Regulatory Systems on Ensuring Access to Quality Medicines

Country Reports

Japan International Corporation of Welfare Services (JICWELS)

Contents

Afghanistan

Kiribati

Ministry of Health & Medical Services

Kiribati

Kiribati Government Pharmacy

Biribo Kararaiti
Acting Chief Pharmacist

1. Introduction:

- Kiribati Government Pharmacy within the Ministry of Health & Medical Services (MHMS), Republic of Kiribati

Job Tenure:

I. pharmacy assistant from 2000 to 2007 – assisting in dispensing of medicine and stock control
II. Procurement pharmacist from 2008 to 2017 – ensures that all medicines are procured annually
III. acting Chief pharmacist up to date – now involving in health related policy making and review, budget planning for pharmaceutical and medical annual spending

Introduction

Regulatory Services

- National Medicine Therapeutic Committee (Secretary)
- Reprductive,Maternal,Neonatal,Child,Aldolescent Health (RMNCAH)
- Surveillance committee (member)

Roles of pharmacist

- Ensures rational prescribing of medicine by prescribers
- Medicine information sharing to health professionals
- Checking of medicines availability in the country
- Participating in training of nurses on basic pharmacology
- Medicine forecasting and quantification for annual order (tender)
- Pharmacy to patient effective counselling

2. Good Practice

Achievement;

Medicine Act 2018 review and updated

Establishment of New Pharmaceutical warehouse

Capacity building among pharmacy staff supported by health programs (UNFPA, UNICEF,

Establishing of clinical pharmacy to cater for a daily ward round

Developing of AMR National action Plan

Storage

•Examples

- ✓ Achievements
- ✓ Solutions for past problems
- ✓ On-going projects to deal with current problems
- ✓ Successful countermeasures against problems

3. Difficulties/Lessons Learned from Past Experience

1. ADR un-reported – New Zealand help to establish but un-successful. Up to now there was no report.
2. Stock out in the country – A chronic issue that really affect the quality health care service delivery
3. Mis-use of medicine by the public or community
4. Un regulated medicine imported into the country by private pharmacy and general stores - No National Regulatory Authority
5. Poor pharmacist to doctors intervention

4. Your interests

- The safety of our patient is our priority and therefore I am more interested in acquiring technical and specialize skills in the following;

(1). Ensures that stock availability was well maintained through out the procuring period

(2). Enforcing regulations and laws in medicine importation into the country

(3). Improving work collaboration between health and NGOs to improve on the use of medicine.

Challenges

- Very poor GMP – Lack of equipment, poor manufacturing area – not meeting WHO standard
- Multiple task for pharmacy department
- Lack of specialized staff – need professional continuous education (due to Government training policy)
- Demographic

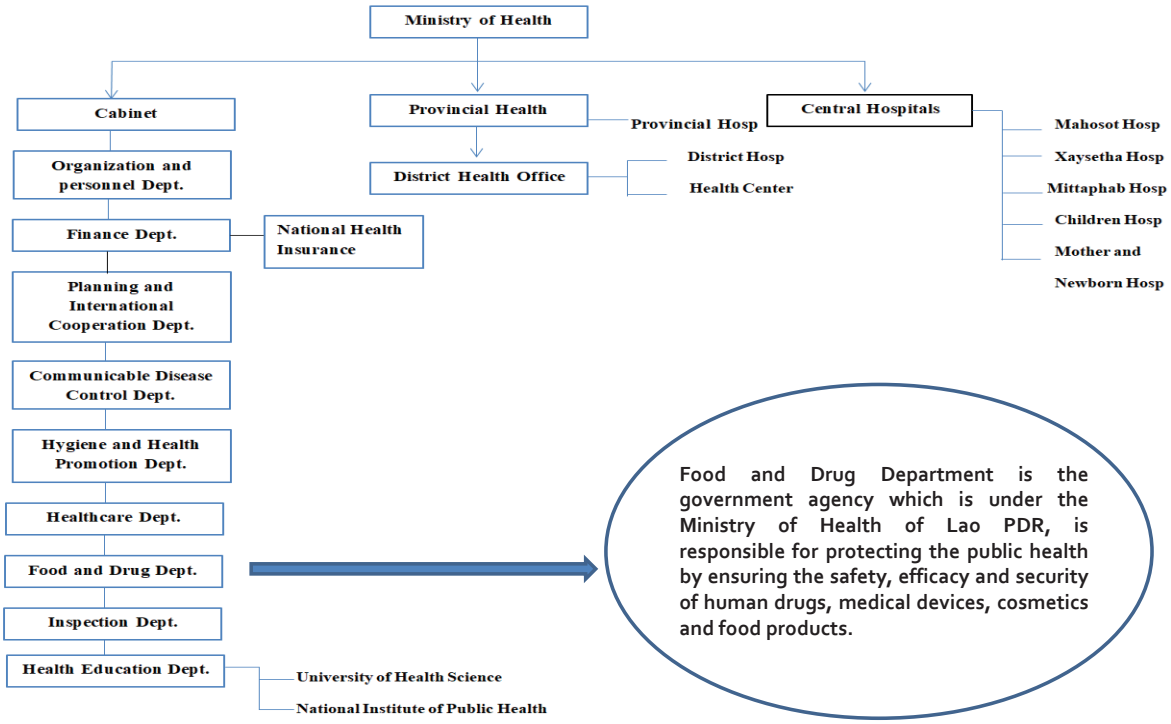
Laos

LAO PDR

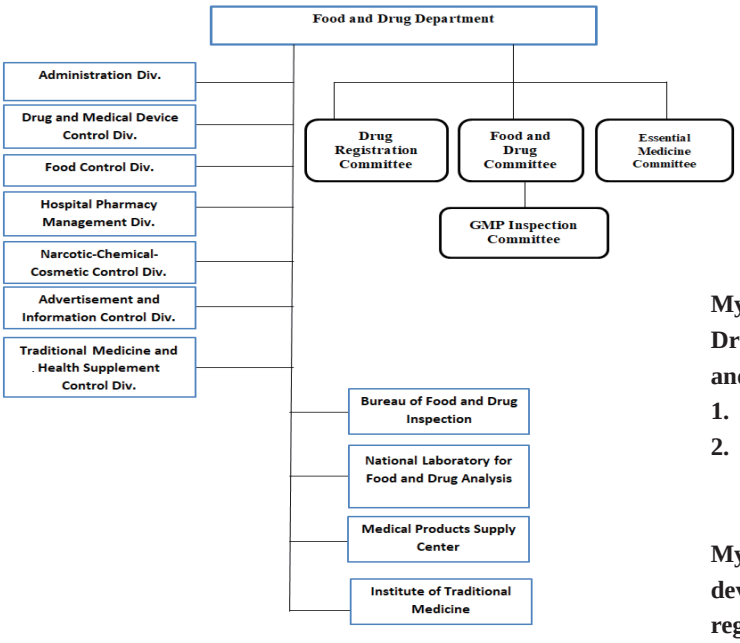
Food and Drug Department, MoH

Ms. Davone Duangdany

1. Organization Chart of Ministry of Health



2. Food and Drug Department (FDD)



Drug and Medical Devices Control Division is a division within Food and Drug Department which is responsible for:

1. **Drug registration**
2. **manufacturer, pharmaceutical products import-export companies and community pharmacies licensure**
3. **Import permission of pharmaceutical products and medical devices.**

My current position is a deputy head of Drug and Medical Device Control Division, and my major responsibility is:

1. **Drug registration dossier evaluation**
2. **Medical device import permission and development of related to drug registration regulations.**

My current project is to participate in the development of online system for drug registration and the establishment of Pharmacists Association.

3. Role of pharmacists in Lao PDR

- In Lao PDR, the role of the pharmacist in the health care system has been neglected and is not well defined.
- In current, Food and Drug is working on the establishment of Pharmacists Association in order to improve the pharmacists licensing system and to give the pharmacists rightful position in the society.

4. Good Practice

- In the area of drug registration

In the situation of shortage of human resources, the dossier evaluation could not be completed as the appointed timeline.

In order to improving the efficiency while maintaining standard for evaluating the quality, safety and efficacy of pharmaceutical products, there is a need to have a greater and more effective technology. Therefore, the online system for drug registration and guidelines are developing.

4. Good Practice

- In the area of medical device regulation

Medical device registration is still not implemented in Lao PDR. In the period of COVID-19 pandemic, to assure the availability and accessibility to good quality facemask and disinfectants, the temporary requirement for testing and analysis, the temporary for local production of facemask and disinfectant were developed and the role of community pharmacy in prevention of COVID-19 were established.

5. Difficulties/Lessons Learned from Past Experience

- Unqualified Licensed pharmacists (Past experience learned)
- How to improve the time efficiency on dossier evaluation (Should we have the list of priority drugs for registration?) (Past experience learned)
- The effort on establishment of Pharmacists Association, which need to have the pay attention from social and the awareness of pharmacists role.(Difficulties)

6. My interests

(1) The drug approval process in Japan, especially for the biological products such as: vaccine.

(2) The pharmacist licensing in Japan, the history and lesson learn of the national licensing examination.

(3) GMP and Quality regulation in Japan

Thank you for your attention!

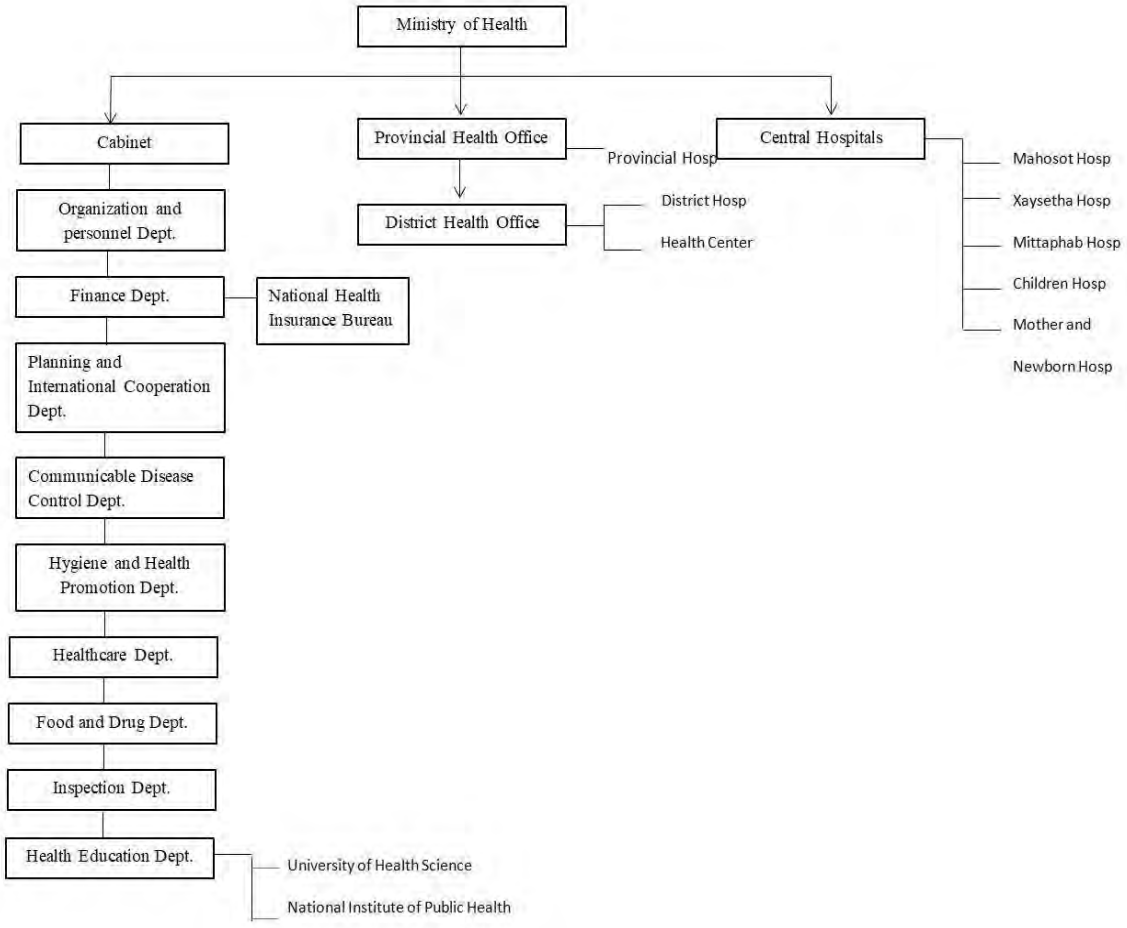
Part I: INFORMATION SHEET

Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2020）

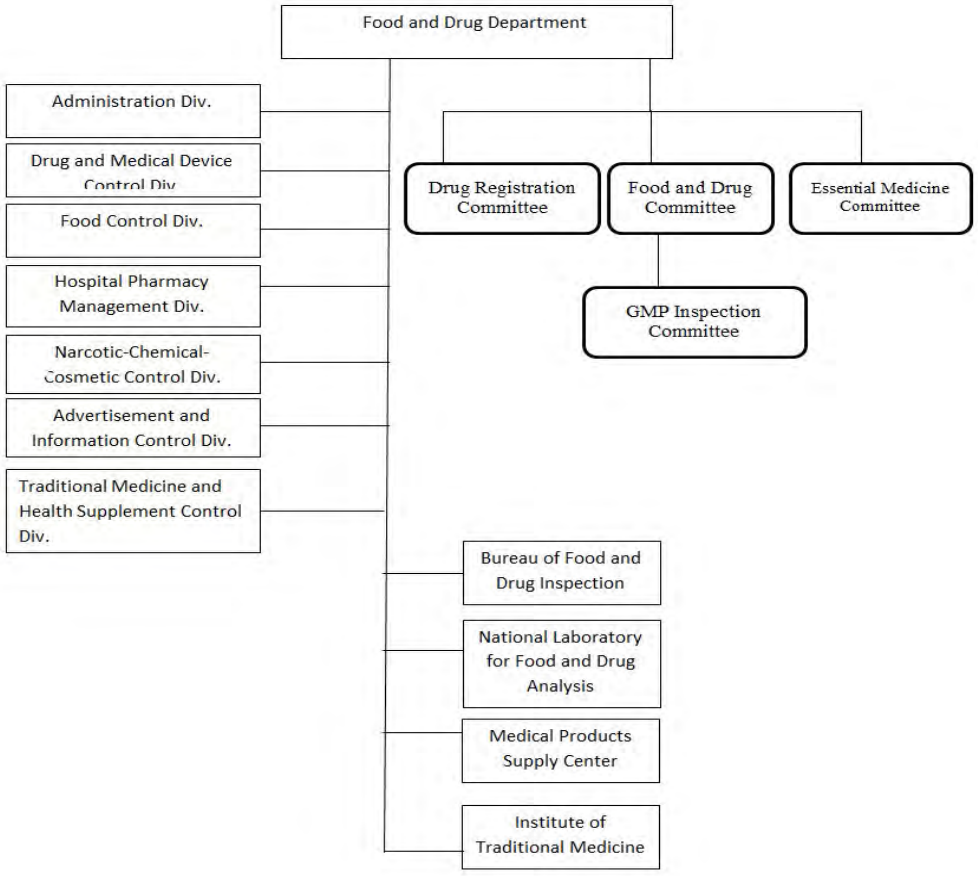
Name: Ms. Davone DUANGDANY
Country: Lao PDR
Organization/Department/Division:Drug and Medical Device Control Div, Food and Drug Department, Ministry of Health

① **Organizational Chart**

- **The organization chart of Ministry of Health**



- **The organization chart of Food and Drug Department**



- Food and Drug Department is the government agency which is under the Ministry of Health of Lao PDR, is responsible for protecting the public health by ensuring the safety, efficacy and security of human drugs, medical devices, cosmetics and food products.
- Drug and Medical Devices Control Division is a division within Food and Drug Department which is responsible for the drug registration, manufacturer, pharmaceutical products import-export companies and community pharmacies licensure and import permission of pharmaceutical products.

② Legislation on pharmaceutical administration

- Lao National Drug Policy (First Revision, 2003)
- Law on Drug and Medical Products No. 07/NA , dated: 21 December 2011
- Regulation on Business Establishment for Medicine and medical Product Company No. 1820/MoH, (Revision dated 25 August 2017)
- Regulation on Drug registration No.1441, dated 13 August 2003.
- Regulation on the manufacturing of medicine and medical products No. 937/MoH, dated 12 May 2004.
- Regulation on Pharmacy No.2922 (Revision dated 21 September 2016)
- Regulation on Good Manufacturing Practice and Quality Control of Drugs No. 1021, dated 11 Aug 1999.
- Regulation on Drug and Medical Products Donation No. 2579/MoH, dated 12 November 2003.
- Regulation on Drug and Medical Products Diposal No. 1862, dated 5 August 2016.
- Lao National Essential Drug List 2019

- PIC/S

Yes OR No (Non PIC/S member)

③ **Regulatory Services**

◆Pharmaceutical Manufacturing

- Pharmaceutical Manufacturing regulated by Law on Drug and Medical Products No. 07/NA, dated: 21 December 2011, Regulation on the manufacturing of medicine and medical products No. 937/MoH, dated 12 May 2004 and Regulation on Good Manufacturing Practice and Quality Control of Drugs No. 1021, dated 11 Aug 1999. (Administration by National central level: Food and Drug Department, Licensing Approval by Ministry of Health)

◆Drug Import/Export

- Drug Import/Export regulated by Law on Drug and Medical Products No. 07/NA, dated: 21 December 2011 and Regulation on Business Establishment for Medicine and medical Product Company No. 1820/MoH, (Revision dated 25 August 2017).
- Import/Export permit is issued by Food and Drug Department, the Import/Export at the border checkpoint is inspected by inspectors of Bureau of Food and Drug Inspection.

◆Marketing Authorization

- Marketing Authorization regulated by Law on Drug and Medical Products No. 07/NA, dated: 21 December 2011 and Regulation on Drug registration No.1441, dated 13 August 2003. (Administration by Food and Drug Department)
- The procedure of registration is divided into 2 steps:
  Step 1: Application for the permission to import or manufacture drug sample intended to be registered
  Step 2: Application for the Drug Registration approval
- ➢ The registration certificate is to be renewed every 3 years

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

- Drug distribution is administrated by Medical Products Supply Center, while the distribution is followed the Good Distribution Practice (GDP).
- The selection of drug is done by committee, which the national essential medicines list is publicly available criteria and transparent procedures for the selection process for inclusion in or deletion from the list.
- The procurement of pharmaceutical products regulated by Procurement Manual, Ministry of Finance, dated: April 2009. The procurement committee is to make decision on procurement. Most of time price comparison is being used.
- The sale of pharmaceutical products regulated by Law on Drug and Medical Products No. 07/NA , dated: 21 December 2011, Regulation on Business Establishment for Medicine and medical Product Company No. 1820/MoH,

(Revision dated 25 August 2017) and Regulation on Pharmacy No.2922 (Revision dated 21 September 2016).

◆Medicine Safety (post-marketing)

- Post- marketing surveillance is responsible by the Bureau of Food and Drug Inspection.
- The pharmacovigilance is regulated by Law on Drug and Medical Products No. 07/NA, dated: 21 December 2011 and the guideline on pharmacovigilance practice (administration by Food and Drug Department, implemented by Hospital Pharmacy Management and Adverse Reaction Committee).

◆Relief System for Adverse Drug Reactions

- Vigilyze is used and ADR is reported to VigiFlow (the relief System is not yet to develop)

④ **Drug pricing**

- Drug price control is regulated by Law on Drug and Medical Products No. 07/NA, dated: 21 December 2011, which is mentioned in Chapter 3: Price control of drug and medical products, but there is no instituted mechanisms intended to control drug price. There is the need to develop the mechanisms to control factory-gate price and measures at the provincial level and reference-based pricing. The drug distributed in public sector is limits of markup not more than 20%. However, the price control in Lao PDR faced challenges by all of API and more than 50% of drugs are imported and the pharmaceutical industries in Laos are small production scale.

⑤ **Statistic data**

1. Number of pharmacists 2300 (2020)
   * In current, there is just the data on licensing pharmacists who established the pharmacy, pharmaceutical company and pharmaceutical manufacturing which licensing issued by Food and Drug Department available, not included the pharmacists who work in another field such as: hospital pharmacy, education facilities and others, since the licensing is not a requirement for their career.

2. Number of GMP inspector (National & Local) 14 (2020)
   *The GMP inspectors are from the GMP inspection committee which is approved by Ministry of Health, of them 9 inspectors are Modern drug GMP inspectors, 5 are Traditional and Health Supplements GMP inspectors.
3. Number of pharmaceutical manufacturers / manufacturing sites 10 (2020)
4. Number of traditional medicine manufacturers / manufacturing sites 4 (2020)
5. Number of pharmaceutical importers 86 (2020)
6. Number of pharmaceutical wholesalers 11 (2020)

⑥ Education and License of Pharmacists in your country

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

Primary 5 years
Secondary 3 years
High school 4 years

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

University / college: 5 years
Professional education: years
Practical training: years
Duration of training by each facility: years
Hospital pharmacy: weeks
Community pharmacy: weeks
Pharmaceutical company: weeks
Others: weeks
Age at graduation: 22 years old

* There is no specific pharmacy training center in Lao PDR, the training on pharmacy for hospital and community pharmacy is trained by Food and Drug Department, regularly 2 times per year on specific title such as: rational use of drug, Good Pharmacy Practice and drug regulations.

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

Yes

Academic Exams days
Clinical Exams days

No:

* There is no any national examination for pharmacists, the pharmacist who licensed by FDD are intend to establish the pharmacy, pharmaceutical import/export company or pharmaceutical manufacturing factory, the license approval base on their working experience on the field of pharmacy and others document evaluation without the examination.

（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)
* There is no any training required in order to obtain a pharmacist's license, but after license approve, the training is provided by FDD annually.

（5） Number of pharmaceutical university or college graduates:

150 people / per year

The alumni's placement rate (%)

a. Hospital: %

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

Thailand

THAILAND

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

Ministry of Public Health

Narisa Chalaemvaree

Pharmacist, Registration Section, Drug Registration and Pharmacovigilance Division

独立行政法人 国際協力機構

Introduction of the work

Roles and Position of Pharmacists in Thailand

Research pharmacist

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

Industrial pharmacist

- Drug manufacturing control
- Quality assurance and quality control

Marketing pharmacist

- Medical representative

Education pharmacist

Hospital pharmacist

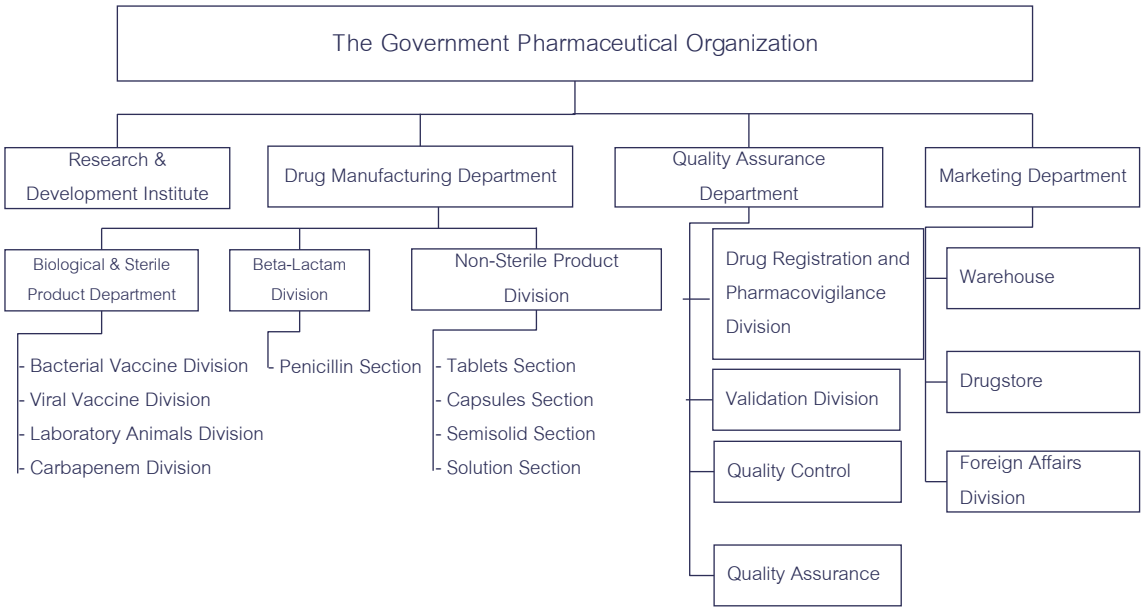
- Drug warehouse
- Extemporaneous preparation
- Therapeutic drug monitoring
- Drug dispensing

Drugstore pharmacist

- Drug distribution and dispensing
- Follow up and patients visit

Introduction of the work

Organization and Department



Introduction of the work

My Roles and Positions

Organization and Department

- Drug Registration and Pharmacovigilance Division, Registration Section

Job Tenure

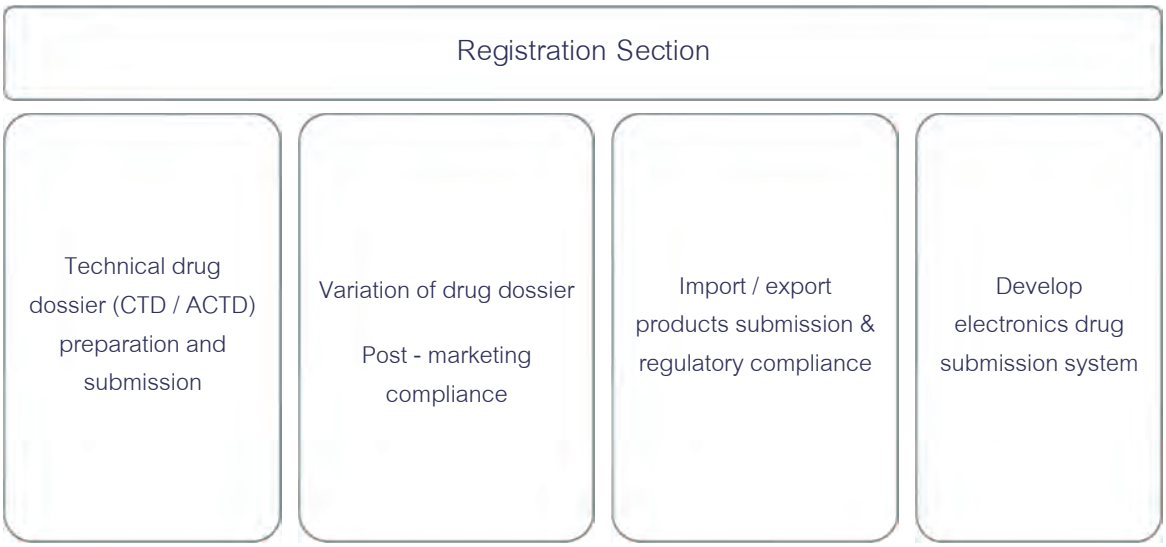
- Drug registration, and variation technical dossier preparation and submit to FDA

Engaging Regulatory Service

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

Good practice

Experiences About Good Practice



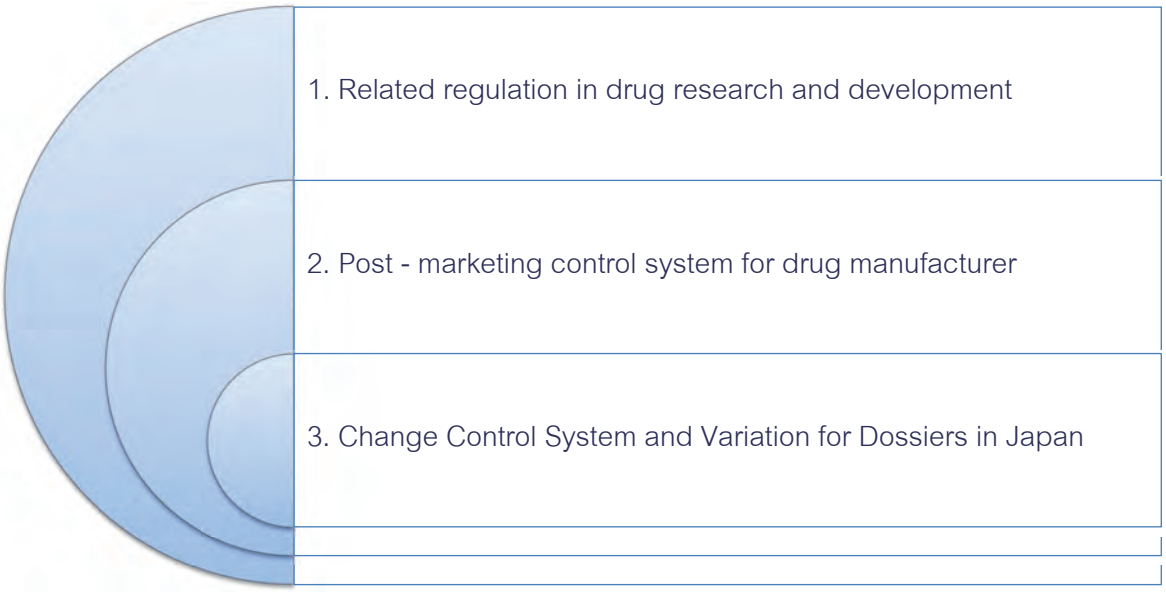
Difficulties / Lessons learned from past experiences

Difficulties or Struggled

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

Interests

Expected Issues to This Program



Part I: INFORMATION SHEET

Regulatory Systems on Ensuring Access to Quality Medicines (JFY 2020)

Name: NARISA CHALAEMVAREE
Country: Thailand
Organization/Department/Division:
Drug Registration Section,
Drug Registration and Pharmacovigilence Division
The Government Pharmaceutical Organization

① Organizational Chart

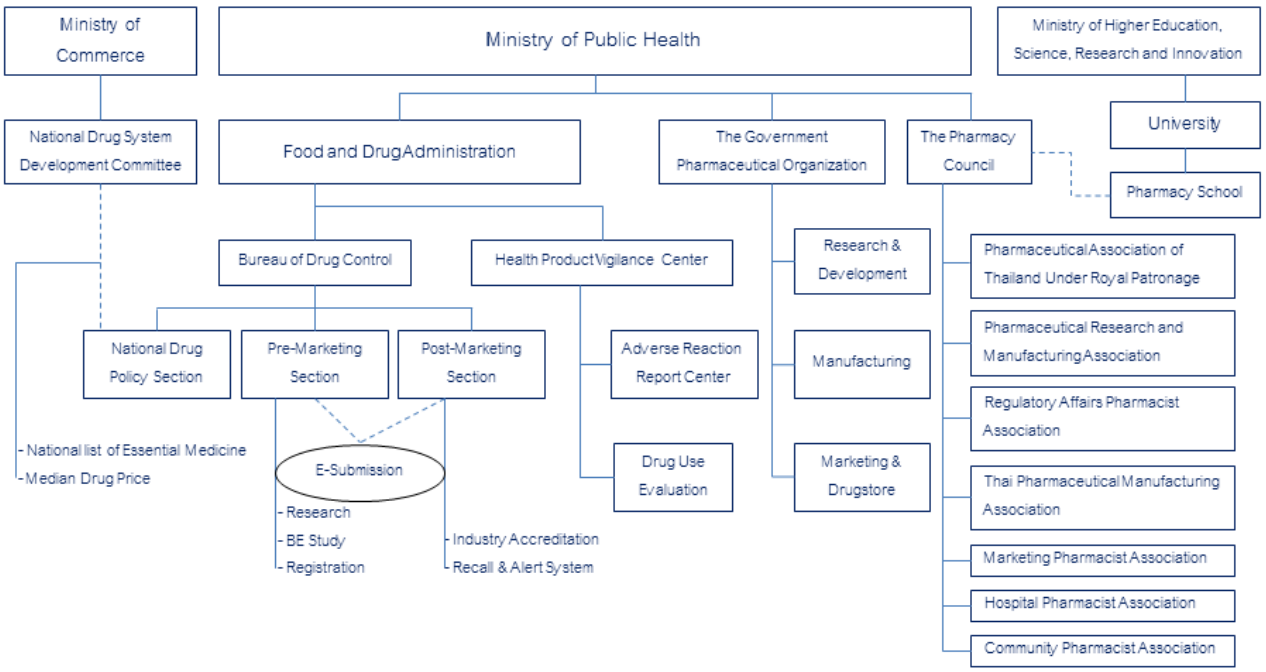


Chart: Thailand's National Drug system

Pharmaceutical Administration

Food and Drug Administration (FDA) responsibilities including of;

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

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

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

• Consumer Education: To provide health products' information.

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

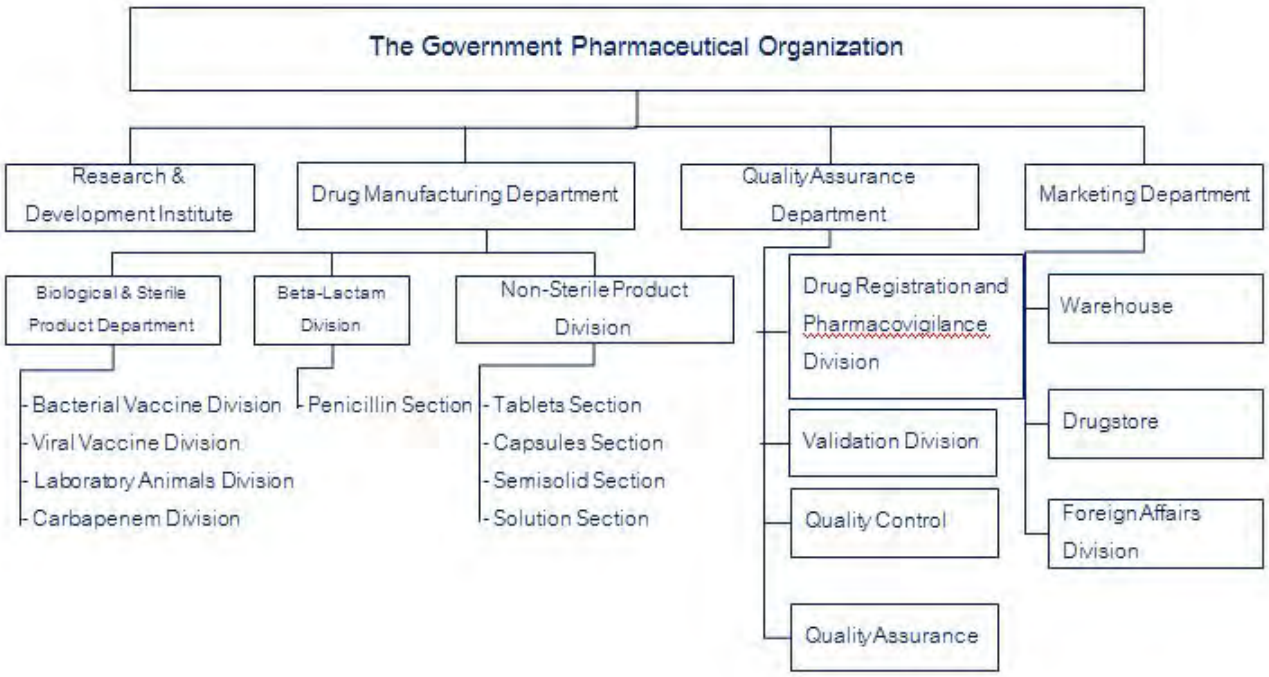


Chart: The Government Pharmaceutical Organization

Pharmaceutical Research, Manufacturing and Marketing

The Government Pharmaceutical Organization (GPO)

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

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

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

② Legislation on pharmaceutical administration

◆ National Level

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

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

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

◆ Local Level

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

・Ministry Announcement administered by FDA & Public Health Office

◆ PIC/S

・Yes since August 1st, 2016

③ Regulatory Services

◆ Pharmaceutical Manufacturing

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

◆ Drug Import/Export

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

◆ Marketing Authorization

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

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

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

◆ Medicine Safety (post-marketing)

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

◆ Relief System for Adverse Drug Reactions

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

Abbreviation and Acronyms

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

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

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

A: First line drug complied with medical guideline

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

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

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

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

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

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

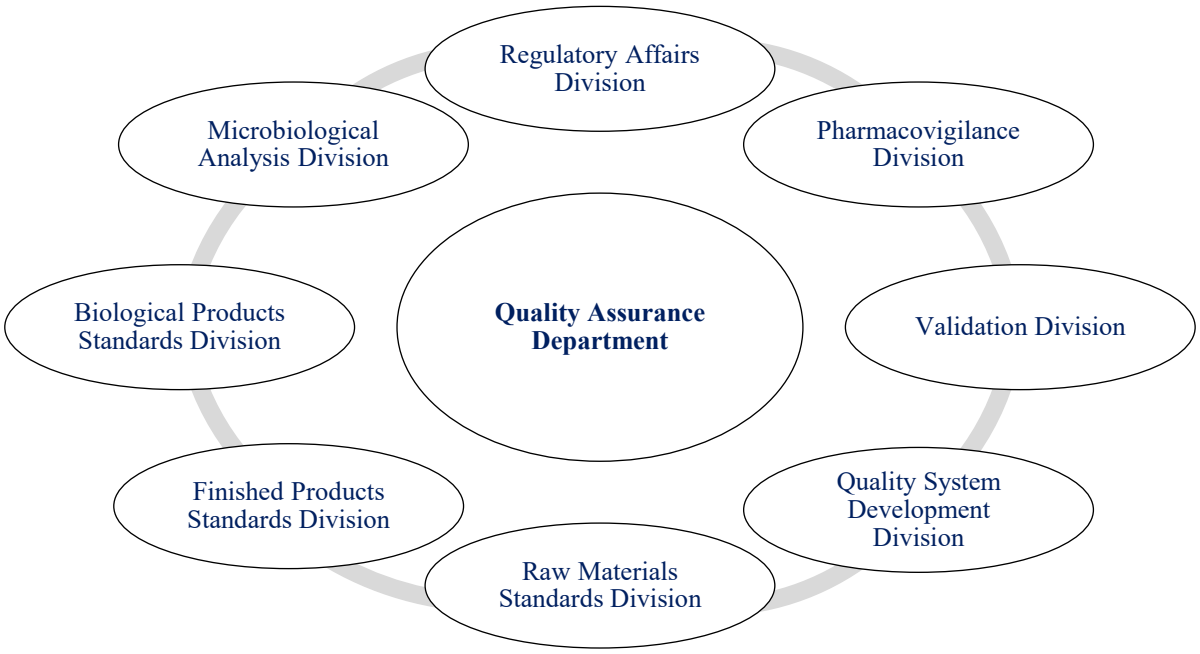
National Drug Median Price affected only at the government hospital. For private sectors, the median price or ceiling is not set. But the drugs' price must have been announced to the patients, including of purchased price and selling price.

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

⑤ **Statistic Data**

1. Number of pharmacists		40,152	(2019)
2. Number of GMP inspector (National & Local)	National	38	(2019)
3. Number of pharmaceutical manufacturers / manufacturing sites		142	(2020)
4. Number of traditional medicine manufacturers / manufacturing sites		481	(2019)
	GMP accredited	53	(2020)
5. Number of pharmaceutical importers		649	(2019)
6. Number of pharmaceutical wholesalers		194	(2018)

⑥ Information on your industrial pharmacy



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

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

(2) Number of staff

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

(3) Number of the kinds of drug products

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

⑦ Education and License of Pharmacists in your country

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

Primary	6 years
Secondary	3 years
High school	3 years

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

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

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

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

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

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

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

The alumni's placement rate (%)

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

⑧ Side effect report

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

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

Surveillance system including of;

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

Timor-Leste

TIMOR LESTE

SAMES

SATURLINA XIMENES

WAREHOUSE MANAGEMENT AND DISTRIBUTION.

1. Introduction of the work

- SAMES is an autonomous institution, which is engaged in the health sector, responsible for procurement, storage and Distribution of medicines, consumables and reagents.@@
- I am the Director of Warehousing and Distribution.@@
- SAMES has regulation of Ministry of Health number 21/2016, 9 March which was recently changed to 36/2020, 8 March.
- Pharmacist hold multiple roles in SAMES, DNFM, hospitals and pharmacies in TL.

2. Good Practice

- We use mSupply to assist us in managing our stock.
- **It is an electronic system that assists in procurement, receipt and distribution, stock taking, expired medicines and reporting.**

Good Practice Continue

- We are expanding mSupply to hospitals and other facilities in TL to help them manage the stocks medicines, Consumables and Reagent.
- SAMES established 3 warehouses in each region to speed up distribution to hospitals and health facilities in the district.

3. Difficulties/Lessons Learned from Past Experience

- One of the challenges in SAMES is not being able to test the quality of medicines.
- Sometimes we have items where we are concerned about the quality but cannot test.
- Therefore, we are looking to establish medicines testing in TL

4. Your interests

(1)Warehouse stock management system and Distribution.

(2) Quantification

(3) Test Quality of Medicines

THANK YOU

OBRIGADO

出典：2020 年度 JICA 課題別研修カントリーレポート
2020 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」

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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