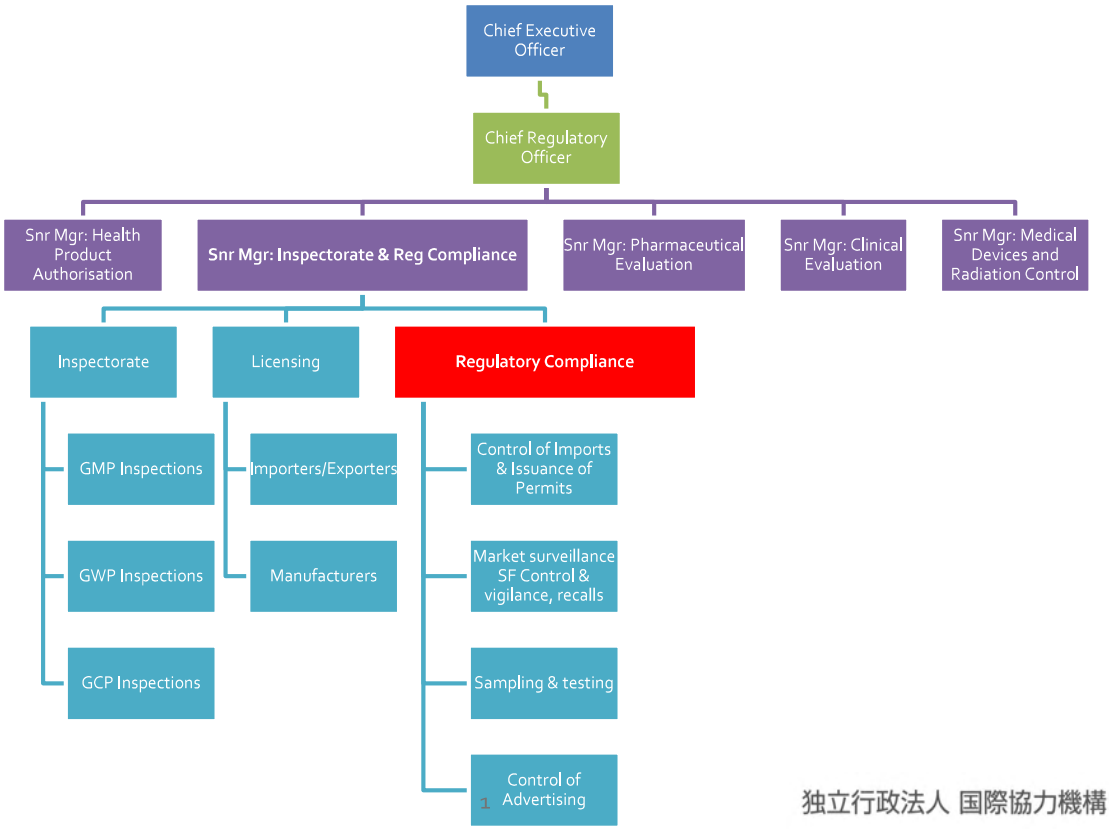
Republic of South Africa

SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Daphney Fafudi

1. Introduction of the work

Organogram of SAHPRA (Regulatory)



Job tenure and current regulatory responsibilities

- Registered pharmacist with 21 years experience
- Experience in Policy making for pharmaceutical regulatory compliance; practice, registration and education, clinical- hospital & retail, drug utilization review, QMS
- Current Regulatory Responsibilities:
  - Overseeing Regulatory Compliance to the RSA legislation relating to medicines-imports, market surveillance &control vs SF, control of advertising & promotion, and lab testing

Pharmacist Roles in RSA

- 4 main categories of pharmacists in South Africa. Regulatory Oversight by Medicines Act and Pharmacy Act
  - Hospital Pharmacists
    - Clinical / Clinicians
    - Dispensing
  - Retail Pharmacists
    - Dispensing
    - Clinical Services
  - Industrial Pharmacists
    - Production
    - QA
    - Registration / Regulatory Affairs
    - Research
    - Marketing / Sales
    - Pharmacovigilance
  - Academia
    - Education & training roles

2. Good Practice

- SAHPRA was established in 2018
- Previously called Medicines Control Council(MCC) under National DoH
- Now semi-autonomous public entity → not tall structure → quicker decisions → more flexibility
- PIC/S member country
- Initiated assessment of WHO accreditation: ML3

3. Difficulties/Lessons Learned from Past Experience

- Difficulties
  - Control of imports: Port of entries, need efficient system of import authorization of medical products
  - Establishing direct communication channels of the Regulatory Compliance Unit with specific networks, like GSMS, PIC/S and other relevant partners
  - Strategies for active surveillance of internet channels and social networks
  - Support in training for execution of MC duties
  - Resource constraints for functional regulatory systems and processes

4. Your interests

- Cooperation and collaboration with best practicing stakeholders
- Better control of Substandard and Falsified Medical products
- Effective and efficient Communication to stakeholders regarding quality issues re medicines/medical products
  - Protecting the public vs SFproducts
- Training opportunities to empower staff in quality execution of compliance surveillance

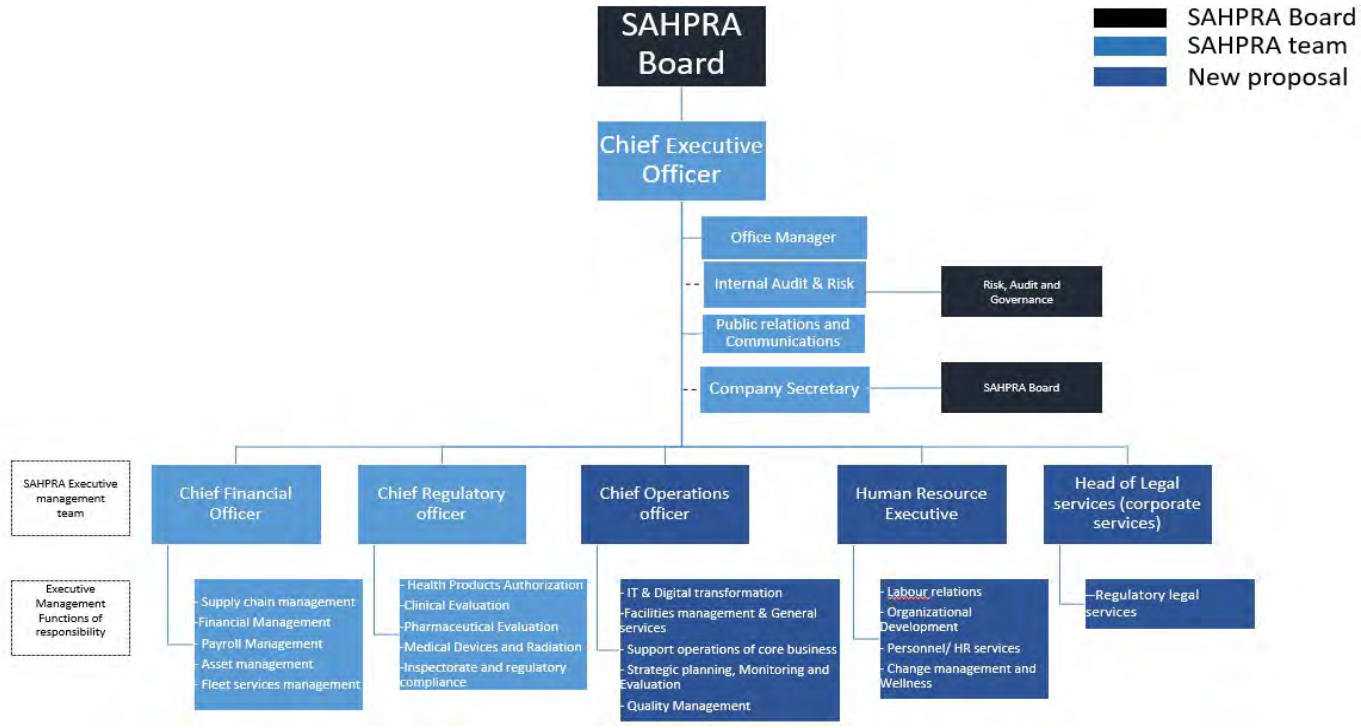
Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2021）

Name: Daphney Fafudi
Country: South Africa
Organization: SAHPRA: Regulatory Compliance

① Organizational Chart

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

The SAHPRA Board reports to the Minister of Health



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

Health Products Authorisation

Provides administration support necessary for SAHPRA to deliver on its mandate and comply with the relevant legislative requirements. It coordinates process of registration/amendment of applications in respect of medicines within a legislative framework that defines the requirements necessary for application to the Authority, to receive record and distribute all documents submitted to SAHPRA, and to manage and maintain SAHPRA's main registry.

Inspectorate and Regulatory Compliance

Ensures the public access safe health products through inspections, market surveillance and control activities. The focus of this programme includes assessment of site compliance, with good regulatory and vigilance practices

Medicines Evaluation and Registration (Clinical and Pharmaceutical Evaluation)

Evaluates the safety, quality and therapeutic efficacy of medicines and register them for use. Units included in this function include:

- Clinical Evaluation

- Clinical Trials
- Pharmaceutical Evaluation
- Authorisation of sale of unregistered medicines
- Pharmacovigilance
- Complementary and Alternative Medicines
- Veterinary Medicines

Medical Devices and Radiation Control

regulatory oversight of medical devices, ionizing and non-ionizing radiation emitting devices; and radioactive nuclides.

※Hospital pharmacy only

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

② Legislation on pharmaceutical administration

−Please briefly bulletined major laws/acts

◆National Level

- National Health Act 61 of 2003 Administered by Department of Health (NDOH)
- The Medicines and Related Substances Act (previously Drugs Control Act) 101 of 1965 administered by SAHPRA and NDOH)
- Pharmacy Act 53 of 1974 administered by South African Pharmacy Council and DOH
- National Drug Policy for South Africa administered by NDOH
- drugs and drug trafficking act 140 of 1992 administered by Department of Justice and Constitutional development

◆International Level:

・ PIC/S: Yes 2007

If yes, joined when

・ Others if any

INCB administered by UN

③ 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

・Systems, Regulations, etc.

・GMP, GDP, GWP, GCP, GLP administered by SAHPRA

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

◆Drug Import/Export

・Systems, Regulations, etc.

・Permit Application and Approval administered by SAHPRA

◆Marketing Authorisation

・Systems, Regulations, etc.

・Good Regulatory Review Practice　administered by WHO

※Example: Good Quality Practice

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

・Systems, Regulations, etc.

・Good Wholesaling Practice　administered by　SAHPRA

◆Medicine Safety (post-marketing)

・Systems, Regulations, etc.

・Market Surveillance and Control　administered by　SAHPRA

※Example: Good Pharmacovigilance Practice

◆Relief System for Adverse Drug Reactions

・Systems, Regulations, etc.

・Pharmacovigilance and Market Surveillance administered by SAHPRA

④ Drug Pricing

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

South Africa applies the single exit price (SEP) mechanism which lists the maximum price that a medicine can be charged at. This is regulated under Section 22G of the Medicines Act.

(ANNUAL SINGLE EXIT PRICE ADJUSTMENT (SEPA) OF MEDICINES AND SCHEDULED SUBSTANCES FOR THE YEAR 2021)

In terms of Regulation 8 (1) of the Regulations Relating to the Transparent Pricing System for Medicines and Scheduled Substances of the Medicines and Related Substances Act,1965 (No.101 of 1965) as amended, the Minister of Health is required to determine on an annual basis, the extent to which medicine prices may be adjusted. In making this determination the Minister considers the following provisions of Regulation 8 (1)-

(a) the average CPI for the preceding year;
(b) the average PPI for the preceding year;
(c) changes in the rates of foreign exchange and purchasing power parity;
(d) international pricing information relating to medicines and scheduled substances;
(e) comments received from interested persons in terms of regulation 8(2); and
(f) the need to ensure the availability, affordability and quality of medicines and scheduled substances in the Republic.

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　<600　(year)
2. Number of GMP inspector (National & Local)　13　(year)

3. Number of pharmaceutical manufacturers / manufacturing sites 127 (year)
4. Number of traditional medicine manufacturers / manufacturing sites Unknown (year)
5. Number of pharmaceutical importers 155 (year)
6. Number of pharmaceutical wholesalers 153 (year)

※Hospital pharmacy only

⑥ **Information on your hospital pharmacy**

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

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

（2） Number of staff

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

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

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

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

a. For inpatients:
b. For outpatients:

（5） Equipment of the pharmacy in your hospital

a. Does your hospital have a dispensary room?
If "Yes", how large is it?
Yes _____ ㎡ No

b. Does the pharmacy have a clean room or laminar flow hood?
Yes / No
If "Yes", please describe it in detail
Detail: _____

c. Does the pharmacy have computers?
Yes / No
If "Yes", what is the purpose of using them.
Purpose: _____

d. Do you implement Therapeutic Drug Monitoring (TDM : Therapeutic Drug Monitoring) in your Hospital?
Yes / No

e. Do you prepare TPN (Total Parental Nutrition)
Yes / No

f. Can you use Internet at the pharmacy?
If "Yes", what is the purpose of using it.
Yes / No
Purpose:

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

⑦ Education and License of Pharmacists in your country

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

Primary	8 years
Secondary	part of primary years
High school	5 years

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

University / college:	4 years
Professional education:	4 years
Practical training:	1 years
Duration of training by each facility:	1 years
Hospital pharmacy:	(400hrs)weeks during & post university but during pre-reg year
Community pharmacy:	(400hrs) weeks during & post university but during pre-reg year
Pharmaceutical company:	(400hrs) weeks during & post university but during pre-reg year
Others:	weeks
Age at graduation:	22 years old

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

Yes

Academic Exams 1year pre-registration exam to test competence with

Clinical Exams Submission of Continued Professional Developments for competence evaluation

（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.

1year pre-registration Internship at either a hospital, manufacturing, academia or community pharmacy. The curriculum includes medicines management, good pharmacy practice (sector specific),

medicine supply management, dispensing, human resources and application of medicines policies & legislations.

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

（５）Number of pharmaceutical university or college graduates:

600 / per year

The alumni's placement rate (%) 98-100%

a. Hospital: 40 %
b. Community Pharmacy: 50 %
c. Government Organization: 5 %
d. Enterprise: 4 %
e. Others: 1 %

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 Marketing Authorisation holder is responsible for receipt of the complaint and for liaising with SAHPRA. There are also mechanisms for the public and users of the health product to contact SAHPRA directly and report.

5. Thailand

Thailand

The Government Pharmaceutical Organization (GPO)
Ministry of Public Health

Mr. Atit Sodsangaroonngam

Acting Director of Regulatory Operation Division

Regulatory Affair Department

Introduction of the work

Roles and position of pharmacists in Thailand

R&D pharmacist

- Drug formulation development
- Clinical research

Industrial pharmacist

- Production pharmacists
- Quality assurance and Quality control pharmacists
- Regulatory affair pharmacists

Marketing pharmacist

- Medical Representatives

Hospital pharmacist

- Pharmaceutical care practitioners
- Extemporaneous preparation
- Therapeutic drug & Adverse event monitoring
- Drug inventory and dispensing

Community pharmacist (Drugstore)

- Good Pharmacy Practice
- Drug inventory and dispensing

Educational pharmacist

- Lecturers
- Researchers

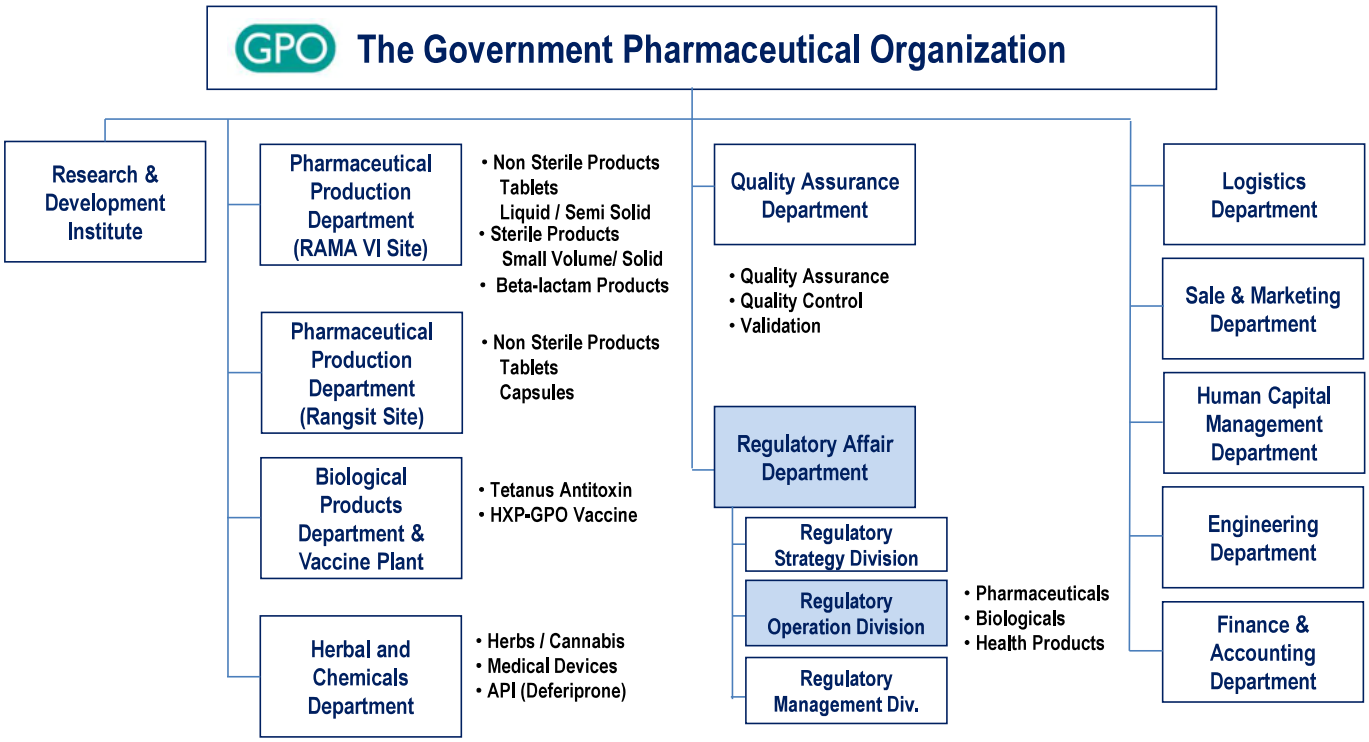
Pharmaceutical and Health Consumer Protection Pharmacist

- Government Sector

(Thai FDA, Provincial Public Health Office, Department of Medical Sciences)

Introduction of the work

Organization and department



Introduction of the work

Job tenure and Regulatory services

Acting Director of Regulatory Operation Division
Regulatory Affair Department

Job Tenure

- Drug registration, and variation technical dossier preparation and submit to FDA.
- Preparation data of non-pharmaceutical products (i.e. dietary supplements, food, herbals, cosmetics, medical devices) and submit to FDA for registration.

Engaging Regulatory Service

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

Good Practice

Quality Assurance	Regulatory Affair
Pharmaceutical Quality System	Technical drug dossier (CTD / ACTD) preparation and submission
Good Manufacturing Practice (GMP)	Variation of drug dossier
Good Distribution Practice (GDP)	Post - marketing compliance

Difficulties/Lessons Learned from Past Experience

- Utilization of drug database
- Data storage and management of registered data
- Estimate variations
- Handling post-marketing control
- Implementation of Good Distribution Practice (GDP)

My interests

(1) Good Distribution Practice (GDP) Implementation, especially countermeasure against falsified medicinal products

(2) Post - marketing control system for pharmaceutical manufacturer

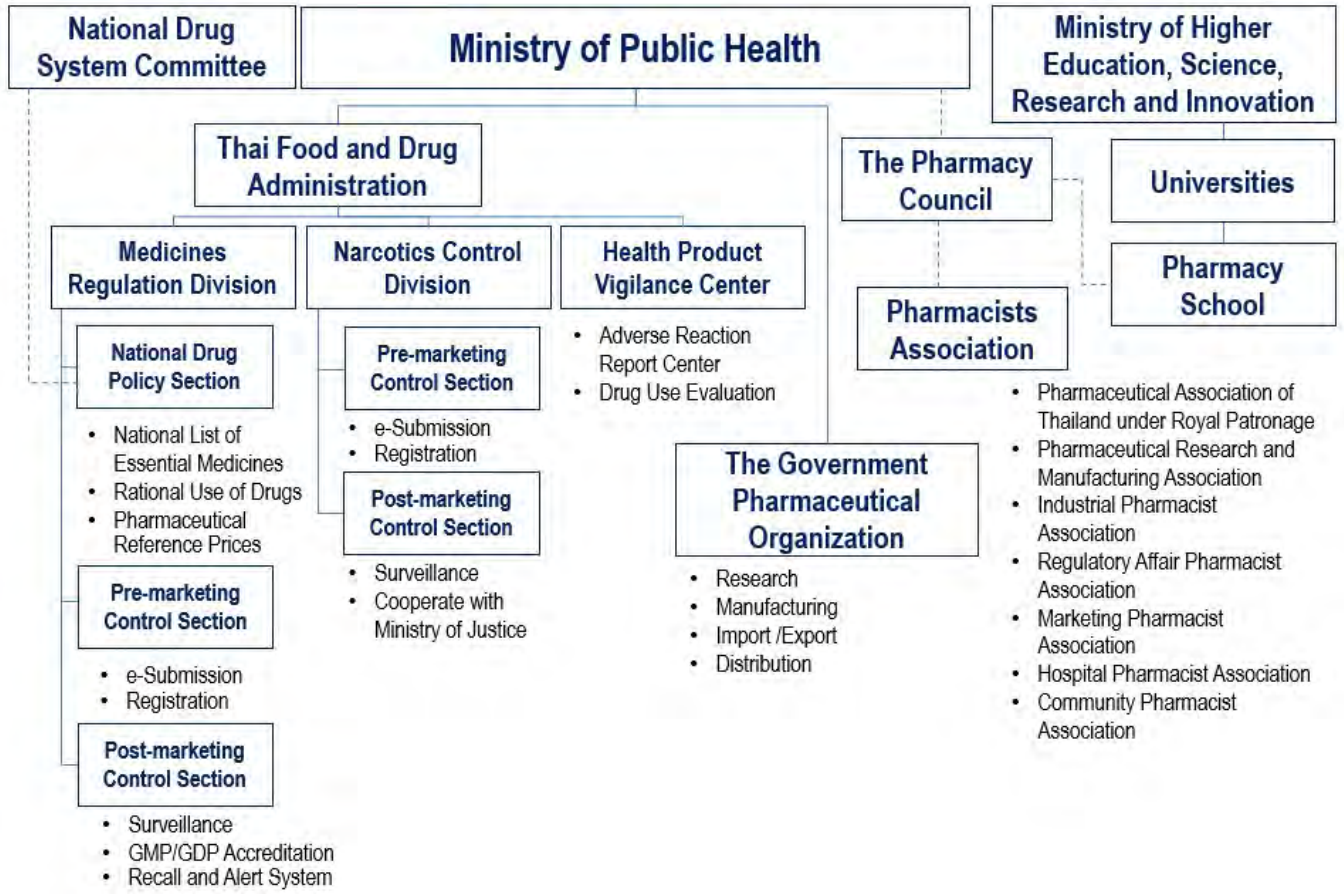
(3) Change control system and variation for dossiers in Japan

Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2021）

Name: ATIT SODSANGAROONNGAM
Country: Thailand
Organization/Department/Division:
The Government Pharmaceutical Organization
Regulatory Affair Department, Regulatory Operation Division

① Organizational Chart

Figure 1: Thailand's National Drug System



Pharmaceutical Administration

Thai Food and Drug Administration (Thai FDA) under supervision of the Ministry of Public Health which responsibilities include but are not limit to;

• National Drug Policy: To prepare and publish the National List of Essential Medicines, Guide to Rational Use of Drug and Pharmaceutical Reference Price.

• Pre-marketing Control: This includes control of drug registration (eCTD/ACTD), product quality and advertising before product-launch to the market.

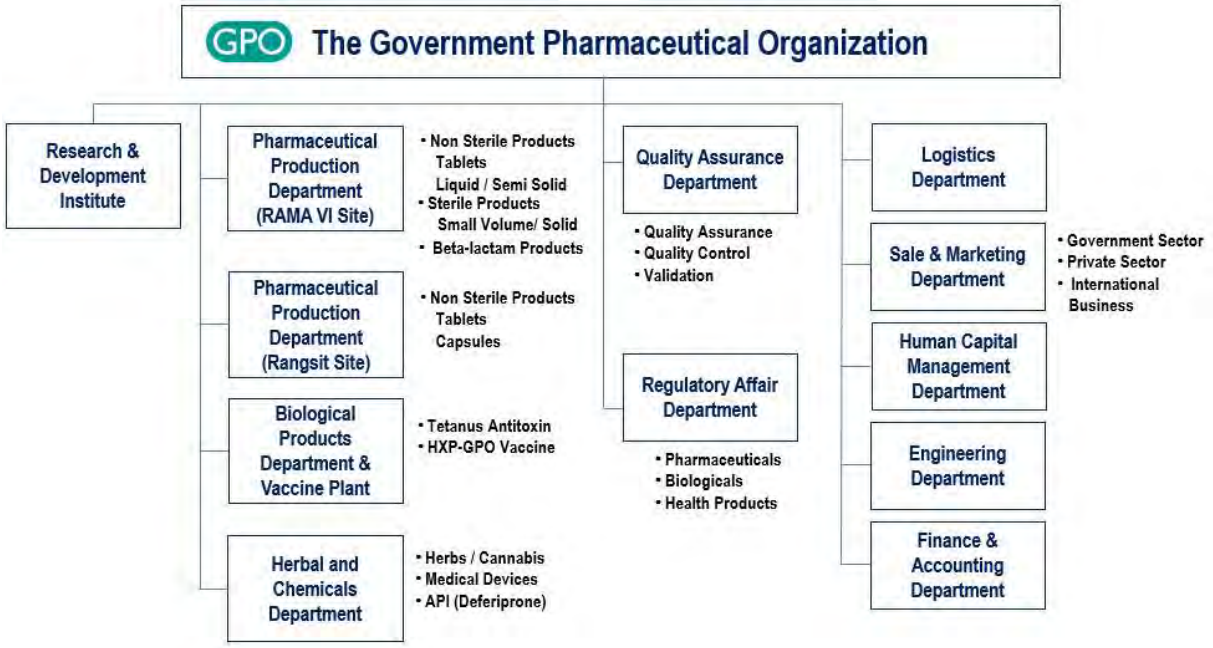
• Post-marketing Control: To maintain compliance with approved manufacturing facilities, products and with legislation and regulations, and recall and alert system.

• Health Product Vigilance Centre (HPVC) established the system for Adverse Drug Reaction (ADR) monitoring, signal detection and assessment.

• Consumer Education: To provide health products' information.

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

Figure 2: The Government Pharmaceutical Organization



The Government Pharmaceutical Organization (GPO) is a Thai state enterprise under supervision of the Ministry of Public Health which manufactures pharmaceutical products in Thailand.
• To manufacture, import, and supply drug products to public and private sectors.
• To research and develop new generic pharmaceutical products and medical supplies to respond to the need of the Thai society.
• To maintain price level of pharmaceutical products and medical supplies necessary for the Thai society to ensure people's accessibility.

② Legislation on pharmaceutical administration

◆ National Level

- Drug Act, B.E.2510 (1967) and its amendments administered by Drug Control Division, Thai FDA
- Act Promulgating the Narcotic Code, B.E. 2564 (2021) administered by Narcotics Control Division, Thai FDA and the Office of Narcotics Control Board, Ministry of Justice
- Pharmaceutical Profession Act, B.E. 2537 (1994) administered by the Pharmacy Council of Thailand

◆ Local Level

- Ministerial Regulation by Ministry of Public Health administered by Thai FDA and Provincial Public Health Office
- Ministry Announcement administered by Thai FDA and Provincial Public Health Office

◆ International Level:

- PIC/S since August 1st, 2016

③ Regulatory /Administrative Services

◆Pharmaceutical Manufacturing

• Good Manufacturing Practice	administered by Thai FDA
• Good Laboratory Practice	administered by Thai FDA
• Good Clinical Practice	administered by Thai FDA
• GXP Knowledge sharing	administered by TIPA, TPMA
• Drug Registration	administered by Thai FDA, RAPAT

◆Drug Import/Export

・Drug registration	administered by Thai FDA
・Knowledge sharing from FDA	administered by PReMA, RAPAT

◆Marketing Authorization

・National Reference Prices	administered by National Drug System Development Committee
・Drug advertisement control	administered by Thai FDA, MPAT, PReMA

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

・Drug procurement	administered by National Drug System Development Committee
・Good distribution practice	administered by Thai FDA

◆Medicine Safety (post-marketing)

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

◆Relief System for Adverse Drug Reactions

・Safety Monitoring Program	administered by Drug manufacturers, Hospitals
・Spontaneous ADR report	administered by Drug manufacturers, CPA
・Post-Market surveillance	administered by Thai FDA, HPVC

Abbreviation and Acronyms

Thai FDA	Thai Food and Drug Administration
GPO	The Government Pharmaceutical Organization
RA	Regulatory Affairs / Regulatory Authorities
PAT	Pharmaceutical Association of Thailand under Royal Patronage
RAPAT	Regulatory Affairs Pharmacist Association
PReMA	Pharmaceutical Research and Manufacturing Association
TPMA	Thai Pharmaceutical Manufacturing Association
MPAT	Marketing Pharmacist Association
HP	Hospital Pharmacist Association
CPA	Community Pharmacist Association

④ Drug Pricing

National Drug System Development Committee (NDSDC) is which consist of governmental authorities, independent technical experts and other stakeholders. NDSDC give measures for pharmaceutical cost containment in order to save pharmaceutical expenditure as well as increase access to medicines.

The Committee announced The National list of Essential Medicines (NLEM) since 2013 and has been annually revised. NLEM can be divided into 6 groups including of

A: First line drug complied with medical guideline
B: Second line drug, after the first line drug was ineffective or ADR occurred
C: Drugs with multiple indications, must have been prescribed by medical specialist
D: Drugs with multiple indications, higher price than A and B lists. The drug may have chance of improper drug use. This drug group must have been prescribed by medical specialist
E1: The drug is in clinical researching, all patients must be monitored
E2: Patients need a special management to access the drug.

There are 2 importantly measurable projects which involved drug prices:

・ Reference Prices (RPs) for Public Procurement

RPs are setting for conventional and traditional & herbal medicines both NLEM medicines and non-NLEM medicines. RPs were set on the calculation basis of "median". The RPs measures introduce maximum purchasing prices which means that medicine procurement is now actually purchased at lower prices than the RPs due to the negotiating and bargaining power of hospital purchasers.

・Targeted List of Priority Medicines (PRIMEs)

The PRIMEs were selected mainly based on essential medicines with local unavailability or with a single brand and imported high-cost medicines for which government support were necessarily needed to motivate and incentivize local manufacturers. To encourage the availability of generic drugs, the Thai FDA issued 2 announcements putting integrated inventions in place to enhance local production and importation including provision of drug patent information to local manufacturers to induce their interests on generic production, 50% reduction in registration fee, fast-track drug approvals and RP setting for fast-track registered drugs.

⑤ Statistic Data

1.	Number of pharmacists	45,706 (2021)
2.	Number of GMP inspector (National & Local)	17 (2021)
3.	Number of pharmaceutical manufacturers / manufacturing sites	151 (2021)
4.	Number of traditional medicine manufacturers / manufacturing sites	762 (2021)
	GMP Accredited 53 (2020)	
5.	Number of pharmaceutical importers	667 (2021)
6.	Number of pharmaceutical wholesalers	614 (2021)

⑥ Education and License of Pharmacists in your country

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

Primary	6 years
Secondary	3 years
High school	3 years

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

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

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

√ Yes

Academic Exams

Multiple Choice Question (MCQ) 2 days for 4th year pharmacy student
and 1 day for 6th year pharmacy student

Clinical Exams

Objective Structured Pharmacy Examination (OSPE) 1 day for 4th year pharmacy student
Case presentation 1 day for 6th year pharmacy student

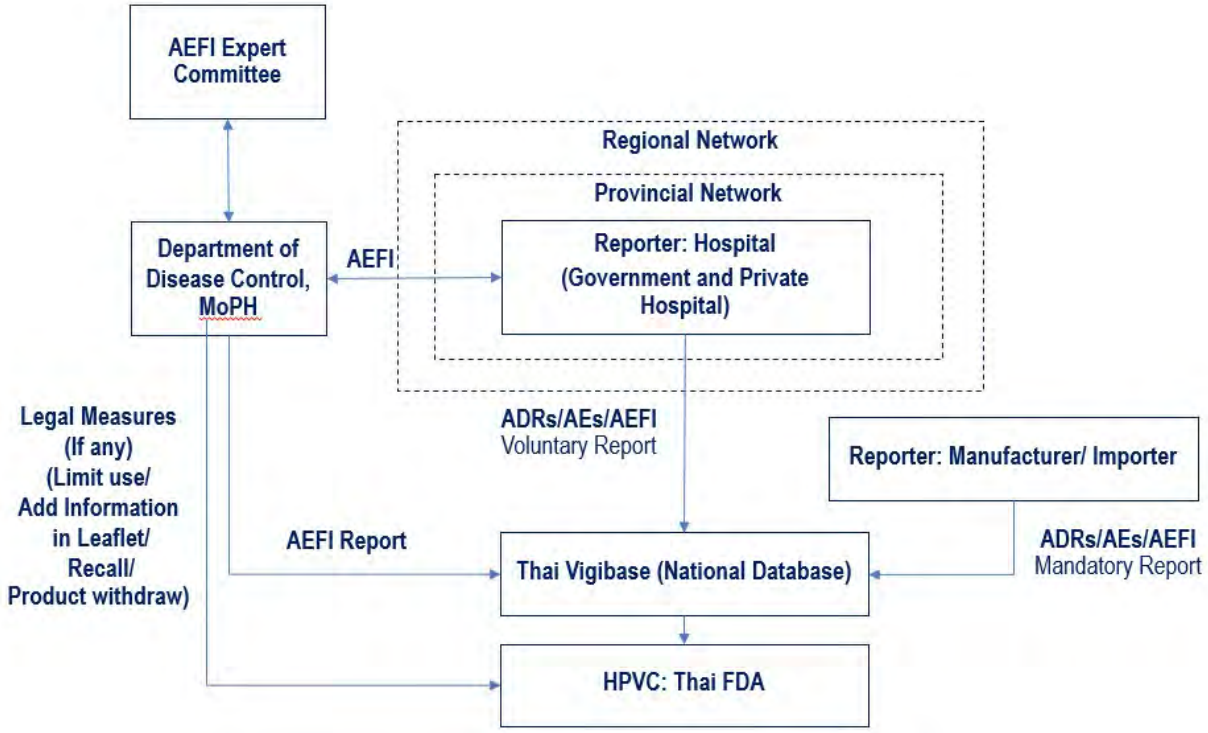
（4） Which of the followings must you fulfill to obtain a pharmacist's license?

Every pharmacy student must obtain clerkship training not less than 2,000 hrs.
(Mandatory Clerkship in hospitals/drug store 400 hrs. and
Professional Clerkship in pharmaceutical industry or pharmaceutical care 1,600 hrs.)

（５）Number of pharmaceutical university or college graduates: 1,500 people / per year
The alumni's placement rate (%)
a. Hospital: 35 %
b. Community Pharmacy: 15 %
c. Government Organization: 20 %
d. Enterprise: 25 %
e. Others: 5 %

⑦ ADR(Adverse Drug Reaction) report

Figure 3: Thailand Vigilance Network



Abbreviation and Acronyms
HPVC Health Product Vigilance Centre
ADRs Adverse Drug Reactions
AEs Adverse Events
AEFI Adverse Event Following Immunization

1. Medical institution (government and private hospital): Multidisciplinary collaboration team must assign at least 1 pharmacist for evaluate the relationship between the suspected drug and the observed symptoms/ adverse events and then ADR spontaneous report to HPVC by using designated HPVC forms.
2. Provincial and regional network: To promote and support surveillance systems, develop teams and solve problems by network meeting and knowledge sharing.
3. Manufacturer and Importer: To report every ADRs to HPVC.
4. Health Product Vigilance Center (HPVC), under supervision of Ministry of Public Health responsible for collecting ADR report from other local and international sections. Health products surveillance program are including drugs, medical devices, herbal medicine, vaccines and biologics drugs.
After collecting of report, HPVC collaborates with FDA to monitor safety of health products, including recall and alert system. Classification of ADRs can be divided into Non-serious ADR, and Serious ADR including; Death, Life threatening, Comorbidity, Teratogenicity.

Surveillance system consists of;
1. Spontaneous Reporting
2. Intensified (Stimulated) Reporting
3. Targeted Spontaneous Reporting
4. Cohort Event Monitoring
5. Registry which only on case pure red cell aplasia (PRCA) in renal failure patient who treated with erythropoiesis stimulating agents (ESAs)

Thailand

Thai FDA

Sataporn Lumpaiboonsuk (Job ジョブ)

https://www01.do-johodai.ac.jp/wdc/workshop/iWDC2014_workshop/iWDC2014_G3/#Home

1. Introduction of the work

- I am working as a pharmacist at ThaiFDA in a Medicines Regulation Division.
- My responsibility is to take care of post approval changes for chemical drugs (Brand name and generic drugs).

1. Introduction of the work

Roles and position of pharmacists in Thailand

- Clinical pharmacist (Hospital)
- Community pharmacist (Pharmacy)
- R&D/production/QA/QC/RA pharmacist (Manufacturer)
- Clinical Research Assistant/ product specialist (Drug company)
- Lecturer (University)
- Pharmacoeconomic pharmacist (Private and gov sectors)
- Consumer protection pharmacist (FDA)

2. Good Practice

−In this section, please describe your experiences about Good Practices

Trainee inspector on

- Good Manufacturing Practice
- Good Distribution Practice
- Good Storage Practice

3. Difficulties/Lessons Learned from Past Experience

− In this section, please describe your experiences which you have faced difficulties, or struggled;

- Adoption and a mix of different standards from several countries
  - Don't know which one should be selected
  - A lot of international regulations to follow (ASEAN, PIC/S, EU, US, PMDA, TGA)
- No regulations or detailed standards on some topics
  - Some regulations are vague.
  - Standing between public protection and supporting local business
- A lot of opinions while working
  - Colleagues
  - Executives
  - Political impact

4. Your interests

- In this section, please describe issues you are expecting to this Program.
- At Maximum THREE issues!

(1) International standards and regulations

(2) How Japan plans and has regulations

(3) Networking and connections

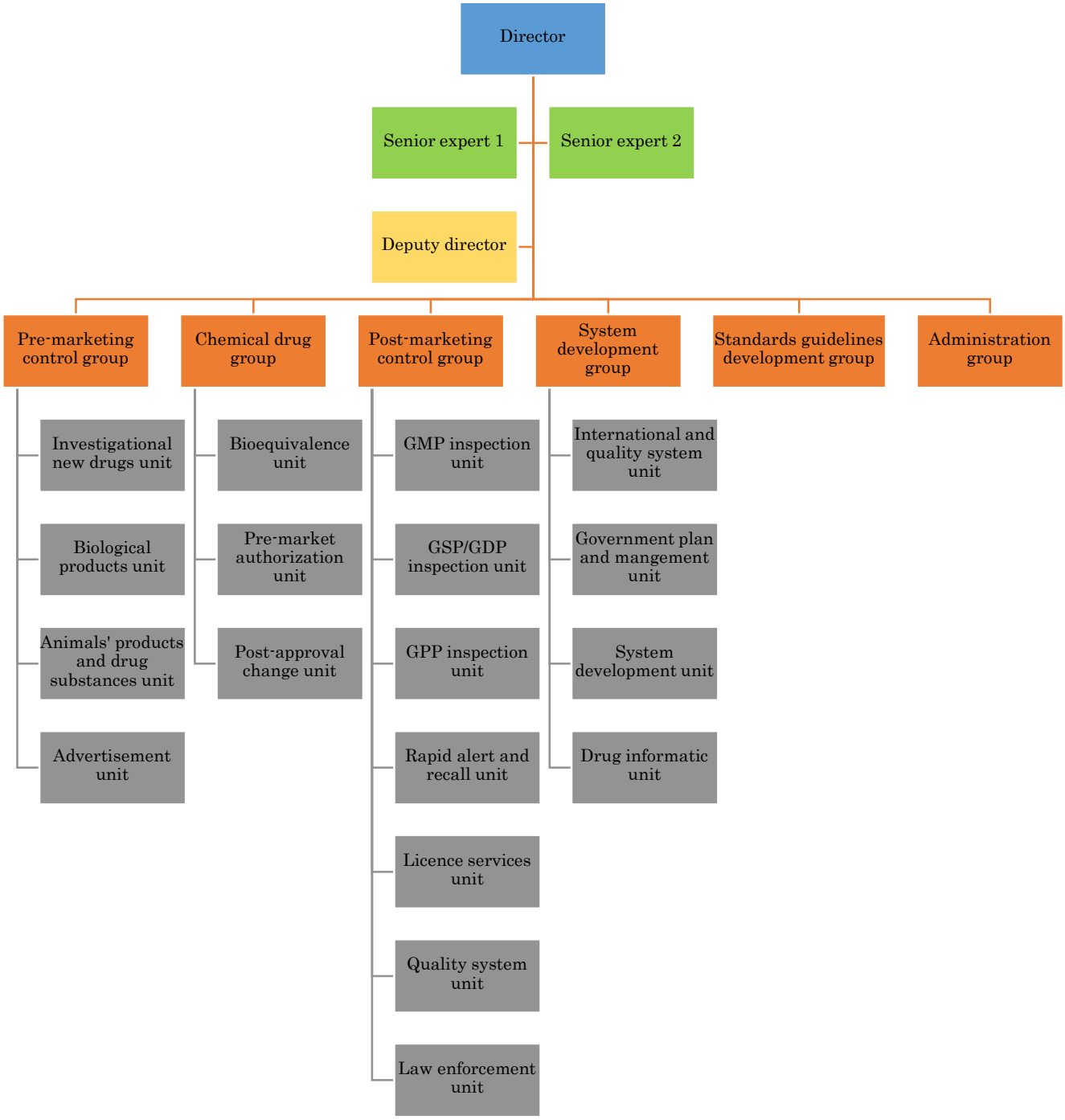
Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2021）

Name: Sataporn Lumpaiboonsuk (Job ジョブ)
Country: Thailand
Organization/Department/Division: Thai FDA

① Organizational Chart

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

Medicines Regulation Division, Thai FDA



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

- Chemical drug group, biological products unit, and animals' products and drug substances unit
  - To authorized the registration of drug products
  - To approve and monitor any changes/variations to those products that are already approved and granted marketing authorization
- Investigational new drugs unit
  - To approve and monitor clinical trial studies that involve drugs
- Advertisement unit
  - To review and monitor of advertisements for drugs
- Post-marketing control group
  - To surveillance drug in the market
  - To inspect and monitor the compliance of GMP, GSP/GDP and GPP
  - To comply with PIC/S standard
  - To enforce the law
  - To license and monitor drug importation and distribution
  - To issuance the WHO-format Certificates of Pharmaceutical Product for the purposes of export
- System development group
  - To ensure quality system of the division
  - To make plans and arrange the management
- Standards guidelines development group
  - To develop standard and new regulation

※Hospital pharmacy only

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

② Legislation on pharmaceutical administration

−Please briefly bulletined major laws/acts

◆National Level

・The Drug Act of B.E. 2510 administered by Thai FDA

・ administered by

◆Local Level

・The Drug Act of B.E. 2510 administered by Thai FDA

・ administered by

◆International Level:

・ PIC/S: **Yes** OR No

If yes, joined when **August 1st, 2016**

・ Others if any

by

③ 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

・Systems, Regulations, etc.

・Good Manufacturing Practice administered by ThaiFDA

・Good Distribution Practice administered by ThaiFDA

・Good Storage Practice administered by ThaiFDA

・Good Clinical Practice administered by ThaiFDA

・Good Laboratory Practice administered by DMSC

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

◆Drug Import/Export

・Systems, Regulations, etc.

・Good Storage Practice administered by ThaiFDA

・Good Distribution Practice administered by ThaiFDA

◆Marketing Authorization

・Systems, Regulations, etc.

・N/A administered by

・ administered by

※Example: Good Quality Practice

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

・Systems, Regulations, etc.

・Good Pharmacy Practice administered by ThaiFDA

・ administered by

◆Medicine Safety (post-marketing)

・Systems, Regulations, etc.

・Rapid Alert and Recall system administered by ThaiFDA

・ administered by

※Example: Good Pharmacovigilance Practice

◆Relief System for Adverse Drug Reactions

・Systems, Regulations, etc.

・Health Product Vigilance System administered by ThaiFDA

・ administered by

④ Drug Pricing

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

The drug price for government reimbursement is controlled by a list of drug prices published on the website and everybody can get access to it. The government hospitals must purchase the drugs by using this price list as ceiling prices. However, for the private hospitals which are optional for patients, there is no standard price for

both buying and selling. Therefore, the drug price in private hospitals will be higher. For community pharmacy, the price of the drugs varies but generally it is about the same price as that in government hospital or a little bit higher. There is no control on selling and buying price for community pharmacy.

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	45,706	people
2.	Number of GMP inspector (National & Local)	17	people
3.	Number of pharmaceutical manufacturers / manufacturing sites	178	sites
4.	Number of traditional medicine manufacturers / manufacturing sites	762	sites
5.	Number of pharmaceutical importers	110	sites
6.	Number of pharmaceutical wholesalers	1,050	sites

※Hospital pharmacy only

⑥ Information on your hospital pharmacy

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

a. Number of section chiefs:

b. Number of deputy chiefs:

c. Number of managers:

（2） Number of staff

a. Number of pharmacists:

b. Number of clinical pharmacists:

c. Number of technicians:

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

a. Oral medicine:

b. Injections:

c. Medicines for external use:

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

a. For inpatients:

b. For outpatients:

（5） Equipment of the pharmacy in your hospital

a. Does your hospital have a dispensary room?

If "Yes", how large is it?

Yes _____ ㎡ No

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

Yes / No

If "Yes", please describe it in detail

Detail:

c. Does the pharmacy have computers?

Yes / No

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

Purpose:

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

Yes / No

e. Do you prepare TPN (Total Parental Nutrition)

Yes / No

f. Can you use Internet at the pharmacy?

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

Yes / No

Purpose:

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

⑦ Education and License of Pharmacists in your country

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

Primary	6 years
Secondary	3 years
High school	3 years

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

University / college:	6 years
Professional education:	varies years
Practical training:	varies years
Duration of training by each facility:	varies years
Hospital pharmacy:	6 weeks
Community pharmacy:	6 weeks
Pharmaceutical company:	6 weeks
Others:	- weeks
Age at graduation:	24 years old

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

Yes

Academic Exams 2 days

Clinical Exams 1 days

No

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

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

Practical training is a part of university education.

* If practical training is optional, give the reasons.

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

（５） Number of pharmaceutical university or college graduates:

about 1,700 people / per year

The alumni's placement rate (%)

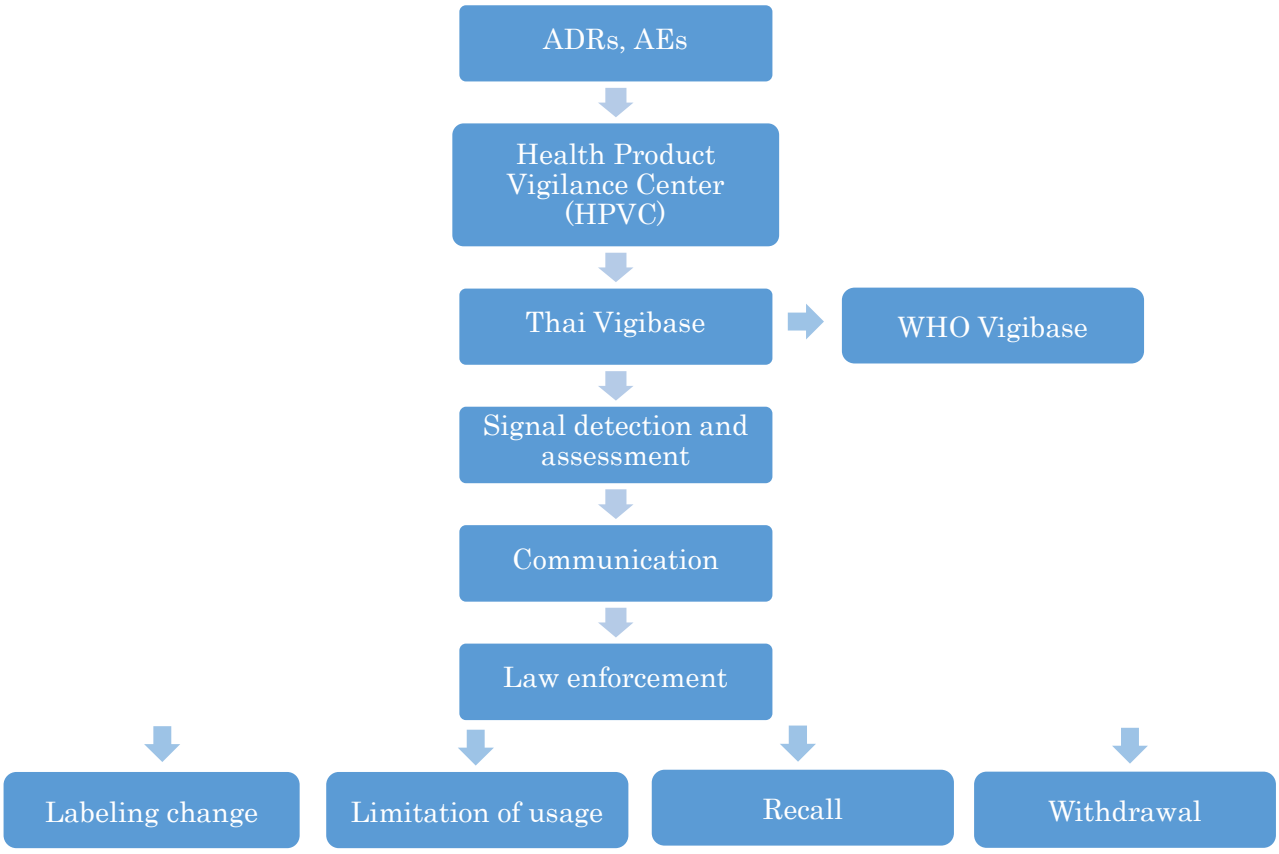
a. Hospital: N/A %
b. Community Pharmacy: N/A %
c. Government Organization: N/A %
d. Enterprise: N/A %
e. Others: N/A %

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.

Thai Health Product Vigilance Center (HPVC) is the main center under ThaiFDA. They take care of the ADRs or AEs reported from any sources of information. After getting the data, the staff will use the Thai Vigibase as a database for collecting data. The data may be sent to WHO Vigibase for further collection. After that, the information they get will be evaluated and assessed. If they find a relationship with medical products, the data will be distributed to related parties. Sometimes, law enforcement such as labeling change, limitation of use, recall and withdrawal will be implemented by related organizations to ensure safety of medical products for public. Generally, HPVC will contact an agency for each product for further actions.

ADR reporting flow chart



6. Timor-Leste

Republic Democratic of Timor-Leste
Ministry of Health
National Directorate of Pharmacy and Medicines / National Regulator Authority

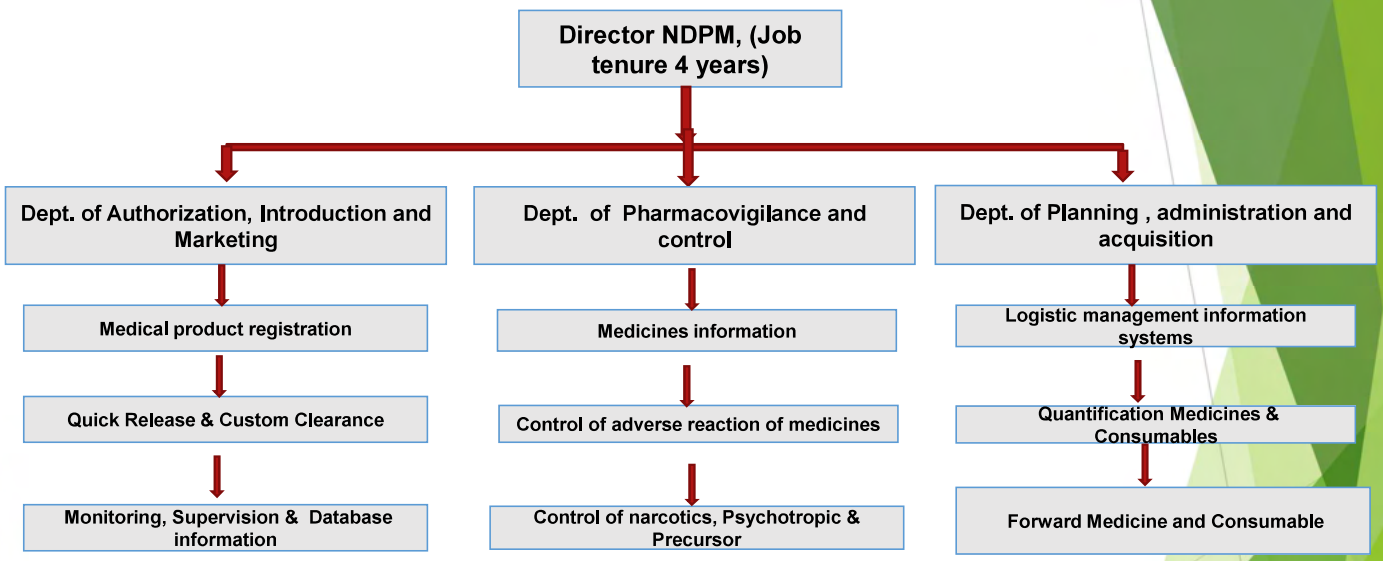
By : Alipio Gusmao Lopes

Timor-Leste

1. Introduction of the work

The National Directorate of Pharmacies and Medicines, responsible for the execution, monitoring and evaluation of the national drug policy, pharmaceutical activity and health laboratories.

NDPM- Organization Chart



Regulatory services

- Draw up technical rules for the installation and operation of pharmaceutical establishments, namely manufacturers and wholesalers, workshop pharmacies, pharmaceutical services of public and private hospitals and clinics, as well as drug sales outlets.
- Ensure the procedures for issuing marketing authorizations for medicinal products and maintain the respective records.
- Ensure inspection for the purposes of licensing pharmaceutical and laboratory activities.
- Issue authorizations for the licensing of industrial and commercial establishments for the production and sale of medicines, consumables and medical equipment.
- Ensure compliance with international obligations assumed within the scope of pharmaceutical activities, namely protocols relating to medicines and other potentially toxic, narcotic and psychotropic substances.
- Control of adverse reaction, falsified and sub standard medicines.

2. Good Practice

- All importers that have register to import medicines, Ministry of Health will authorized to the importers within 3 years and renew after 3 years.
- Registration of Medicines from 2012.
- Individuals Authorization in 2021
- Traditional Medicines (Herbal) register in 2020
- Consumables and Health Equipment, item Laboratory including reagents will register in 2022
- Row materials for the pharmaceutical product will register in 2022

Criteria importer to register medicines, Consumables, reagents, traditional medicines (Herbal medicines)

- ✓ Letter request for registration
- ✓ Identification office, Certificate of Licencing importer from MoH, and certificate of Licencing from SERVE.
- ✓ Monographic of Medicines.
- ✓ Sample labelling
- ✓ Sample that will register
- ✓ Others official documents :
  - GMP (Good Manufacture Product)
  - CoA (Certificate of Analysis)
  - CoPP /SIE/Free Sell
  - Ect

3. Difficulties/ Lesson learn from past experience

- Timor-Leste not yet established National Regulatory Authority
- No mechanism for controlling medicines price
- No laboratory testing for pharmaceutical products
- Lack of HR especially Pharmacist

4. Interest

- To know how to have good regulatory systems, relate to establishment of National Regulator Authority in Timor-Leste
- To know how to Control Medicines prices
- To know establishment Laboratory testing for pharmaceutical products

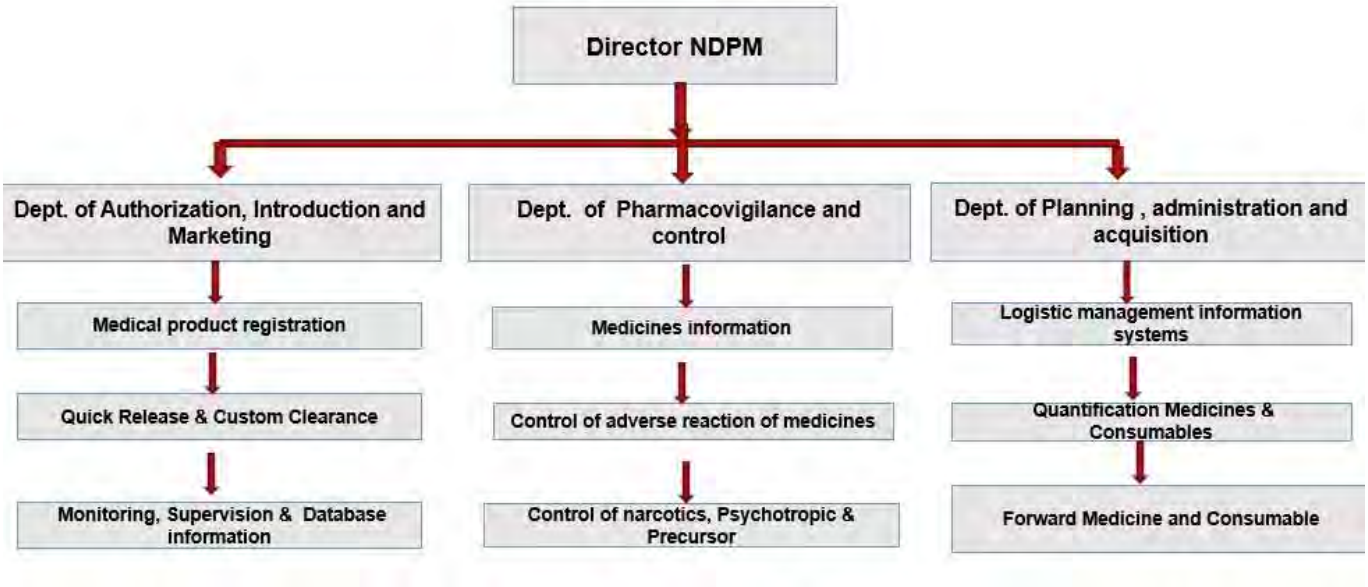
Thank You
Arigato

Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2021）

Name: Alipio Gusmao Lopes
Country: Timor-Leste
Organization: Ministry of Health National Directorate of Pharmacy and Medicines National Regulatory Authority

① Organizational Chart

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



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

1. Dept. of Authorization, Introduction and Marketing

a) Draw up technical rules for the installation and operation of pharmaceutical establishments, namely manufacturers and wholesalers, workshop pharmacies, pharmaceutical services of public and private hospitals and clinics, as well as drug sales outlets
b) Ensure the procedures for issuing marketing authorizations for medicinal products and maintain the respective records;
c) Ensure inspection for the purposes of licensing pharmaceutical and laboratory activities
d) Issue authorizations for the licensing of industrial and commercial establishments for the production and sale of medicines, consumables and medical equipment

2. Dept. of Pharmacovigilance and control

a) Ensure compliance with international obligations assumed within the scope of pharmaceutical activities, namely protocols relating to medicines and other potentially toxic, narcotic and psychotropic substances,

b) Control of adverse reaction, falsified and sub-standard medicines.

3. Dept. of Planning, administration and acquisition

a) Plan the needs in medicines, consumables and medical equipment to meet the needs of the National Health Service institutions;

b) Request from SAMES, the supply of medicines, reagents, medical consumables and health equipment for the institutions of the National Health Service;

※Hospital pharmacy only

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

② Legislation on pharmaceutical administration

−Please briefly bulletined major laws/acts

◆National Level

- Decree Law number 12/2004 administered by Ministry of Health
- administered by

◆Local Level

- administered by
- administered by

◆International Level:

- PIC/S: Yes OR No
  If yes, joined when
- Others if any
  by

③ 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

・Systems, Regulations, etc.

・ None administered by

・ administered by

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

◆Drug Import/Export

・Systems, Regulations, etc.

・ Authorized by Ministry of Health administered by NDPM

・ administered by

◆Marketing Authorization

・Systems, Regulations, etc.

・ Drugs registration with other documents administered by NDPM

・ administered by

※Example: Good Quality Practice

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

・Systems, Regulations, etc.

・Essential Medicines List for Timor-Leste administered by NDPM

・ administered by

◆Medicine Safety (post-marketing)

・Systems, Regulations, etc.

・ None administered by

・ administered by

※Example: Good Pharmacovigilance Practice

◆Relief System for Adverse Drug Reactions

・Systems, Regulations, etc.

・ Investigate and recall if have any problem administered by NDPM

・ administered by

④ Drug Pricing

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

Not yet established mechanism for control drugs price.

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 (Technical pharmacy 200 and pharmacist 20) (year) 2021
2. Number of GMP inspector (National & Local) None (year) 2021
3. Number of pharmaceutical manufacturers / manufacturing sites None (year) 2021

4. Number of traditional medicine manufacturers / manufacturing sites Unregister (year) 2021
5. Number of pharmaceutical importers 23importers (year) 2021
6. Number of pharmaceutical wholesalers more than 50 (year) 2021

※Hospital pharmacy only

⑥ **Information on your hospital pharmacy**

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

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

（２） Number of staff

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

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

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

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

a. For inpatients:
b. For outpatients:

（５） Equipment of the pharmacy in your hospital

a. Does your hospital have a dispensary room?
If "Yes", how large is it?
Yes 8 ㎡ 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: Ensure the data for report and request

d. Do you implement Therapeutic Drug Monitoring (TDM : Therapeutic Drug Monitoring) in your Hospital?
Yes / No

e. Do you prepare TPN (Total Parental Nutrition)

Yes / No

f. Can you use Internet at the pharmacy?

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

Yes / No

Purpose: _____

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

⑦ Education and License of Pharmacists in your country

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

Primary	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
Practical training:	6 months
Duration of training by each facility:	Monthly
Hospital pharmacy:	4 weeks
Community pharmacy:	4 weeks
Pharmaceutical company:	4 weeks
Others:	weeks
Age at graduation:	24 -26 years old

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

Yes

Academic Exams _____ days

Clinical Exams _____ days

No, Not yet established the mechanism

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

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

_____

* If practical training is optional, give the reasons.

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

_____

（５） Number of pharmaceutical university or college graduates: 20-50 people / per year

The alumni's placement rate (%)

a. Hospital: 30 %
b. Community Pharmacy: 50 %
c. Government Organization: 10 %
d. Enterprise: 5 %
e. Others: 5 %

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.

ADR is detected in a hospital or health facilities, the pharmacists should fill the form and send it to the NDPM, based on that from National directorate technically investigate and will decide for the medicines that detected ADR.

7. Uganda

KABALE REGIONAL REFERRAL HOSPITAL

RODNEY TABARUKA TIBARUHA

1. Introduction of the work

- In this section, please describe below.

Organization and department that you belong to

KABALE REGIONAL REFERRAL HOSPITAL-DEPARTMENT OF PHARMACY

Job tenure

10 YEARS

Regulatory services that you are engaged in

Liaising with National Drug Authority in ensuring that all medicines conform to prescribed standards.

Roles and position of pharmacists in your country

- Requisitioning and ensuring that medical supplies are available.
- • Advising and updating clinicians on prescriptions.
- • Liaising with Ward management in ensuring that drugs are properly recorded and stored.
- • Participating in planning and budgeting for the pharmacy unit and accounts for the medicines and infusions.
- • Participating in drugs and clinically related research.
- • Compiling reports to the Hospital Director
- • Ensuring equipment are functional and well maintained.
- • Liaising with National Drug Authority in ensuring that all medicines conform to prescribed standards.
- • Advising patients and communities on the proper use and storage of drugs and vaccines.
- • Imparting knowledge and skills to students and Staff.

2. Good Practice

−In this section, please describe your experiences about Good Practices

- Examples
  - ✓ Achievements

    Detection of counterfeit medicines such as Gentamycin injection and Some batches of Injection Bupivacaine
  - ✓ Solutions for past problems

    Liaising with the National Drug Authority to investigate cases of counterfeit medicines from the user to importers(upstream supply chain)
  - ✓ On-going projects to deal with current problems

    Active Pharmacovigilance wiyhin the hospital and the capturement area.
  - ✓ Successful countermeasures against problems

    14 safety and quality reports submitted to the National drug Authority in 2021/22 financial yearand properly investigated , such counterfeit medicines have been recalled and removed from the circulation

3. Difficulties/Lessons Learned from Past Experience

− In this section, please describe your experiences which you have faced difficulties, or struggled;

- Examples

✓ Problems that cannot be improved or solved

Entry of falsified medicines through porous borders

✓ Failed countermeasures to deal with the problems

Arresting black market dealers in repackaged/ counterfeited medicines

✓ Emerging or Re-emerging Problems, if any

Repackaging medicines, expired medicines being sold to the population, black market medicine sell industry(unregulated trade in Pharmaceuticals)

4. Your interests

- In this section, please describe issues you are expecting to this Program.
- At Maximum THREE issues!

(1) Better detection of counterfeit medicines without relying on user reports of adverse incidents

(2) How Japan ensures safe and efficacious medicines to its population.

Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2021）

Name: RODNEY TABARUKA TIBARUHA
Country: UGANDA
Organization: KABALE REGIONAL REFRRAL HOSPITAL

① Organizational Chart

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

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

※Hospital pharmacy only

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

Key Responsibilities and accomplishments

• Requisitioning and ensuring that medical supplies are available.

• Advising and updating clinicians on prescriptions.

• Liaising with Ward management in ensuring that drugs are properly recorded and stored.

• Participating in planning and budgeting for the pharmacy unit and accounts for the medicines and infusions.

• Participating in drugs and clinically related research.

• Compiling reports to the Hospital Director

• Ensuring equipment are functional and well maintained.

• Liaising with National Drug Authority in ensuring that all medicines conform to prescribed standards.

• Advising patients and communities on the proper use and storage of drugs and vaccines.

• Imparting knowledge and skills to students and Staff.

② Legislation on pharmaceutical administration

−Please briefly bulletined major laws/acts

◆National Level

- _____ administered by _____
- _____ administered by _____

◆Local Level

・ administered by

・ administered by

◆International Level:

・ PIC/S: Yes OR No

If yes, joined when

・ Others if any

by

③ 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

・Systems, Regulations, etc.

・ NATIONAL DRUG AUTHORITY administered by

・ INSPECTORATE administered by

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

◆Drug Import/Export

・Systems, Regulations, etc.

・ NATIONAL DRUG AUTHORITY administered by

・ administered by

◆Marketing Authorization

・Systems, Regulations, etc.

・ NATIONAL DRUG AUTHORITY administered by

・ DRUG ASSESSMENT administered by

※Example: Good Quality Practice

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

・Systems, Regulations, etc.

・ NATIONAL DRUG AUTHORITY administered by

・ INSPECTORATE DEPARTEMNT administered by

◆Medicine Safety (post-marketing)

・Systems, Regulations, etc.

・ NATIONAL DRUG AUTHORITY administered by

・ PRODUCT SAFETY DEPARTMENT

administered by

※Example: Good Pharmacovigilance Practice

◆Relief System for Adverse Drug Reactions

・Systems, Regulations, etc.

・ NATIONAL DRUG AUTHORITY administered by

・DEPARTMENT OF PHARMACOVIGILANCE administered by

④ Drug Pricing

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

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	1045 (year)
2.	Number of GMP inspector (National & Local)	54 (year)
3.	Number of pharmaceutical manufacturers / manufacturing sites	12 (year)
4.	Number of traditional medicine manufacturers / manufacturing sites	(year)
5.	Number of pharmaceutical importers	(year)
6.	Number of pharmaceutical wholesalers	(year)

※Hospital pharmacy only

⑥ Information on your hospital pharmacy

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

a. Number of section chiefs: 3
b. Number of deputy chiefs: 5
c. Number of managers: 9

（２） Number of staff

a. Number of pharmacists: 2
b. Number of clinical pharmacists: 0
c. Number of technicians: 2

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

a. Oral medicine: 88
b. Injections: 72
c. Medicines for external use: 12

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

a. For inpatients: 145
b. For outpatients: 70

（５） Equipment of the pharmacy in your hospital

a. Does your hospital have a dispensary room?

If "Yes", how large is it?

Yes ✓ 22 ㎡ 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: SUPPLY CHAIN MANAGEMENT, REQUISITIONS/ ISSUES, ACCOUNTABILITIES

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

⑦ Education and License of Pharmacists in your country

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

Primary	7 years
Secondary	4 years
High school	2 years

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

University / college:	4 years
Professional education:	4 years
Practical training:	1 years
Duration of training by each facility:	4 years
Hospital pharmacy:	1 weeks

Community pharmacy: 8 weeks

Pharmaceutical company: 8 weeks

Others: 8 weeks

Age at graduation: 24/25 years old

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

Yes

Academic Exams 2 days

Clinical Exams 2 days

No

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

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

HOSPITAL CLINICAL PHARMACY, SUPPLY CHAIN MANAGEMENT, INDUSTRIAL PHARMACY, REGULATORY AFFAIRS(NATIONAL DRUG AUTHORITY)

* If practical training is optional, give the reasons.

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

ITS MANADATORY

（５） Number of pharmaceutical university or college graduates:

120 people / per year

The alumni's placement rate (%)

a. Hospital: 1 %

b. Community Pharmacy: 91 %

c. Government Organization: 2 %

d. Enterprise: 5 %

e. Others: 1 %

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.

When we detect an adverse drug Reaction, it’s reported to the department of Pharmacy which is the official liaison office with the National Drug Regulator, The National Drug Authority. The Pharmacy department first constitutes local investigations using the Pharmacovigilance Subcommittee of the Medicines. After these investigations are complete, a form is filled detailing the adverse event and the probable drugs behind the drug event and submitted online to the National Drug Authority Pharmacovigilance office under the product safety department. This department collects all reports from across the country on the same issue and if found to be a widely occurring side effect, its investigated by the National Drug Authority and its supply is halted in the country, and also sometimes issues a product recall, to ensure the safety of the population.

出典：2021 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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