Regulatory Systems on Ensuring Access to Quality Medicines

Country Reports

FY2022

Japan International Corporation of Welfare Services (JICWELS)

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1. Iraq

Part I: INFORMATION SHEET

Regulatory Systems on Ensuring Access to Quality Medicines （JFY 2022）

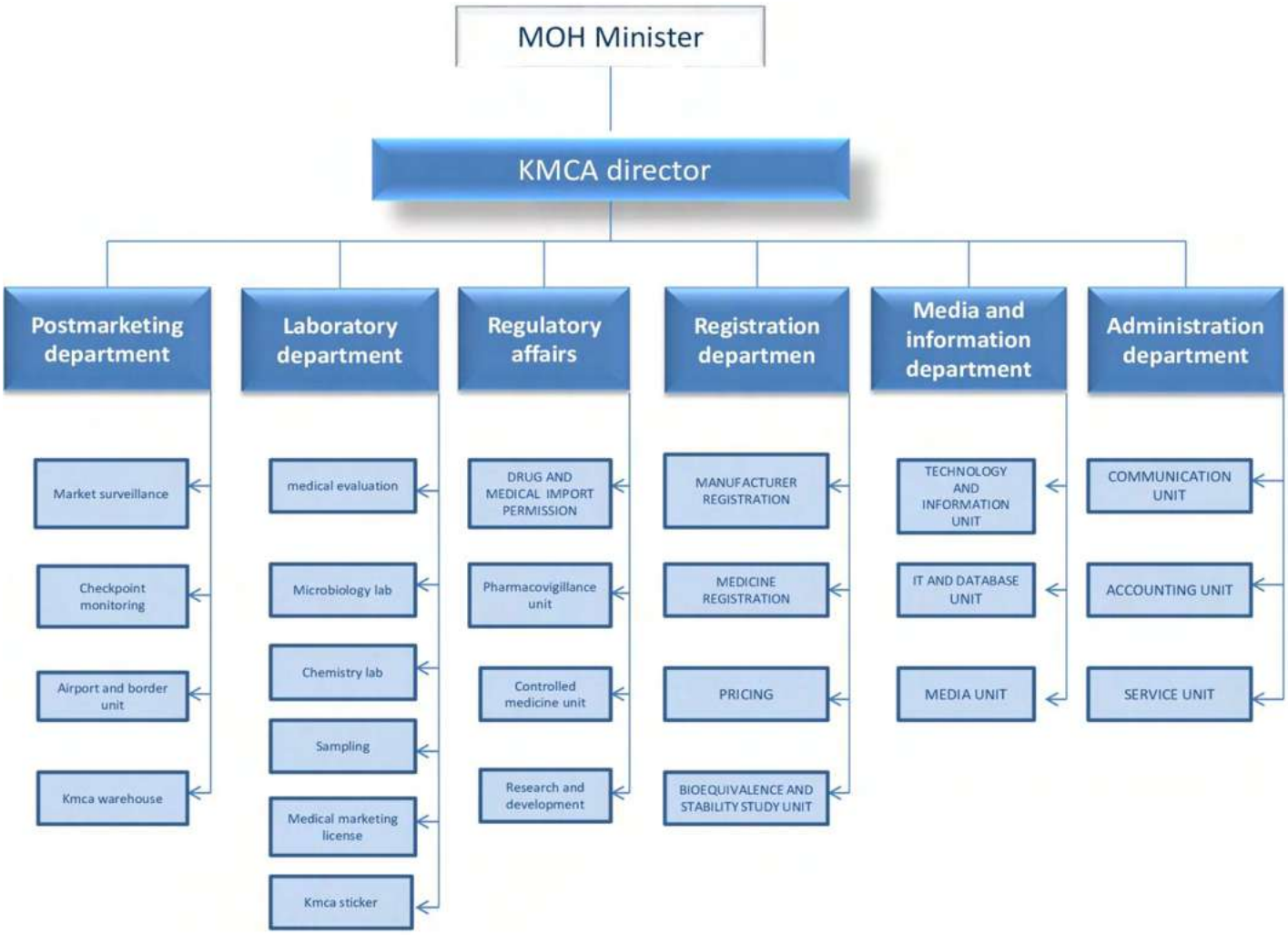
Name: Mamand Rashid Mamand

Country: Iraq/ Kurdistan region

Organization/Department/Division: Ministry of health krg/ Kurdistan medical control agency

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- administration department

this department covers both administrative and financial units to organize the affairs of the office and human resources, plays an important role for giving incentives to employees and organize expenditures

2- media and informative department

this department consist of three different units with different role

a/ technology and information unit, this unit is to provide and repair all electronic equipment's of the organization

b/ IT and Database unit is responsible for kmca system and online service which is available for all legalized applicant.

c/ media unit, publishes the latest information on medicines and activities of KMCA and publish necessary guidelines on medicines and pharmaceutical products to the community.

3-Registration department

Is the most important department in KMCA which is responsible for registration of manufactures and medicines according to legal documents.

4-regulatory affairs

a/This department is responsible for issuing permits to pharmaceutical importing companies into the country after insuring the status of manufacturing registration. Aplicants submit their documents online like COA, COO. Packing list and invoice

b/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.

5-Laboratory department

a/ This department is responsible for evaluation all imported pharmaceutical products to decide which item is needed to be tested and which item is getting quick release.

b/ printing KMCA stickers for all batches that has release decision or its comply after testing

each sticker has name of importer, name of item, kmca logo, and price.

6- Post marketing department

a/Several teams of inspector pharmacists in working under this department in all cities and towns to monitor all places where pharmaceutical products are sold and in coordination with local polices to take action against whom who do not obey rules of ministry of health and arrest those who is dealing fake medicines.
b/ controlling borders and airports for regular custom clearance

※About the Hospital pharmacy only, if possible;
−Please briefly describe the position and role of pharmacist in the medical institution and the medical care system in your country.

② Legislation on pharmaceutical administration

−Please briefly bulletined major laws/acts

◆National Level

- 2014 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.
- NON administered by
- administered by

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

◆Drug Import/Export

- Systems, Regulations, etc.
- ministry of health administered by KMCA
- administered by

◆Marketing Authorization

- Systems, Regulations, etc.
- non administered by
- administered by

※Example: Good Quality Practice

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

・Systems, Regulations, etc.

・ non administered by

・ administered by

◆Medicine Safety (post-marketing)

・Systems, Regulations, etc.

・ authorized by MOH administered by KMCA

・ administered by

※Example: Good Pharmacovigilance Practice

◆Relief System for Adverse Drug Reactions

・Systems, Regulations, etc.

・ recalling medicines if there is any problem administered by KMCA

・ administered by

④ Drug Pricing

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

There is a regulation on going to equalize and control pricing upon pricing procedure and install one system in all end user pharmacies connected directly with MOH

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 2150 pharmacist 2022 (year)
2. Number of GMP inspector (National & Local) none (year)
3. Number of pharmaceutical manufacturers / manufacturing sites 3 local manufacturer 2022 (year)
4. Number of traditional medicine manufacturers / manufacturing sites none (year)
5. Number of pharmaceutical importers 350 2022 (year)
6. Number of pharmaceutical wholesalers around 75 2022 (year)

※About the Hospital pharmacy only, if possible;

⑥ Information on your hospital pharmacy

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

a. Number of section chiefs: 1 pharmacist
b. Number of deputy chiefs: 1 pharmacist
c. Number of managers: 1

（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 no

e. Do you prepare TPN (Total Parental Nutrition)

Yes / No no

f. Can you use Internet at the pharmacy?

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

Yes / No 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: 5 years

Professional education: 2 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: 23 years old

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

Yes

Academic Exams _____ days

Clinical Exams _____ days

No

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

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

_____

* 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:

300 people / per year

The alumni's placement rate (%)

a. Hospital: _____ %

b. Community Pharmacy: _____ %

c. Government Organization: _____ %

d. Enterprise: _____ %

e. Others: _____ %

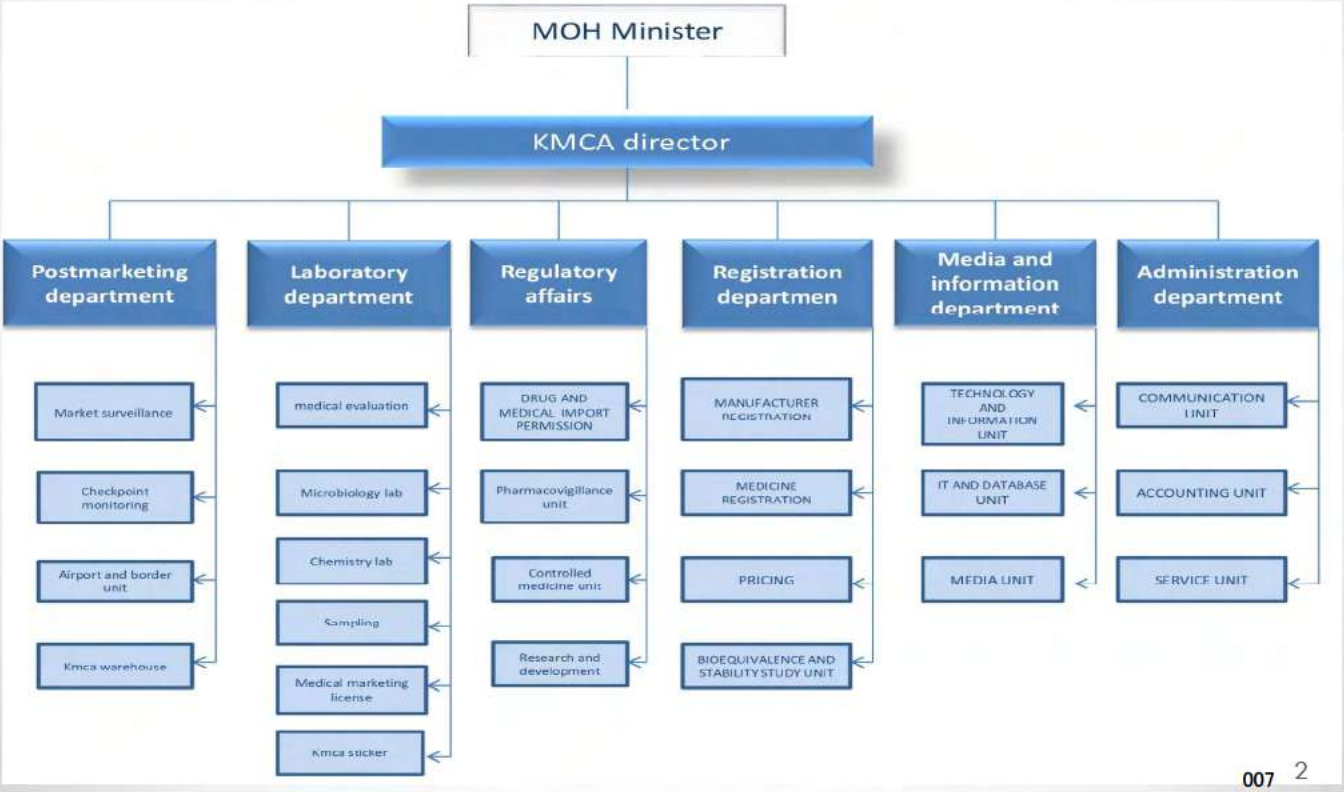
⑧ ADR(Adverse Drug Reaction) report

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.

Not applicable yet

Kurdistan Regional Government-Iraq
Council of Ministers
Ministry of Health
Kurdistan Medical Control Agency

Introduction of the work



Regulation service

- 350 imported company authorized to import registered medicines.
- Firstly Companies register their manufacturer factory and production line and products through registration department.
- Applicants has their own user in kmca online system and request their needs and submit importation documents (COO,COA,Packilng list, invoice, artwork, method of analysis)

Regulation service

- After reviewing all documents by pharmacists through regulatory affairs, companies get their permission and import approval is printed for custom clearance.
- Cargo to be quarantined in their warehouse unit getting market authorization.
- Medicine evaluation unit has decided if the sample is needed to be tested or the items is getting quick release!

Role of pharmacist

Pharmacists has a vital role in KMCA. 65 certified pharmacists are working in different departments of Kmca to regulate and control medicine in the region.

3. Difficulties/Lessons Learned from Past Experience

- KMCA established in 2010 , before that time there was no regulation for the import of medicines, no lab to test imported medicines, no pharmacist inspector.
- In 12 years time, based on past experience we have KMCA guideline it almost close to developed country standards.
- We learned how to limit and regulate the importation of medicines
- Created national list of medicines

Difficulties/Lessons Learned from Past Experience

- Have a better regulation on controlled medicines and narcotics.
- Create special stickers for each medicines for the community to be easily separated with illegal or fake medicines

4. Your interests

- Understand more and improvement about manufacturing registration
- To have a better control on drug pricing
- Quality assurance
- Control parallel importation
- Lab capasity

2. Laos

Part I: INFORMATION SHEET

Regulatory Systems on Ensuring Access to Quality Medicines (JFY 2022)

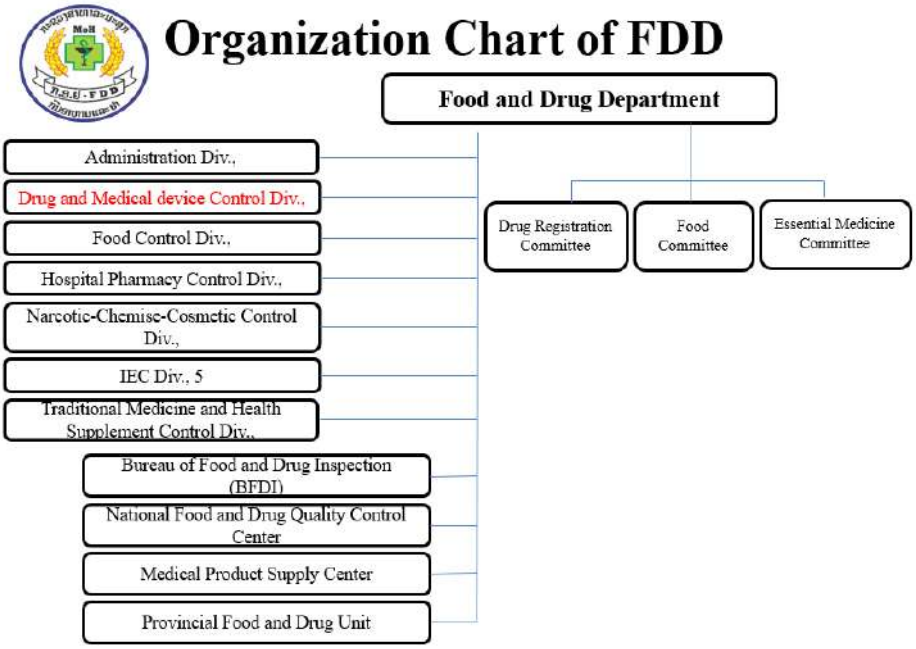
Name: Mr Kongchack PHOMMACHACK

Country: Laos

Organization/Department/Division: Food and Drug Department

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.

※About the Hospital pharmacy only, if possible;

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

② Legislation on pharmaceutical administration

−Please briefly bulletined major laws/acts

◆National Level

・Drug and Medical Products Law No 07/NA, dated 21 December 2011; administered by

・Regulation Governing Drug registration No.1441/MoH, dated: 13 August 2003 administered by

・Regulation on Business Establishment for Medicine and Medical Product Company No 1820/MoH, dated: 25 August 2017 administered by

・Regulation on Drug and Medical Products Production, No 937/MOH, Dated 12 July 2004 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.

・Regulation on Drug and Medical Products Production, No 937/MOH, Dated 12 July 2004 administered by

・PIC/S Good Manufacturing Practice PE 009-12 October 2015 administered by

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

◆Drug Import/Export

・Systems, Regulations, etc.

・Drug and Medical Products Law No 07/NA, dated 21 December 2011; administered by

・ _____ administered by _____

◆Marketing Authorization

・Systems, Regulations, etc.

・Regulation Governing Drug registration No.1441/MoH, dated: 13 August 2003 administered by

・ _____ administered by FDD

※Example: Good Quality Practice

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

・Systems, Regulations, etc.

・AUCTION SYSTEM administered by Medical Product supply Center

・ _____ administered by _____

◆Medicine Safety (post-marketing)

・Systems, Regulations, etc.

・Lao Pharmacovigilance guideline administered by FDD

・ _____ administered by _____

※Example: Good Pharmacovigilance Practice

◆Relief System for Adverse Drug Reactions

・Systems, Regulations, etc.

・ _____ administered by _____

・ _____ 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 >2000 (year) 2022
2. Number of GMP inspector (National & Local) 13 (year) 2022
3. Number of pharmaceutical manufacturers / manufacturing sites 12 (year) 2022
4. Number of traditional medicine manufacturers / manufacturing sites 2 (year) 2022
5. Number of pharmaceutical importers 96 (year) 2022
6. Number of pharmaceutical wholesalers 11 (year) 2022

※About the Hospital pharmacy only, if possible;

⑥ Information on your hospital pharmacy

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

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

（2） Number of staff

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

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

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

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

a. For inpatients:
b. For outpatients:

（5） Equipment of the pharmacy in your hospital

a. Does your hospital have a dispensary room?
If "Yes", how large is it?
Yes _____ 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	5 years
Secondary	7 years
High school	years

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

University / college:	3-5 years
Professional education:	3-5 years
Practical training:	years
Duration of training by each facility:	0.2 years
Hospital pharmacy:	3-4 weeks
Community pharmacy:	weeks
Pharmaceutical company:	weeks
Others:	weeks
Age at graduation:	21-23 years old

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

Yes

Academic Exams	days
Clinical Exams	days

(No)

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

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

* 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:

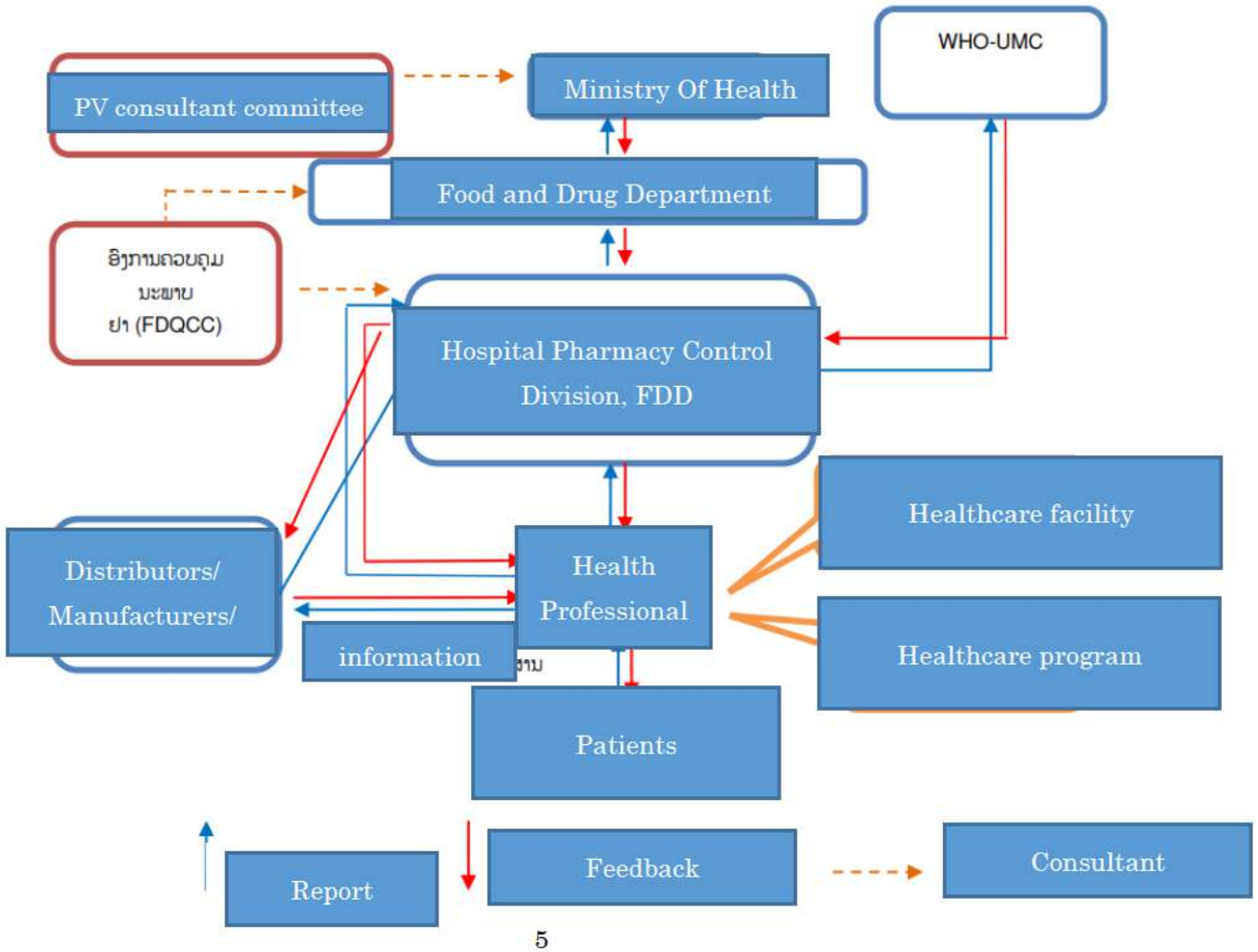
90-100 people / per year

The alumni's placement rate (%)

a. Hospital: 20 %
b. Community Pharmacy: 15 %
c. Government Organization: 30 %
d. Enterprise: 30 %
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.



LAOS

Food and Drug Department

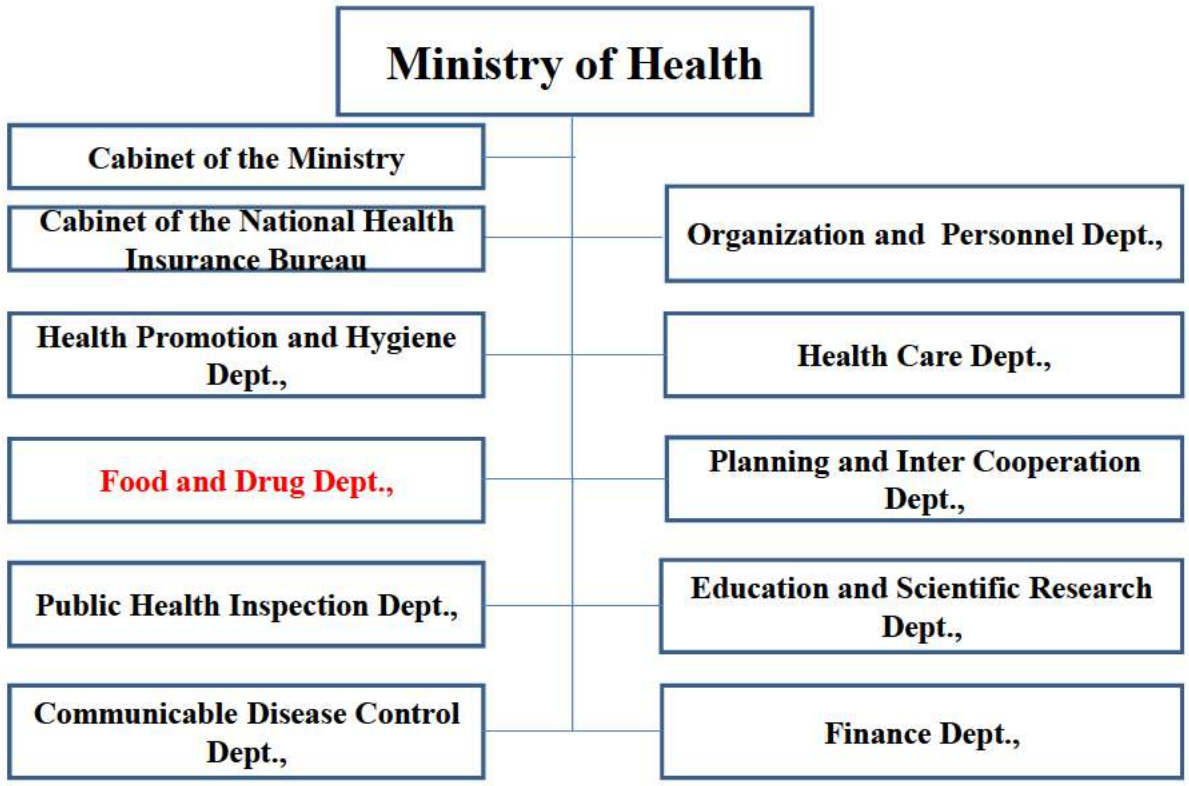
Ministry Of Health

Kongchack PHOMMACHACK

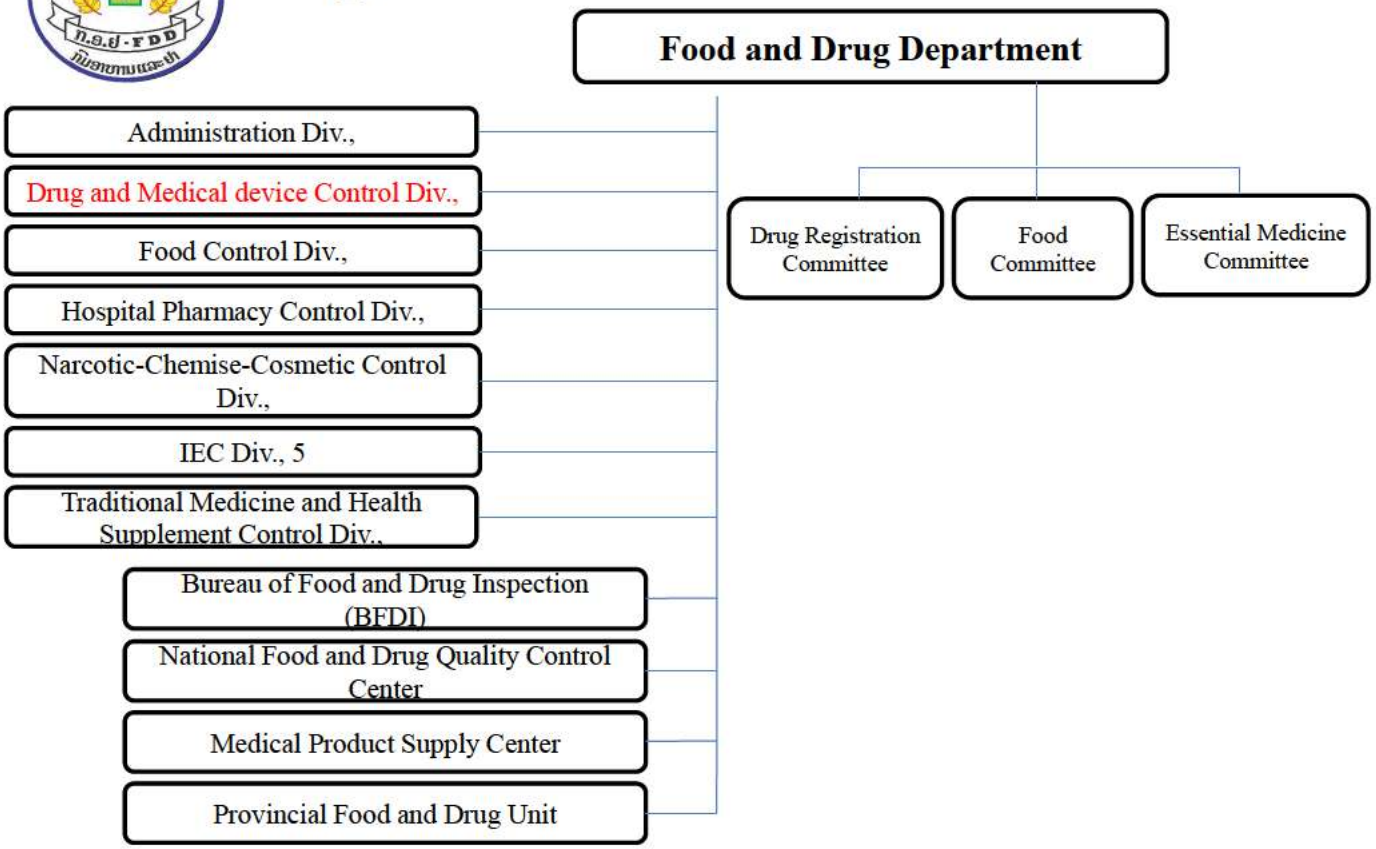
Outline

(1) My Organization and department
(2) Job tenure
(3) Regulatory services that engaged in
(4) roles and position of pharmacists in your country
(5) Achievements
(6)On-going projects to deal with current problems
(7)Difficulties/Lessons Learned from Past Experience
(8) My interests

Organization Chart of MoH



Organization Chart of FDD



1. Introduction of the work

(2) **Job tenure:** 4 years

(3) Regulatory services that you are engaged in

- Evaluation on new drug registration
- Evaluation on Renewal, Variation.

1. Introduction of the work

(4) roles and position of pharmacists in Laos

1.**Pharmacists in hospitals**

- Validate prescription and drug dispensation.
- Manage the supply chain of drug store

2. **Pharmacists in Research**

-Carrying out in analytical research of drugs and clinical trial

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

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

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

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

-Manage GPP and GSP of pharmacies

7. **Regulators** in food and drug department

8. **GMP inspector**

2. Good Practice

❑Achievements

-ACTD format submission for Drug registration
-Reliance Pathway for evaluation
-Initial GPP training to 100 pharmacies
-GMP training

2. Good Practice

❑On-going projects to deal with current problems

- Training on implementation the ACTD format submission to local company
- Establish SOP of each type of Product to be evaluated for regulators
- Evaluate GPP implementation in 100 pharmacies

3. Difficulties/Lessons Learned from Past Experience

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

1. Evaluation of Biological products
2. Site master file evaluation
3. On-site GMP inspection

4. My interests

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

(1) Major and minor variation
(2) Evaluation of Biological products
(3) Method validation

Thank you

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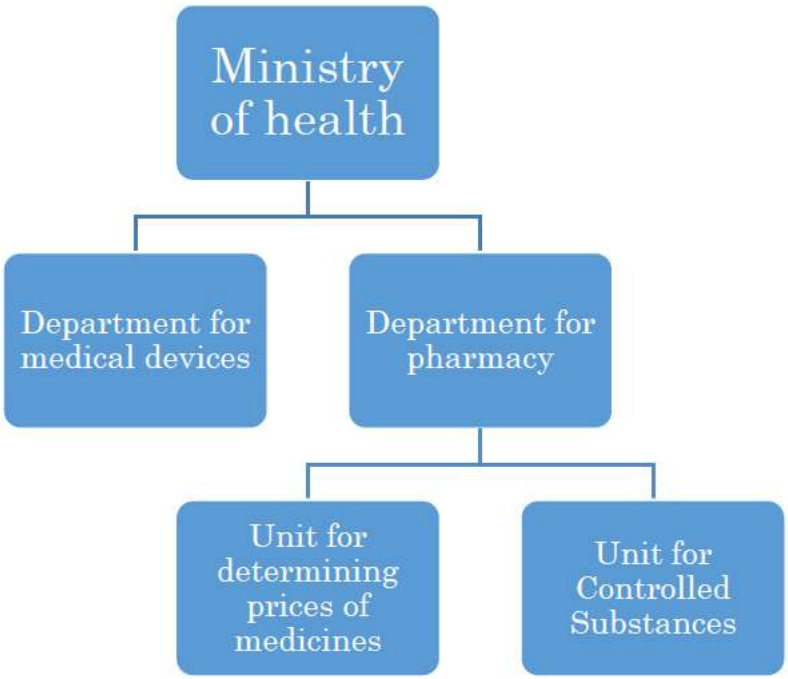
3. North Macedonia

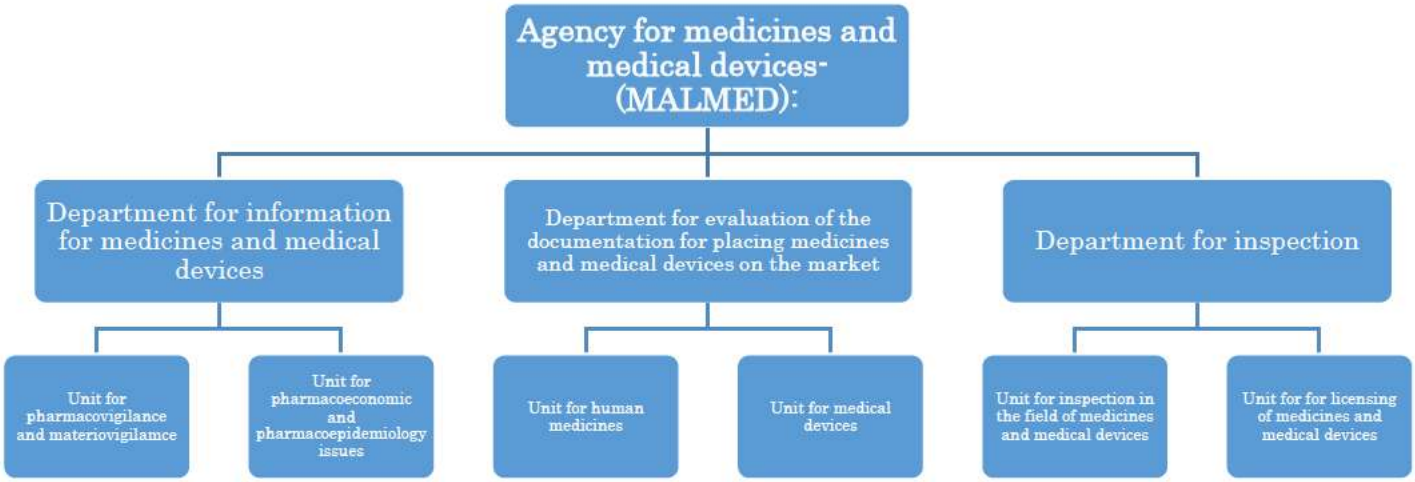
Part I: INFORMATION SHEET

Regulatory Systems on Ensuring Access to Quality Medicines (JFY 2022)

Name: Blerina Tushi
Country: North Macedonia
Organization/Department/Division: Health Insurance Fund of Republic of North Macedonia (HIFRNM)

① Organizational Chart





Ministry of health (MoH):

Department for medical devices

Department for pharmacy:

- Unit for determining prices of medicines
- Unit for Controlled Substances

Agency for medicines and medical devices-(MALMED):

Department for information for medicines and medical devices

- Unit for pharmacovigilance and materiovigilamce
- Unit for pharmacoeconomic and pharmacoepidemiology issues

Department for evaluation of the documentation for placing medicines and medical devices on the market

- Unit for human medicines

- Unit for medical devices

Department for inspection

- Unit for inspection in the field of medicines and medical devices
- Unit for for licensing of medicines and medical devices

Health insurance fund of Republic of North Macedonia (HIFRNM)

Pharmacy department

Ministry of health, Department of pharmacy - Unit for determination of prices of medicines is in charge for:

Determination of wholesale prices and retail prices for medicines that have an authorization for placing on the market, issued by the MALMED for drugs and are issued on prescription.

Determination of wholesale prices and retail prices of medicines for which MALMED has issued an import permit.

Agency for medicines and medical devices-MALMED is in charge for:

1) issuing approvals for medicine manufacturing ;
2) issuing approvals for manufacturing of medical devices;
3) issuing approvals for wholesale trade for medicines and medical devices;
4) issuing approvals for retail trade for medicines and medical devices;
4a) issuing a marketing authorization for each batch of imported medicine;
5) issuing approvals for placing medicines on the market, as well as changes, supplementation or renewal of the approval;
6) approval for advertising of medicines and medical devices;
7) keeping a Register for medicines, for traditional herbal medicines, homeopathic medicines, and a Register for medical devices in the Republic of North Macedonia;
8) keeping a Register of medicine manufacturers and a Register of manufacturers of medical devices in the Republic of North Macedonia;
9) keeping a Register of entities for wholesale trade and a Register of entities for retail trade with medicines and medical devices in the Republic of North Macedonia;
10) issuing approvals and / or notifications for clinical trials of medicines;
10a) keeping Register for clinical trials;
11) issuing approvals and / or notifications for clinical examinations of medical devices;
11a) evaluation of the expected health benefit in relation to the potential risk of the respondents (assessment document of pre-clinical and clinical documentation with evaluation of the benefit-risk ratio) for the medicine which is subject to clinical trial;
12) issuing approvals for import, parallel import and for export of medicines;
13) issuing certificates of compliance with the principles of good practice;
14) issuing certificates for the needs for export of medicines and medical devices;
15) classification of products as medicines or medical devices;
16) establishment and maintenance of a system for pharmacovigilance and materialovigilance;
16a) preparation of an annual report on reported adverse reactions to medicines in the Republic of North

Macedonia
17) establishment and maintenance of a database;
18) inspection of medicines and medical devices;
19) inspection of entities for manufacturing, wholesale and retail;
20) activities for ensuring the quality control of medicines and medical devices;
21) implements measures for monitoring of consumption of medicines;
22) promotion the rational use of medicines and medical devices;
23) integration in the international network of information on drugs and medical devices;
23-a) analyzes and evaluates the safety and side effects on the respondents in clinical trials;
23-b) performs inspection supervision over the clinical trials, side effects and drug malfunction;
23-c) analyze and evaluate the pharmacoeconomic data related to medicines;
23-d) conducts an urgent procedure for withdrawal of the medicine and medical device from market;
23-e) plans and implements activities in the field of systematic control of medicines;
23-f) prepares and publishes professional publications related to the competencies of the Agency;
23-g) conducts from its own funds a procedure for public procurement of medicines which are not on the List of medicines covered by the Fund for health insurance of Republic of North Macedonia, at the request of the Ministry of health and
24) perform other activities related to medicines and medical devices in accordance with the Law.

Health Insurance fund of Republic of North Macedonia- Pharmacy department is in charge for:

Setting referent prices for medicines which are included in the List of medicines on burden of HIFRNM (Positive List).
Inspection of the work of retail pharmacies which has contract with Fund for issuing medicines on burden of HIFRNM.
Monitoring consumption of medicines which are covered in Positive List.
Participates in the creation of health policies related to medicines covered in the Positive list.

② <u>Legislation on pharmaceutical administration</u>

- National Level
  - Law on medicines and medical devices - administered by MALMED
  - Law for health insurance - administered by Ministry of Health and HIFRNM
  - Law on health care – administered by Ministry of health
- Local Level
  - Regulation for the network of health institutions - administered by MoH
  - Methodology for determination of medicines prices - administered by MoH

- Rulebook on the manner and procedure for clinical trials of medicines and the content of the documentation - administered by MoH and MALMED
- Rulebook on obtaining approval for placing a medicinal product on the market- administered by MALMED
- Rulebook on the detailed conditions for the manner of prescribing and issuing or selling medicines - administered by MALMED
- Rulebook on the manner and procedures for analytical examination of drugs- administered by MALMED
- Rulebook on the manner and procedure for pharmacological-toxicological and clinical examination of medicines – administered by MALMED
- Rulebook on the manner of quality control of medicines and the manner of recognition of the analyzes of the batches of medicines- administered by MALMED
- Rulebook on the manner of reporting, the content of the form for reporting adverse drug reactions and the manner of organization of the pharmacovigilance system- administered by MALMED
- Rulebook on registration of traditional herbal medicines - administered by MALMED
- Rulebook on the content of the request and the closer conditions regarding the space, equipment and staff for obtaining approval for wholesale of medicinal products - administered by MALMED
- Rulebook on the content of the request and the manner of obtaining approval for import of drugs - administered by MALMED
- Rulebook on the manner of prescribing and dispensing prescription medicines - administered by MALMED
- Rulebook on the manner and procedure for clinical trials of drugs and the content of the documentation - administered by MALMED
- Rulebook on authorizations and manner of work of the control of the Health Insurance Fund - administered by HIFRNM
- Rulebook for determining the criteria and procedure for determining the reference prices of medicines - administered by HIFRNM

◆ International Level:

- PIC/S: Yes _____ OR **No** _____

  If yes, joined when

- Others if any

_____/_____by_____/_____

③ Regulatory /Administrative Services

◆Pharmaceutical Manufacturing

- Guideline for the principles of Good Manufacturing Practice - administered by MoH and MALMED

- Guideline for the principles of Good Pharmaceutical Practice - administered by MoH and MALMED

- Guideline for the principles of Good Laboratory Practice - administered by MoH and MALMED

- Guideline for the principles of Good Clinical Practice - administered by MoH and MALMED

- Rulebook on the content of the request, documentation and detailed conditions regarding the space, equipment and staff for obtaining approval for production of medicine - administered by MALMED

- Rulebook on obtaining approval for wholesale trade - administered by MALMED

Pharmaceutical manufacturing- production of medicines is regulated with bylaw administered by MALMED. The regulations related to the production of medicines provide detailed information on what conditions need to be met and how to carry out the procedure for approval of production and wholesale of medicines. This Rulebook contains detailed information about conditions and requirements regarding the space, equipment and staff which manufacturers should provide for obtaining approval for production of medicine.

Rulebook for obtaining approval for wholesale trade is consisted of detailed description of the documentation that the manufacturer must submit in order to obtain approval for the wholesale trade of medicinal products.

Guidelines for good production practice contains the basic principles of good manufacturing practice as basic conditions for manufacturing of medicines; manufacturing of: sterile, biological, radiopharmaceuticals, medical gases, herbal medicines, liquid pharmaceutical forms, creams and ointments, inhalations, computerized systems, use of ionizing radiation, medicines for clinical trials, medicines derived from blood and blood plasm; qualification and validation; issuance of a certificate for placing a batch of a medicine on the market; parametric placing of a batch of drug on the market; reference and control samples. This guidelines are in accordance with the European directives that prescribes the principles of GMP and are adopted by the European Commission.

Guidelines for principles for good laboratory practice - the principles of good laboratory practice are a quality system that is established for the laboratories in which laboratory and pharmacological-toxicological tests are performed.
The guidelines for the principles of good laboratory practice prescribes the principles for organization of planning, conducting and monitoring of pre-clinical examinations, safe for human health and environment; Conditions for planning, conducting and monitoring pre-clinical examinations, safe for human health and the environment; Manner of reporting and documenting pre-clinical trials, safe for human health and the environment

The Principles of Good Clinical Practice cover international ethical and scientific

quality standards in the planning, implementation, monitoring and reporting of clinical trials conducted on humans. Adherence to these standards provides public protection of the rights, safety and best interests of the respondents in accordance with the principles set out in the Helsinki Declaration, as well as that the data obtained from the clinical trial are reliable. The purpose of these ICH guides is to provide a single standard for the European Union (EU), Japan and the United States of America to facilitate mutual acceptance of clinical data by the competent authorities of these countries.

The guidelines have been developed taking into account the current good clinical practices of the European Union, Japan and the United States, but also Australia, Canada, the Nordic countries and the World Health Organization (WHO). These guidelines should be followed when preparing the data from the clinical trials that are given for inspection to the competent body (MALMED), ie the competent bodies (Commission for Clinical Trials and Ethics Commission). These principles can be applied to other clinical trials that may affect the safety and best interests of the respondents.
The guidelines for the principles of good clinical practice prescribe the principles for:

- international ethical and scientific quality standards in the planning, implementation, monitoring and reporting of clinical trials conducted on humans;
- the composition, tasks and activities performed by the commission for clinical trials;
- the tasks undertaken by the examiner during the clinical trial;
- the tasks undertaken by the applicant for the clinical trial;
- the clinical trial plan and its changes and additions;
- brochure for the examiner and
- basic documents for conducting the clinical trial

◆Drug Import/Export

- Rulebook on the content of the request and the manner of obtaining approval for import of medicines –administered by MoH and MALMED
- Rulebook on the form and content of the guarantee for imported medicine - administered by MALMED

The Rulebook on the content of the request and the manner of obtaining approval for import of medicines determines the form of the request and the documents that the applicant should submit to MALMED. The import request contains:

- data on the applicant for import;
- data on the manufacturer of the medicinal products that are subject to import;
- data on the supplier of the medicines;
- name of the medicine (brand name, INN or generic name);
- pharmaceutical form, strength and package of the medicine;
- tariff number of the imported medicines;
- identification number of the applicant for import;
- deadline within which the import of medicines will be performed.

An integral part of the request for import of medicines are:
- specification for import of medicines with tariff codes, name of the medicine (brand name, INN or generic name), pharmaceutical form, strength and package of the medicine,
- pro-invoice or invoice for the medicines that are subject to import in three (3) copies,
- quality certificate for the batch of medicine that is subject to import,
- decision for registration of the medicine on the territory of the Republic of North Macedonia,
- decision - license for wholesale of medicines issued by the Ministry of Health.
Rulebook on the form and content of the import guarantee prescribes the form and content of the guarantee that each batch of imported medicine complies with the conditions of the marketing authorization of the medicinal product or the marketing authorization for the import of the medicinal product. This guarantee contains: Name of medicine; ATC code; International nonproprietary name (INN); Pharmaceutical dosage form, strength and size of packaging; Serial number; An Expiration Date; Quantity of imported medicine; Bar code / data matrix check; Visual inspection; Conclusion; Name of the importer; Employed professional; MP; Director of the importer.

◆Marketing Authorization

- Rulebook for obtaining approval for placing a drug on the market – administered by MALMED
- Rulebook for registration of traditional herbal medicines - administered by MALMED
- Rulebook on the content of the request, the manner of registration of homeopathic medicines, the form and the content of the documentation - administered by MoH

Rulebook for obtaining approval for placing a medicine on the market prescribes the content of the request, the form and the content of the required documentation, the manner of recognition of the marketing authorization issued by the countries of the European Union, as well as the manner of obtaining conditional marketing authorization for medicinal products for use in human medicine.
Rulebook for registration of traditional herbal medicines prescribes the manner of registration of traditional herbal medicines, the form and content of the required documentation and the manner of recognition of the registration in the countries of the European Union.

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

・Systems, Regulations, etc.

・ administered by

· administered by

A rulebook for distribution of medicines is being prepared

◆Medicine Safety (post-marketing)

- Rulebook on the manner of reporting, the content of the form for reporting adverse medicine reactions and the manner of organization of the pharmacovigilance system – administered by MoH, MALMED

This Rulebook prescribes the manner of reporting, the content of the form for reporting adverse drug reactions, as well as the manner of organization of the pharmacovigilance system.
MALMED publishes safety information on its website, following information from relevant sources.
MALMED has signed a cooperation agreement with Uppsala Monitoring Center (UMC) - a global electronic database on drug side effects of the World Health Organization based in Sweden. All applications submitted to MALMED are processed and forwarded to the UMC and become part of the documentation for the safety of the drug, on the basis of which recommendations are issued for its safe use in terms of proper dosing, contraindications, special warnings, interactions with other drugs such as and measures to minimize the occurrence of adverse reactions.

◆Relief System for Adverse Drug Reactions

- Rulebook on the manner of reporting, the content of the form for reporting adverse medicine reactions and the manner of organization of the pharmacovigilance system – administered by MoH, MALMED.

Organization and monitoring the manner of collection and assessment of adverse drug reactions, processing and evaluation of the obtained data on drug safety is performed by the MALMED, through the National Center for Monitoring Adverse Reactions of drugs-National Center for Pharmacovigilance.
The system for collecting new data on drug safety, assessing adverse reactions and events, informing about drug interactions and abuse, and proposing appropriate measures to be taken during the period of validity of the marketing authorization or during the implementation of the clinical trial of the drug is performed by the National Center for Pharmacovigilance, which in accordance with the law establishes and maintains the system of pharmacovigilance.
Data on adverse drug reactions may be submitted by the applicant for clinical trial.
Data on adverse drug reactions, suspicion of adverse drug reactions, can be reported by

health care institutions and health professionals by submitting a report of adverse drug reactions, on a form that is an integral part of the rulebook.
Data on adverse drug reactions can also be submitted by person responsible for pharmacovigilance designated by marketing authorization holder in accordance with the law for implementation of the pharmacovigilance system.
Based on the data collected on adverse drug reactions during clinical trials of the drug, the following measures may be proposed by the National Center for Pharmacovigilance:
1) change in the protocol of clinical trial of the drug;
2) conducting control over the clinical trial of the drug;
3) termination of the clinical trial of the drug.
Individual PSURs(Periodical Safety (six-month, one-year and three-year) are submitted to the Agency by the person responsible for pharmacovigilance during the first renewal of the marketing authorization.
Each subsequent renewal of the marketing authorization for the medicinal product, the individual PSURs should cover a period of five years, with cumulative data relating to the period from the first day of approval or to the period from the date of the last renewal of the marketing authorization for placing on the market (Summary Bridging Report), no later than 60 days from the date of expiration of the period to which it refers. Conclusion (it is necessary to state the information on the safety of the medicine that changes the cumulative experience with the drug so far, as well as the specific measures to be taken, with an explanation of the same).
The latest version of the basic reference document for the safety of the drug from the drug manufacturer (summary report on the properties of the drug, patient guide) is submitted to the PSUR by the person responsible for pharmacovigilance.
Upon receipt of a report for a serious adverse reaction to a drug that may have serious consequences for human health, the holder of the approval shall immediately submit to the Agency a proposal for urgent safety measures which may be:
1) withdrawal of the drug from the market;
2) change in the summary report on the properties of the drug, such as the introduction of contraindications, warnings or precautions, reduction of the recommended dose, narrowing of the indication area and
3) informing the health professionals and patients about the newly discovered risk during the use of the medicine, without delay.

④ **Drug Pricing**

Drug prices are regulated by law.
There is a methodology that determines the way of forming wholesale prices and retail prices of medicines that have an authorization for placing on the market issued by the Agency for medicines and medical devices and are issued on prescription.
This methodology also determines the manner of formation of wholesale prices and retail prices of medicines for which the Agency has issued an import permit, in accordance

with the Law on Medicines and Medical Devices.
This methodology determines the manner of formation of wholesale prices and retail prices of medicines for which the Agency has issued an approval for parallel import. Wholesale and retail prices of medicines are formed on a comparative basis wholesale drug price in reference countries. Comparative wholesale price of the drug is determined on each pharmaceutical form, strength and packaging, separately.
The comparative wholesale price of the drug in the reference countries is the average value of all wholesale drug prices according to Article 5 of this methodology, with the same INN, the same pharmaceutical shape, strength and packaging from different manufacturers. Based on the methodology, the Ministry of Health determines the maximum price once a year. The wholesale price of the medicine includes the costs of the wholesale sale of the medicine, customs costs and other import costs, while a margin is added to the retail price depending on the amount of the wholesale price. There are special provisions for medicines from parallel import, original drugs and biosimilar drugs.
Health insurance fund of the Republic of North Macedonia also determines referent prices. There is a Rulebook based on which are determined the manner and methodology for determining reference prices of medicines which are on the List of medicines covered by the Health Insurance Fund of the Republic of North Macedonia
The reference price of the medicine is the maximum amount that the Fund provides for a certain medicine.
The reference price of the medicine is determined at the level of wholesale price including VAT. An integral part of the wholesale price is the margin for wholesale in accordance with the Law on medicines and medical devices.
The basic criteria for determining the reference prices of medicines are the following:
- The reference price (the comparative wholesale price of the medicine with VAT included) in the reference countries,
- The average relative price of the medicine,
- The level of the comparative price according to the purchasing power parity coefficient.
The comparative wholesale price of medicines is determined individually for each pharmaceutical dosage, pharmaceutical form and strength.
If in the reference countries there is a drug of the same strength from different manufacturers at different prices, the lowest price of the drug is taken into account, which is applied when determining the comparative price for all drugs of that generic.
Average comparative price of the drug is the price calculated so that the sum of the two (2) lowest comparative drug prices in reference countries, divided by two.
The level of the relative price is the ratio of the reference price of the drug in the Republic of North Macedonia and the average relative price of the drug in the reference countries, expressed as a percentage.
The comparative price level is adjusted to the purchasing power parity ratio.
Purchasing power parity ratio is a ratio expressed as a percentage of GDP per capita in Republic of North Macedonia and the average of the values of the gross domestic product per capita in reference countries, according to the purchasing power parity methodology established by the International monetary fund from Washington for the last year for which

the International Monetary Fund has published final data.

Rference prices are reviewed at least once a year.

⑤ Statistic Data – No data available

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

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

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

⑥ Education and License of Pharmacists in your country

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

Primary 9 years

Secondary _____ years

High school 4 years

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

University / college: 5 years for master degree/4 years for graduated pharmacist

Professional education: / years

Practical training: 6 months to 1 year

Duration of training by each facility: _____ years

Hospital pharmacy: 1.5months

Community pharmacy with Galen laboratory: 2 months

Pharmaceutical company: / weeks

Others: Pharmacoinformation 1 month and Clinical pharmacy 1 month

Age at graduation: approximately 24/25 years old

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

Yes

Academic Exams _____ days

Clinical Exams _____ days

No

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

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

6 months to 1 year

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

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

The alumni's placement rate (%)

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

According to the information given by Pharmaceutical chamber of RNM, in this moment in the pharmaceutical chamber are registered 3484 graduated pharmacists/ master pharmacists.
Manufacturer 242
Representative offices 167
Education 10
Laboratory 36
Retail Pharmacy 1446
Hospital 10
Other 42
Drug depot 8
Wholesale 168
Hospital pharmacy 98
Not report 1257
Total 3484

⑦ **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.

Health institutions and health professionals report to the National Center for Pharmacovigilance:
1) adverse reactions to a new drug or in case of suspected adverse reactions, as well as reactions that are not serious;

2) serious and unexpected, adverse reactions to a drug that has been in use for more than five years or in case of suspicion of these reactions;
3) information on the increased incidence of the manifestation of the expected reaction, clinically significant interactions, drug abuse, overdose, use during pregnancy and lactation, ineffectiveness, as well as information on medical error.
In the cases referred to in paragraph 1 item 3), it is sufficient only a suspicion that the drug used may have caused an adverse reaction in the patient.
Adverse drug reactions, or suspicion of adverse drug reactions, by health care institutions and health professionals are reported by submitting a report of adverse drug reactions, on a form that is an integral part of rulebook.
The report of adverse drug reactions contains data on:
1) patient (initials, age and sex) and adverse reaction (start date of reaction, description of clinical manifestation, outcome and possible treatment, association between adverse reaction and suspected drug);
2) the suspected drug (brand name and international unprotected name, pharmaceutical form, strength, individual and daily dose, method / s of use, indication for use, date of therapy from / to, duration of therapy) and the course of the adverse reaction upon discontinuation and / or re-use of the suspected drug;
3) concomitant use of another drug (s) with date of use and patient history;
4) the manufacturer of the suspected drug (name and country, batch number) and the applicant (date of application, source and type of application, name and surname, contact telephone, occupation).
The National Center for Pharmacovigilance in performing the activities referred to the rulebook implements the following activities:
1) collects, processes and evaluates data on adverse drug reactions and adverse events related to the use of drugs during the clinical trial or in the marketing of the drug, or in the post-marketing intervention clinical trial of the drug;
2) processes and evaluates periodic reports on the safety of medicines, which it receives from the holder of the marketing authorization;
3) collects, processes and evaluates data from the post-marketing non-intervention clinical trial of the medicine (pharmaco-epidemiological examination), which it receives from the holder of the marketing authorization;
4) notifies the holder of the marketing authorization for serious adverse reactions to the medicinal product immediately, no later than 15 days from the date of receipt of this information;
5) inform the Agency and the health professionals about the serious side effects of the medicine and about the significant changes in the safety of the medicine immediately, and no later than 15 days from the date of receipt of this information;
6) encourages health professionals to report adverse events and adverse reactions to drugs, or suspicion of them;
7) maintains a database of information collected in the pharmacovigilance system that is available to the public and to the competent authorities in the country and abroad;
8) exchanges information collected in the pharmacovigilance system with the competent

authorities for pharmacovigilance in other countries.
The National Center submits to the Agency a report on the reported adverse drug reactions every three months and an annual report on the reported adverse drug reactions.

Republic of North Macedonia

Health Insurance Fund of North Macedonia

Blerina Tushi

独立行政法人 国際協力機構

1. Introduction of the work

- The HIFNM provides health services from the basic package of services to the insured persons based on the principles of comprehensiveness, solidarity and equality.
- Pharmaceutical sector as an independent sector in the HIFRNM has been functioning since 2007 and performs duties and activities related to medicines which are on the burden of HIFRNM.
  - Currently nine graduated pharmacist work in the sector including the director of the sector.

1. Introduction of the work

- As pharmacist – inspector, I am part of this sector more than 15 years.

- Control/Inspection of services insured persons receives in pharmacies;
- Monitoring consumption of medicines which are covered in Positive List;
- Participating in the creation of health policies related to medicines covered in the Positive list;
- Reference prices for medicines on the burden of HIFRNM.

1. Introduction of the work

Roles and position of pharmacists in your country

Most of the pharmacist work in:

- Retail pharmacies;
- Wholesalers and representative offices of pharmaceutical companies;
- Pharmaceutical manufactures;
- Hospital pharmacies;
- Public institutions as Ministry of health, Agency for medicines and medical devices, HIFRNM, Institution for public heath, etc.

1. Introduction of the work

Pharmacist in RNM have different positions in the public and private sector and all of them have a role in the timely provision of medicines to patients, access to quality and safe medicines, rational use of medicines and prevention of misuse of medicines

2. Good Practice

✓ **Achievements**

- Republic of North Macedonia has established national framework of quality standards and guidelines for: Good manufacturing practices, Good pharmaceutical practices, Good laboratory practices, Good Clinical practices. Guideline for good distribution practices is in develop.

- Changes and amendments on Law on Medicines and medical devices are being made to be harmonized to European Union system.

✓ **Solutions for past problems**

- Regulation of parallel import of drugs.

2. Good Practice

✓ **On-going projects to deal with current problems**

- Preparation of new rulebook for inclusion of new medicines in Positive List.
- Collaboration with WHO for antimicrobial consumption

✓ **Successful countermeasures against problems**

- Collaboration and cooperation between public Institutions as well as cooperation with the private sector in order to provide patients with drugs especially new generations of drugs.
- Regular inspections on pharmacies

2. Good Practice

- Public awareness programs
- Continuous trainings and meetings with the controllers from the regional offices
- Continuous meetings with representatives of pharmacies that have concluded an agreement with the HIFRNM

3. Difficulties/Lessons Learned from Past Experience

- Unified medicine labeling system to facilitate tracking of medicines use;
- Strengthening of legal framework in the area of access to quality medicines
- Raising the awareness of all participants in the health system about the negative effects of the irrational use of antimicrobial drugs and creating resistance to them;
- Creating conditions for more medicines, especially newer generations of medicines, to enter the drug market;
- Providing patients and insured persons with new innovative medicines.

4. My interests

1.To get acquainted with the Japanese regulatory system and identify what best practice can be applied in RNM.

2. To explore for solutions of databases for managing and tracking medicines to the last consumer (patient).

3. To explore for solutions for access quality and innovative medicines in conditions of limited financial resources.

4. Timor-Leste(1)

Japan International Cooperation Agency

REGULATORY SYSTEMS ON ENSURING ACCESS TO QUALITY MEDICINES

(JFY 2022)

Inception Report

Name : Ismenia Mateus da Costa Belo

Country : Timor-Leste

Organization/Department/Division : Serviços Autonomos de Medicamentos e Equipamentos da Saude (SAMES)/Warehouse and Distribution Direction/Head of Department Warehouse and Distribution.

PART I: INFORMATION SHEET

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

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

Introduction

TIMOR-LESTE MAP

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

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

Capital: Dili

Population: 1.370 million (2022)

Points of Interest: Atauro Island, Jaco Island, Tatamailau, Cristo Rei of Dili, Ramelau Mountain, Koni Santana National Park and more

Official language: Portuguese and Tetun

The vision of Ministry of Health of Timor-Leste

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

Mission

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

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

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

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

      The Legal and regulatory framework shall include the following:

      Specifics; National Drug Regulatory Authority (synonym: National Drug Administration)

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

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

Access to Medicines and Pharmaceutical Supply

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

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

3. Regulatory Services

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

A. Licensing of Importers, Wholesalers and Pharmacies

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

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

B. Medicine / Drug Registration and Marketing Authorization

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

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

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

C. Post Marketing Surveillance.

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

4. Drug Pricing

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

5. NA

6. NA

7. Education and License of pharmacist in Timor-Leste

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

   Primary 6 years

   Secondary 3 years

2. Category during university

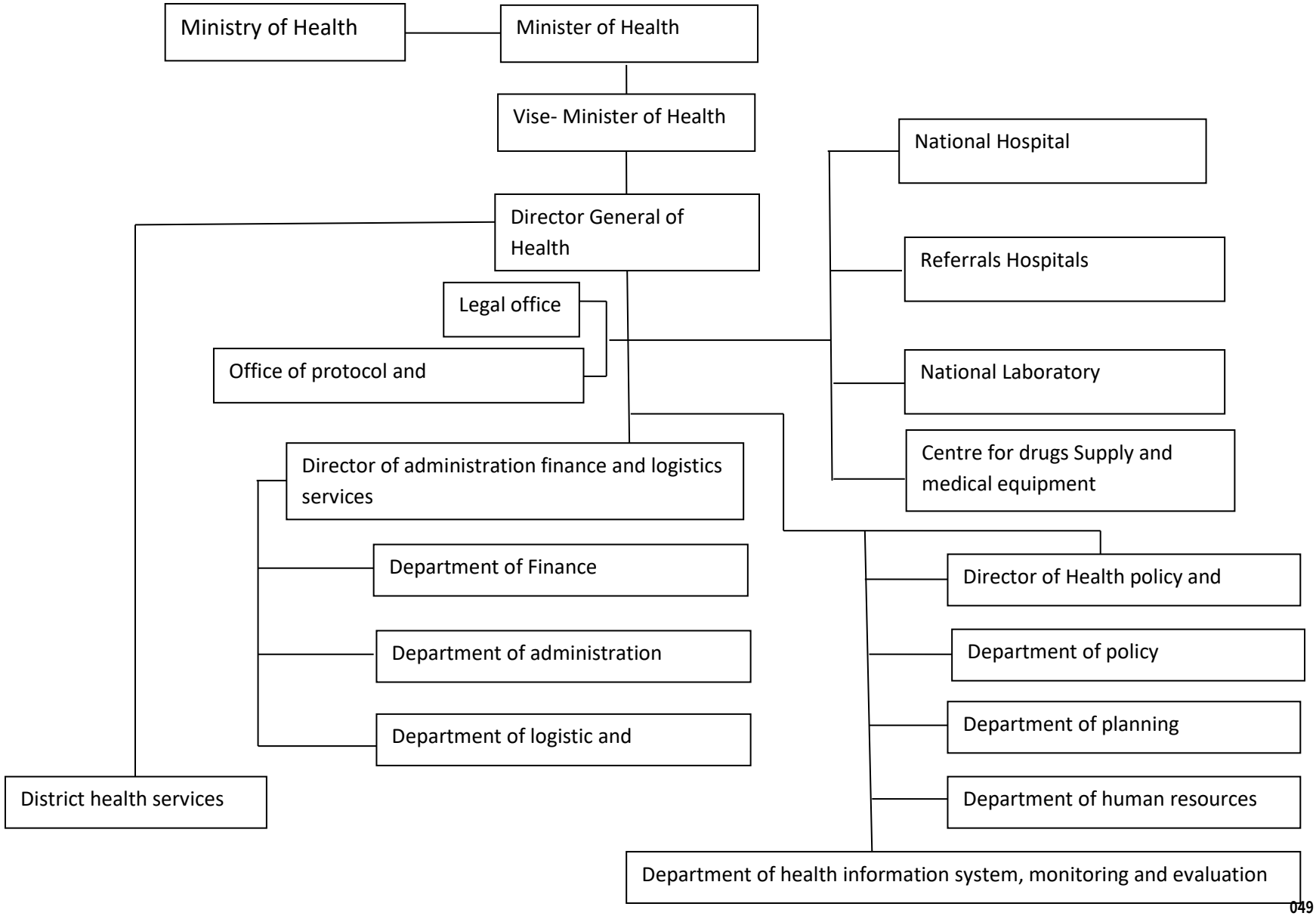
   University : 4 years

   Professional education : 2 years

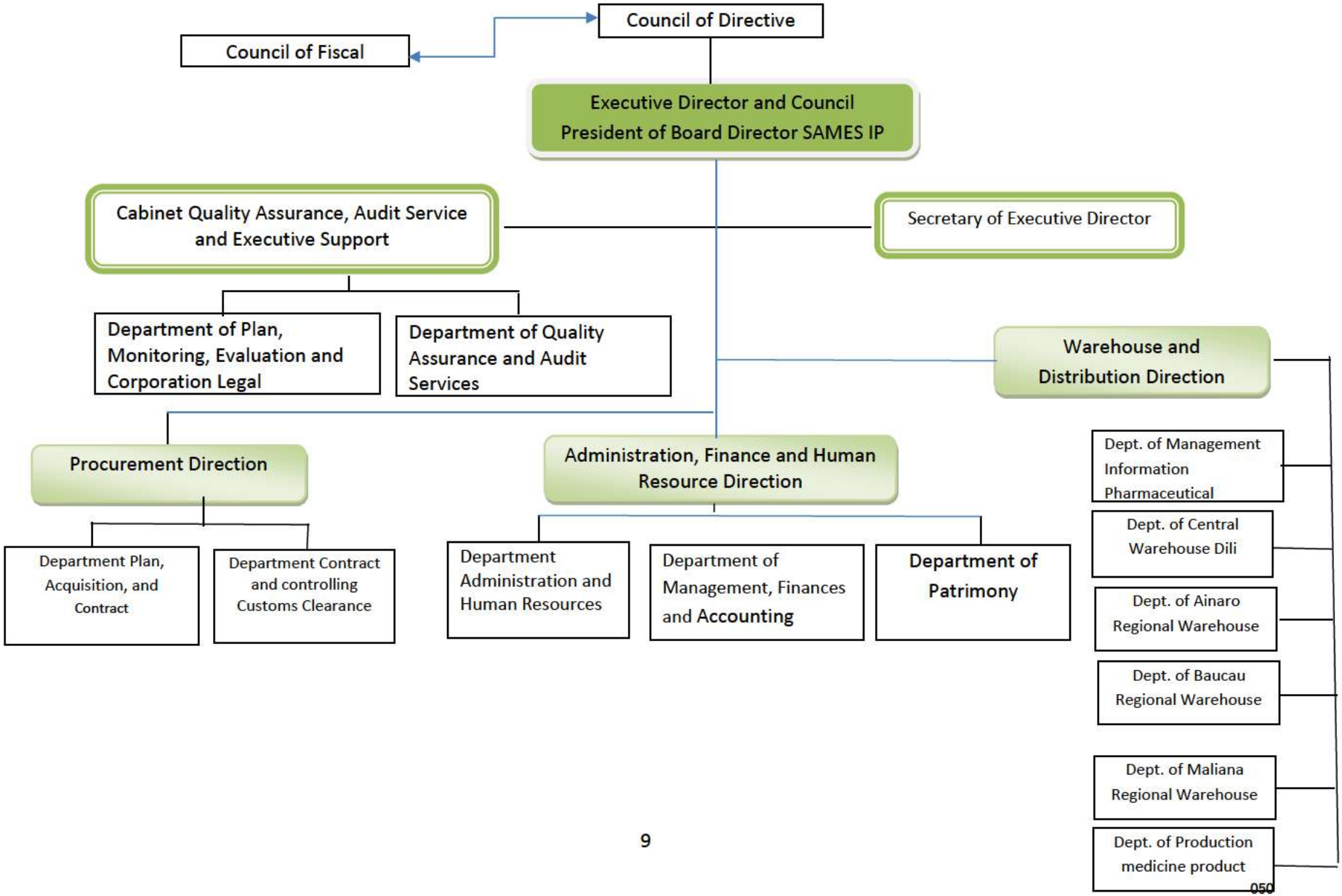
   Practical training 2 or 4months (one month in warehouse, hospitals, private clinics and the community)

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

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



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



TIMOR LESTE

Serviço Autonomo Medicamentos e Equipamentos da Saude

SAMES IP

Ismenia Mateus da Costa Belo

独立行政法人 国際協力機構

TIMOR LESTE

SAMES WAREHOUSE

ACTIVITIES of SAMES

Vision

Ensure for complete access, equal and safe access to essential drugs, consumables for the people of Timor Leste

Mission

Establishes management cycle system for purchase Medicines in strong resilient, fully adhering to national regulations and follow International best practice

1. Introduction SAMES of Timor Leste

- Servico Autonomo Medikamentos e Equipamentos da Saude – SAMES an only National Warehouse in Timor Leste
- SAMES have a three (3) function important are ; Procurement, Storage and Distribution for all product medicine available in Health Facilities in Timor Leste
- SAMES has three (3) Warehouses in three regions are Ainaro regional warehouse, Baucau regional warehouse and Maliana regional warehouse, aiming to bring pharmaceutical services to the population

2. Introduction of the work

1. Servico Autonomos Medicamentos e Equipamentos da Saude (SAMES)/ Warehouse and Distribution Direction/Head of Department Central Warehouse and Distribution.

2. I am Head of Department Central Warehouse and Distribution, responsible for Inventory Management, Distribution Management, Fleet Management system and Human Resources Management

3. SAMES has regulation of Ministry of Health number 21/2016, 9 March which was recently changed to 36/2020, 8 March.

Continue Introduction of the work

4. Roles and Positions of Pharmacist in my Country Timor Leste

- Clinical Pharmacists (in hospitals)(Manage the supply chain of drug store)
- Pharmacists in Research (Carrying out in analytical research of drugs and clinical trial)
- Academic pharmacists (in universities of pharmacy)
- Sale managers (in pharmaceutical companies)

2. Good Practice

Achievements

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

On-going projects

- ✓Implementation of Quality Management System
- ✓Establishment of national electronic system namely MSupply for the Inventory Management system from Municipality Health Service to Health Post
- ✓Establishment of medicines control laboratory

3. Difficulties/Lessons Learned from Past Experience

- More than 99% of pharmaceutical imported
- Low capacity of National Medicine Quality Control Laboratory
- Insufficient competent staff to perform regulatory activities
- Insufficient resources for implementation of laws and regulations
- Insufficient capacity and resource to perform post market surveillance assessments

Continue Difficulties/Lessons Learned from Past Experience

- MRP (Maximum Retail Price) system not implemented
- Limited pharmaceutical human resources against pharmaceutical establishments
- Illegal promotion of medicine and healthcare products
- GMP not implemented for manufacturing sites
- Lack of standard quality control laboratories inside the manufacturing companies

Your interests

The followings are my interests to learn from this program and to deal with mentioned challenges:

1. How to standardized the local manufacturing companies in Timor Leste and how to improve the quality of their products?
2. How to deal with existing and how to avoid more smuggling and illegal medicine in the market of Timor Leste?
3. How to implement normal and fast-track registration system in Timor Leste by minimum use of sources?

THANK YOU

ARIGATO - GOZAIMAS

OBRIGADO BARAK

5. Timor-Leste(2)

Japan International Cooperation Agency

REGULATORY SYSTEMS ON ENSURING ACCESS TO QUALITY MEDICINES

(JFY2022)

Inception Report

Name :Angelica Brito Ribeiro

Country : Timor-Leste

Organization/Department/Division :

SAMES is means: Servico Autonomo de Medicamentos e Equipamentos da Saude/ Service Autonomous of medicines and Medical Equipment/

Warehouse and Distribution Direction/Head of Department Pharmaceutical Information Management.

PART I: INFORMATION SHEET

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

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

The vision of Ministry of Health of Timor-Leste

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

Mission

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

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

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

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

   The Legal and regulatory framework shall include the following:

   Specifics; National Drug Regulatory Authority (synonym: National Drug Administration)

1. The law shall pave the way for the establishment of a National Drug Administration Syn. National Drug Regulatory Authority, in the organization of the Ministry of Health
2. Its duties and powers regarding the enforcement of the Drug Law, with technical regulations for authority and authority, clearly defined in the Drug Law.
3. The National Drug Administration shall be the focal point for implementation of the National Drug Policy.
4. The National Drug Administration shall be advised by an advisory body. (hereinafter called Advisory Board)

Access to Medicines and Pharmaceutical Supply

A centralized procurement and supply system has been established, the SAMES with the aim to ensure availability and supply of medicines to all levels of health care in a predictable manner. The Public Health

b. objectives of the SAMES system shall be defined in the new Drug Law of Timor Leste.

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

3. Regulatory Services

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

A. Licensing of Importers, Wholesalers and Pharmacies

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

Be licensed by the National Drug Administration, and Fulfill standard requirements of the Ministry of Health in providing and maintaining suitable premises and quality procedures including appropriate storage conditions for medicines to preserve their quality and efficacy (Good Distribution Practices) and that qualified personnel are available to endure good pharmacy practices Pharmaceutical personnel, and healthcare personnel with right to prescribe, shall be licensed by the

National Drug Administration, and kept in updated recording database in the Drug Administration, and in updated printed records over licensed prescribers, provided to all pharmacies with 2 updates per year.

B. Medicine / Drug Registration and Marketing Authorization

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

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

C. Post Marketing Surveillance.

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

4. Drug Pricing

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

5. NA

6. NA

7. Education and License of pharmacist in Timor-Leste

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

   Primary 6 years

   Secondary 3 years

2. Category during university

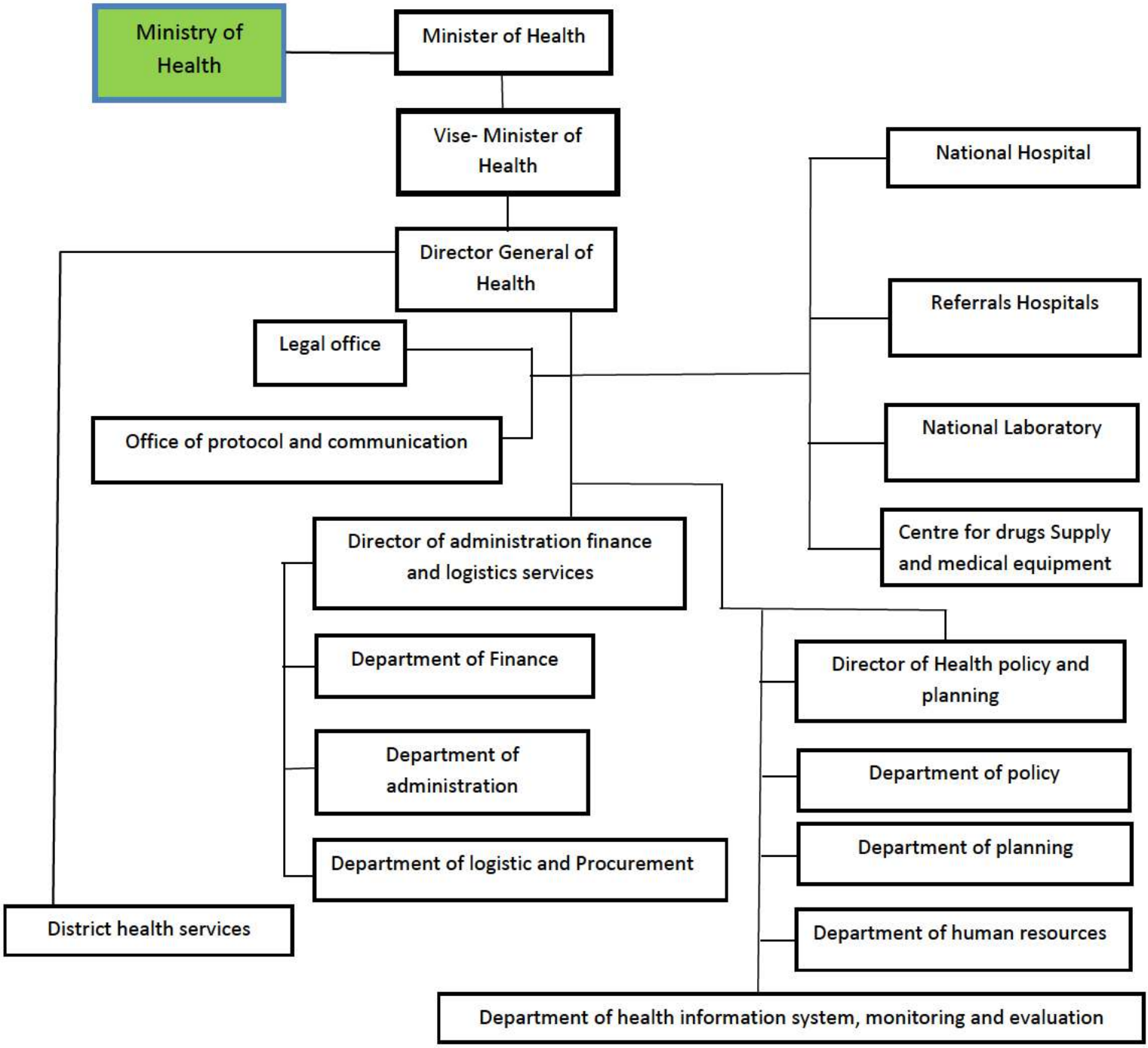
   University : 4 years

   Professional education : 2 years

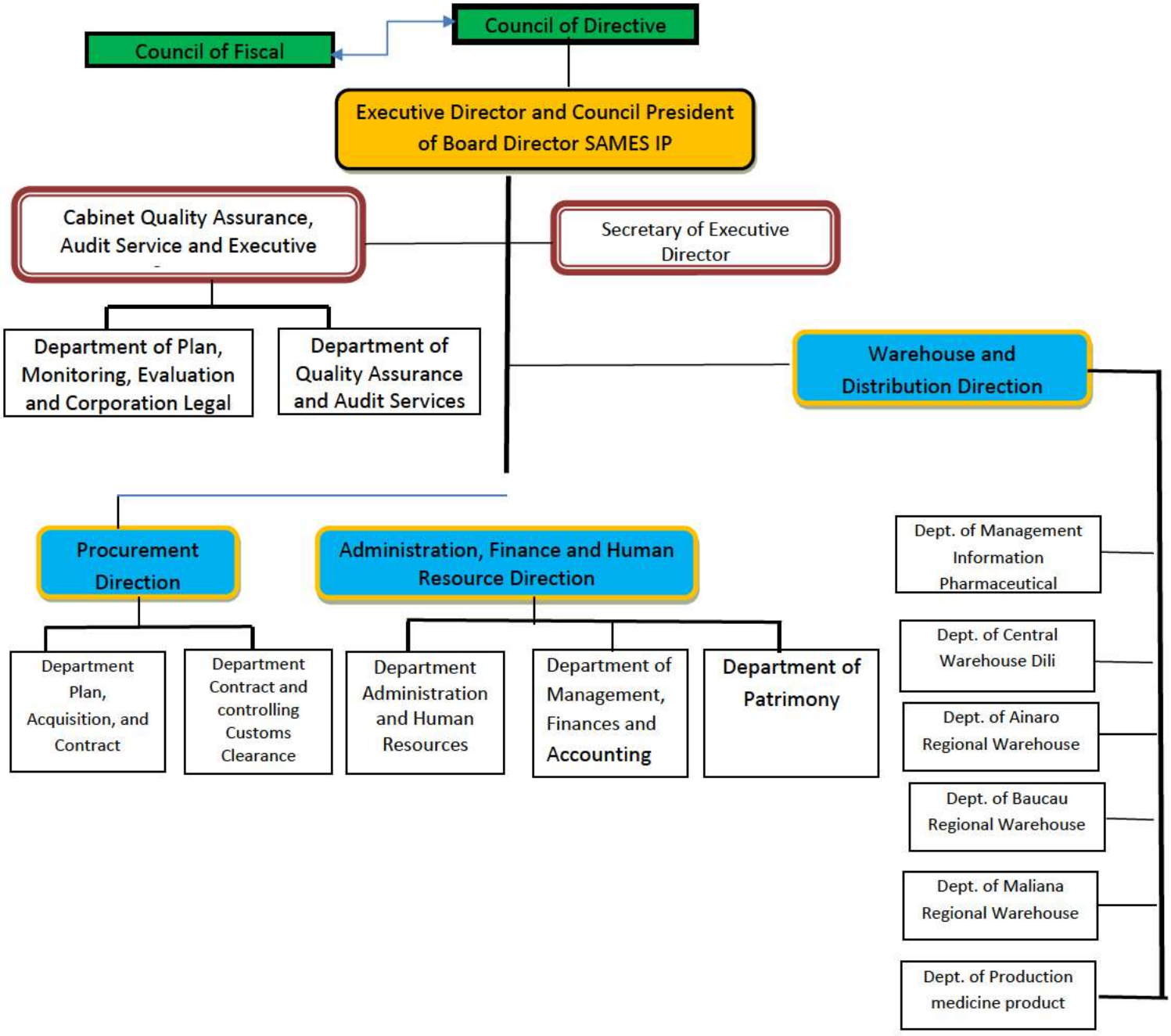
   Practical training 2 or 4months (one month in warehouse, hospitals, private clinics and the community)

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

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



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



TIMOR LESTE

Servico Autonomo de Medicamentos E Equipamentos da Saude (SAMES)

By :Angelica Brito Ribeiro
Head of Department
Pharmaceutical Information Management

1. Introduction of the work

1) SAMES is an autonomous institution, which is engaged in the health sector, responsible for procurement, storage and Distribution.

SAMES is means: Servico Autonomo de Medicamentos e Equipamentos da Saude/Service Autonomous of medicines and health Equipment

Objetives:

> Ensuring continued acces to essential medicine and medical supplies for the Timor-Leste Public health System.

> Building the capacity of the organization and it' s employees so that it may be managed enterily by Timorese nationals.

Direction Struture in SAMES:

> Direction of Quality Assurance and Executive Director Support

> Supply Direction

> Direction of Finance and Human Resources

> Direction of Storage and Distribution

Introduction of the work Continue

2) Department Pharmaceutical Information Management guardianship in the Directive of storage and distribution. (This is my Job now)

2) SAMES has regulation of Ministry of Health, Ministerial Diploma Number. 36/2020 of 8 October. First amandament to ministerial diploma Number 21/2016, 9 March which establishes the internal regulations of SAMES.

4) Pharmacist hold multiple roles in Hospitals,SAMES,DNFM and Pharmacies in Timor Leste.
DNFM Is means: Diresaun Nasional Farmacia e Medicamentos/ Direction National Pharmacy and Medicines

2. Good Practice

1) At the SAMES especially in the direction of storage and distribution using the electronic system mSupply to control the situation stock of the medicine and medical Equipment.

2) SAMES uses an electronic system mSupply to procure, receive, store,distribute and reporting.

3) SAMES brings and expands the electronic system mSupply to hospitals and all health facilities in Timor Leste to help them manage stock of medicine and medical equipment.

4) SAMES has established three (3) warehouse in each region, the aim of speeding up distribution medicine and medical equipment to hospitals and all health facilities in Timor Leste.

5) SAMES already has a mini laboratory to test the quality of medicine, but now it's not active anymore.

3. Difficulties/Lessons Learned from Past Experience

- Which is problematic for the Timor Leste Ministry of health(DNFM),SAMES and all Pharmacies in Timor Leste do not have a laboratory to test medicine making it difficult for us/for Phamacies Timor Leste to determine the quality of medicine.
- **SAMES already has a mini laboratory to test the quality of medicine, but now it's not active anymore.**

- Pharmacy Timor Leste (for me) still lacks knowledge of testing the quality of medicine

- The problem that often occours at SAMES is that the internet signal take a long time to load, difficulties when we serve emergengy distribution in the electronic system msupply.

4. Your interests

- Provide a laboratory to test the quality of medicine and adding equipment and reagents to test medicine (at SAMES).
- Increase the knowledge of testing medicine to the pharmacy Timor Leste (Specially for me).
- Increase internet capacity in the area SAMES to help speed up emergency services.

Thank You

Obrigado Wain

出典：2022 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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