Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

Country Reports

Japan International Corporation of Welfare Services (JICWELS)

Contents

1 .PHILIPPINES ····· 241

2 .MONGOLIA ····· 259

3 .PAPUA NEW GUINEA ····· 279

4 .MYANMAR ····· 293

5 .INDONESIA ····· 307

6 .SRI LANKA ····· 319

7 .AFGHANISTAN ····· 367

8 .MOLDOVA ····· 381

9 .MALAWI ····· 397

10.TANZANIA ····· 409

11.ZAMBIA ····· 423

12.BRAZIL ····· 447

Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

PHILIPPINES

ROLES OF REGULATORY SYSTEMS AND PHARMACISTS ON ENSURING PROPER ACCESS TO QUALITY ASSURED MEDICINES (JFY 2017)

LORALYN P. PASCUA
PHILIPPINES
UNIVERSITY OF THE PHILIPPINES-PHILIPPINE GENERAL HOSPITAL

1. ORGANIZATIONAL CHART

National Pharmaceutical Administration (organizational chart on page 3)
Food and Drug Administration

To ensure the safety, efficacy health products, which includes drugs, the Philippine Bureau of Food and Drugs (BFAD) was established under Republic Act No. 3720, series of 1963 and amended by Executive Order 175, series of 1987, otherwise known as the "Food, Drugs and Devices, and Cosmetics Act". This regulatory agency is under the Department of Health. Bureau of Food and Drugs (BFAD) was later changed to Food and Drug Administration (FDA) by Republic Act No. 9711 otherwise known as "The Food and Drug Administration Act of 2009".

Following the strengthening of the agency, health products under the watch of Philippine Food and Drug Administration included not only food and drugs, but also cosmetics, devices, radio-emitting devices or equipments, and household/urban hazardous substances, pesticides, and toys or other consumer products that may have effect on the health of people.

Relative to the regulation of pharmaceuticals, FDA assumes the following functions:

- Sets standards for efficacy and quality of drugs
- Conducts research to address the drug needs of the country
- Responsible for the collection of samples of drugs, analysis and inspection of drugs
- Establishes analytical data to serve as basis for the preparation of drugs
- Ensures compliance with technical requirements of manufacturers, importers, exporters, distributors, wholesalers, drug outlets, and other establishments and facilities of drugs
- Requires all manufacturers, traders, distributors, importers, exporters, wholesalers, retailers, consumers, and non-consumer users of drugs to report to the FDA any adverse events encountered with the use of drugs
- Orders the ban, recall, and/or withdrawal of drug, after due process, found to have caused serious adverse drug reaction
- Strengthens the post market surveillance system in monitoring of drugs
- Recommends standards, guidelines, and regulations with respect to information, advertisements and other marketing instruments and promotion, sponsorship, and other marketing activities about drugs

The FDA is headed by the Director-General (DG), who is appointed by the President of the Philippines. The Office of the Director General is directly in charge of the Public Assistance Information, and Information and Communication Management, as well as the 4 centers of FDA namely Center for Drug

Regulation and Research, Center for Food Regulation and Research, Cosmetics Regulation and Research, and Center for Device Regulation, Radiation Health and Research.

Assisting the Director General are the Deputy Director General for Internal Management and the Deputy Director General for Field Regulatory Operations Office.

The Deputy Director General for Internal Management is involved in the 1) Policy and Planning Services which includes policy formulation, monitoring and evaluation of the activities of the agency, training and policy dissemination, 2) Legal Services which includes investigation, litigation and enforcement services 3) Administrative and Finance Service which includes human resource management, budgeting, and accounting services

The Deputy Director General for Field Regulatory Operations is in charge of the Regulatory Enforcement Units as well as the operations in regional field offices in North Luzon, South Luzon, Visayas, Mindanao West, and Mindanao East.

FDA collaborates with pharmacists to ensure that regulations with drugs are properly implemented. The umbrella association of pharmacists is called the "Philippine Pharmacists Association" in which the association disseminates administrative orders/ advisories from Food and Drug Administration to its about 18, 000 members who are registered pharmacists in the Philippines.

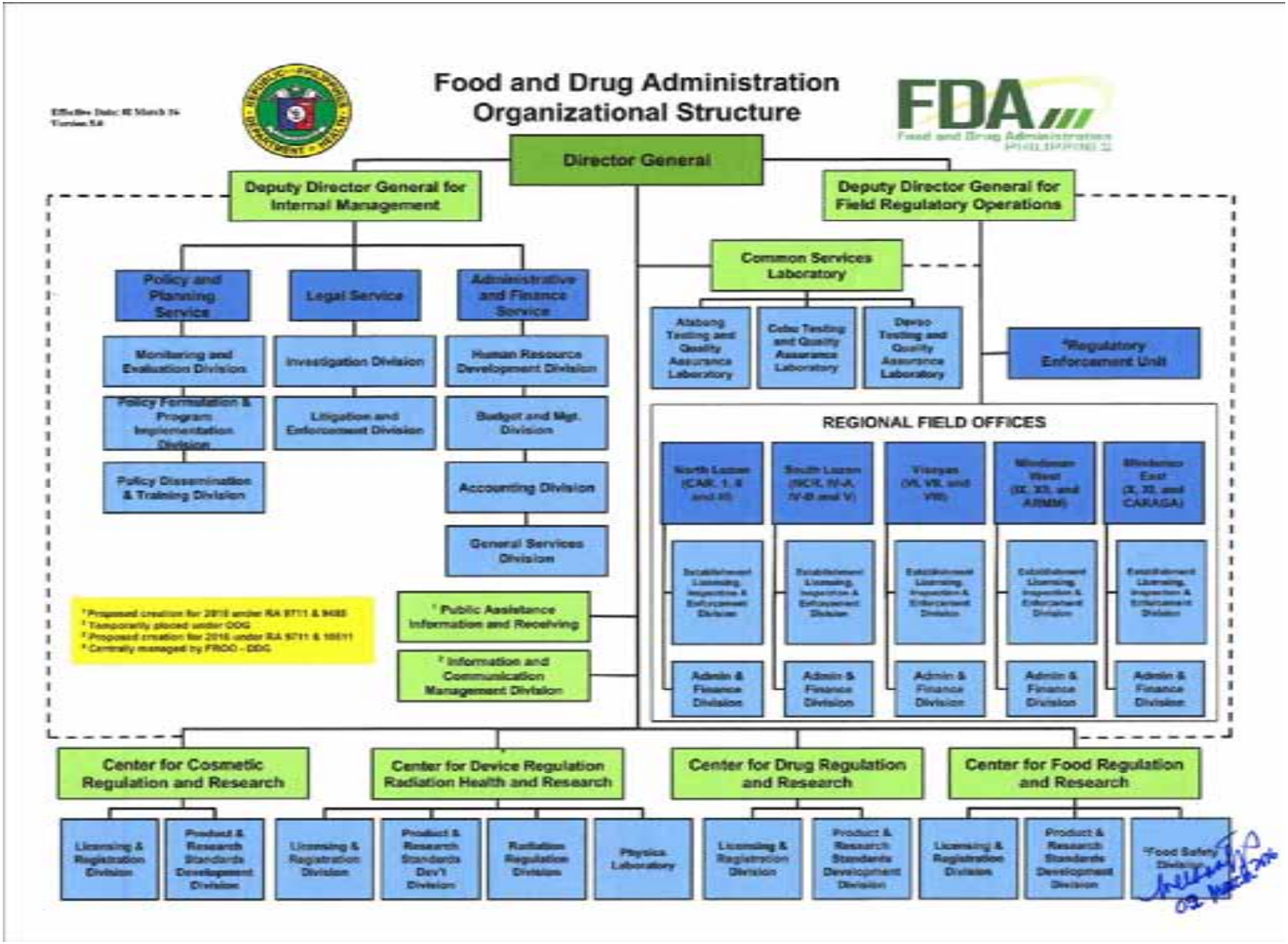
HOSPITAL PHARMACY

Majority of the hospital pharmacists in the Philippines are mainly responsible for the inventory, filling of prescriptions and dispensing of medications to patients.

There are only a few major hospitals with clinical pharmacists whose roles in the medical institutions are to identify drug therapy problems, resolve actual medication problems, and prevent medication problems through prompt clinical pharmacist's interventions which are communicated to the patient or other healthcare professionals directly involved with the care of the patient.

These clinical pharmacists go to clinical wards and read patient medical charts, assess for any drug therapy problems of patients that are not being addressed such as drugs without indication, existing medical conditions of patients warranting the use of drugs, drug orders with incomplete dosage form or dosage strength or route of administration or frequency of administration or duration of therapy or combination of any, actual or potential drug interactions, suspected adverse drug reactions, wrong route of administration to name a few. Drug therapy plan will be prepared by the clinical pharmacists and this will be communicated to the physician-in-charge of the patient.

There are also a few hospitals that have drug information pharmacists who are in charge of provision of information about drugs and drug therapy. Likewise, only a few institutions have pharmacists who counsel their patients about the proper use of medications to optimize the use of drugs for improvement of patients' health condition.


Food and Drug Administration
Organizational Structure
FDA
Director General
Deputy Director General for Internal Management
Deputy Director General for Field Regulatory Operations
Policy and Planning Service
Legal Service
Administrative and Finance Service
Monitoring and Evaluation Division
Policy Formulation & Program Implementation Division
Policy Dissemination & Training Division
Investigation Division
Litigation and Enforcement Division
Human Resource Development Division
Budget and Mgt. Division
Accounting Division
General Services Division
Common Services Laboratory
Alabang Testing and Quality Assurance Laboratory
Cebu Testing and Quality Assurance Laboratory
Davao Testing and Quality Assurance Laboratory
*Regulatory Enforcement Unit
REGIONAL FIELD OFFICES
North Luzon (CAR, 1, II and III)
South Luzon (NCR, IV-A, IV-B and V)
Visayas (VI, VII, and VIII)
Mindanao West (IX, X, and ARMM)
Mindanao East (XI, XII, and CARAGA)
Establishment Licensing, Inspection & Enforcement Division
Admin & Finance Division
[1] Public Assistance Information and Receiving
[2] Information and Communication Management Division
[1] Proposed creation for 2010 under RA 9711 & 9468
[2] Temporarily placed under ODG
[3] Proposed creation for 2010 under RA 9711 & 10611
* Centrally managed by FROO - DDG
Center for Cosmetic Regulation and Research
Licensing & Registration Division
Product & Research Standards Development Division
Center for Device Regulation Radiation Health and Research
Licensing & Registration Division
Product & Research Standards Dev't Division
Radiation Regulation Division
Physics Laboratory
Center for Drug Regulation and Research
Licensing & Registration Division
Product & Research Standards Development Division
Center for Food Regulation and Research
Licensing & Registration Division
Product & Research Standards Development Division
*Food Safety Division

2. LEGISLATION ON PHARMACEUTICAL ADMINISTRATION

National Level:

- Republic Act No. 3720, series of 1963 "Food, Drug, and Cosmetic Act"
  - creation of Food and Drug Administration
  - administered by the Office of the President

- Executive Order 175, series of 1987 "An Act to Ensure the Safety and Purity of Foods, Drugs, and Cosmetics Being Made Available to the Public by Creating the Food and Drug Administration Which Shall Administer and Enforce the Laws Pertaining thereto, and for Other Purposes"
  - amending Republic Act No. 3720
  - administered by the Office of the President
- Republic Act No. 9711 " Food and Drug Administration Act of 2009"
  - an act strengthening and rationalizing the regulatory capacity of the Bureau of Food and Drugs by establishing adequate laboratory centers and field offices, upgrading its equipment, augmenting its human resource complement, giving authority to retain its income, renaming it the Food and Drug Administration (FDA) , amending Certain Sections of Republic Act No. 3720, and appropriating funds
  - administered by the Office of the President

Local level: **none**

PIC/S member: **NO**

3. REGULATORY SERVICES

- *Pharmaceutical Manufacturing*
  The Philippine Food and Drug Administration is in charge of regulating drug manufacturers in the country. The first Good Manufacturing Guidelines for local manufacturers is outlined in Administrative Order No. 43 series 1999 and was issued to the public for dissemination to all concerned last September 1999. This Administrative order was signed by the Secretary of Health (the secretary from which FDA is directly reporting to).

  The said administrative order covered the basic GMP guidelines consisting of the responsibilities of personnel, functions, and the trainings that they should have undergone, standard premise conditions, equipment used in manufacturing drugs and their maintenance, sanitation and hygiene processes, storage of starting and packaging materials intermediates, bulk products and finished products, production and packaging procedures, finished product quarantine and delivery process, quality control, documentation, self-inspection, and handling of product returns, complaints and recalls.

- *Drug Import/Export*
  Since the mandate of FDA is for all drugs that will be registered with the agency should be manufactured using methods, facilities and control procedures adequate to preserve their identity, strength, quality and purity, all drug importers are held responsible for ensuring that all drugs that are brought to the Philippines are manufactured in accordance to GMP.

  If the importer imports raw material or finished products for use in the manufacture of drug products, the importer must submit a certification from the country of origin that the manufacturer is registered in the country of origin (to be authenticated by the Philippine Consulate), and evidence that the manufacturer complies with GMP standards. If inspection by FDA is warranted, the applying drug importer will born the cost of inspection.

  This procedure is outlined in the Administrative Order No. 2013- 0022 entitled "Guidelines for Current Good Manufacturing Practice (cGMP) Clearance and Inspection of Foreign Drug Manufacture" issued by Food and Drug Administration (FDA).

- *Marketing Authorization*
  The Department of Health came up with Administrative Order 2014-0034 entitled "Rules and Regulations on the Licensing of Establishments Engaged in the Manufacture, Conduct of Clinical Trial, Distribution, Importation, Exportation, and Retailing of Drug Products, and Issuance of Other Related Authorizations" to regulate such activities. The Administrative Order clearly defined the classifications of drug establishments and the pertinent requirements for registration and licensing, process of filing, evaluation and inspection of the drug establishment.

  The Philippine FDA is strengthening their power in ensuring the safety and efficacy of pharmaceutical products available in the Philippines. They have expanded the list of products that require Bioequivalence Studies as part of the requirement for the application of product registration through FDA Circular 2016-019 entitled "Revised Guidelines on the Submission of Equivalence Evidence for Registration of Pharmaceutical Products".

- *Drug distribution*
  Food and Drug Administration has issued Administrative Order 2014-026 "Guidelines on Implementation of New Rules and Regulations on the Licensing of Drug Distributors". This administrative order was issued to update and streamline the approaches in licensing of drug importers. The requirements include completely filled up application forms, proof of business name registration, credentials of pharmacists and other qualified personnel, risk management plan, and location plan.

  From those registered drug distributors can any institution procure their drugs. Majority of the hospitals, community pharmacies, and other drug outlets procure their drugs based on the historical drug consumption of their consumers. However, government hospitals and institutions are mandated by Executive Order No. 49 which states that all government institutions can only procure medicines that are listed in the

current Philippine National Formulary which was published by the Formulary Executive Council of the Philippines which is under the Department of Health. With this list of medicines, government institutions rely on the bidding process wherein the major qualification to determine from which drug distributor will the government institution get their drugs from is the cost. The company with the lowest bid price for that specific drug with the specific dosage form and strength will supply the government institution with the specific drug.

With regards to the sale of drugs, drug outlets are required to follow the Maximum Drug Retail Price which was enacted through Executive Order 821 series of 2009.

- *Medicine Safety (post-marketing)*
  To supplement Administrative Order No. 67 series of 1989 "Revised Rules and Regulations on Registration of Pharmaceutical Products", Food and Drug Administration (FDA) issued Administrative Order 2006-0021. This administrative order mandated that all new drugs are required Post Marketing Surveillance (PMS) to complete clinical studies and to pass through 3-year initial registration under monitored release before a market authorization can be granted. However, one of the reasons that FDA has observed that extensions for monitored release status of drugs were requested was the failure to achieve the required 3,000 patients to be included in clinical trials. Likewise, based on reports, the PMS conducted through monitored release were observational and non-experimental studies.

  With this, FDA came up with Circular No. 2013-004 entitled "Post Marketing Surveillance of Authorized Drug Products" which extended the Monitored-release status of drugs from 3 years to 5 years strictly without exemption. Likewise FDA has employed other different PMS approaches such as sampling drug products in the market, inspecting drug establishments and drug outlets, testing drug samples, and investigating spontaneous adverse drug reactions (ADRs) and adverse drug events (ADEs).

- *Relief System for Adverse Drug Reactions*
  Unfortunately, there exist no relief system for adverse drugs reactions encountered by patients in the Philippines. As most of adverse drug reactions are not known to patients/ patients' families, they usually do not ask for compensation for adverse drug reactions.

4. DRUG PRICING

In an attempt to increase the use of generic medicines and reduce medicine prices, President Aquino approved in 1988 Republic Act 6675 known as the Generic Drug Act of 1988. Its goal is to increase the use of generic medicine names throughout the supply chain from importation/manufacture through prescription and dispensing, to increase the availability of low-priced generic medicines, and to encourage use of generic medicines together with advantages in health service training and operation.

According to the Generics Act, drugs should be procured by generic names by all public entities. However, originator brand or other medicines "identified by brand names" may be procured "where price and availability constraints make it necessary". This is intended for circumstances in which the branded medicines are the only products available or offered at more advantageous prices than purely generic medicines.

To make drugs affordable and accessible to Filipinos, the Maximum Drug Retail Price was enacted through Executive Order 821 series of 2009. MDRP is required on drugs that reduce the incidence of morbidity and mortality.

The imposition of MDRP considers the following factors: 1) the retail price in the Philippines and other countries 2) Supply availability 3) Costs including exchange rate, amortization costs of machinery for production, labor costs, and transport costs.

However, not all drugs were regulated by MDRP. To determine drugs covered by the MDRP, the following criteria were used: 1) Conditions that address public health priorities especially those that account for the leading causes of mortality and morbidity 2) Drugs that have high price differentials or arbitrage compared to international prices. 3) Drugs that have limited competition in terms of lack of generic counterparts or lack of market access to these products 4) Drugs where the innovator products is the most expensive yet most prescribed or most dispensed in the market.

MDRP is imposed on all retail outlets, public or private, including drugstores, hospitals and hospital pharmacies, health maintenance organizations, convenience stores, supermarkets, and other sources whether public or private.

During the early stages of the policy implementation, it was the Secretary of Health who led surprise inspection trips of drug stores. A few weeks and months after the policy was implemented, 80-90% compliance rate among 40,000 drugstores and hospital pharmacies had been reported by the media (Pazzibugan and Cabreza, 2009; Esplanada, 2010).

5. STATISTIC DATA

Number of pharmacists: ***approximately 40,000 (based on the number of pharmacists who renewed their license to practice pharmacy within 3-year period from 2014- 2016)***

Number of GMP inspector (National and Local): ***No data exist***

Number of pharmaceutical manufacturers/ manufacturing sites: ***284 (as of December 2009, based on Philippine Institute for Development Studies "A Profile of the Philippine Pharmaceutical Sector" by Reyes et al, published on May 2011)***

Number of traditional medicine manufacturers/ manufacturing sites: ***No data exist***

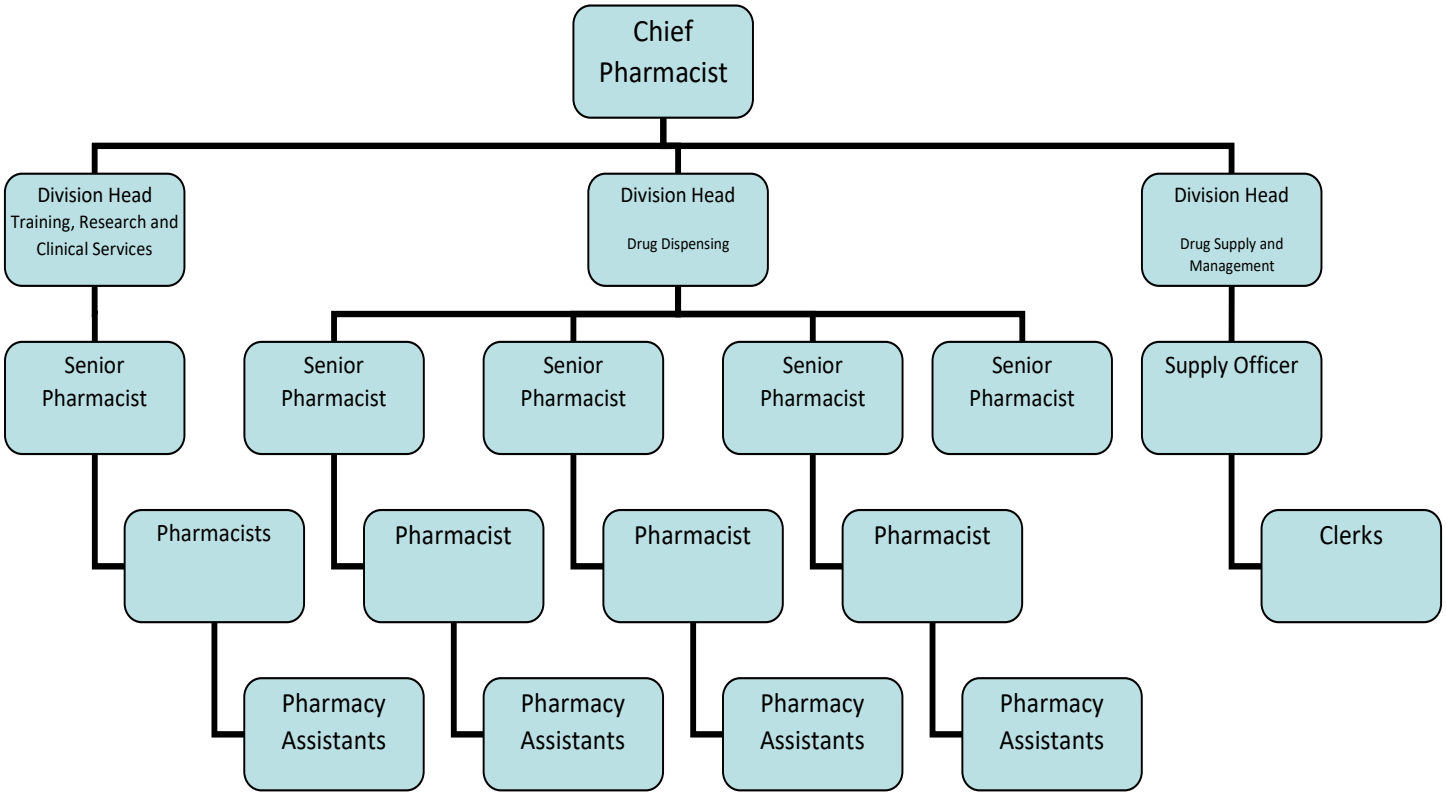
Number of pharmaceutical importers: ***634 (as of December 2009, based on Philippine Institute for Development Studies "A Profile of the Philippine Pharmaceutical Sector" by Reyes et al, published on May 2011)***

Number of pharmaceutical wholesalers: ***3,956 (as of December 2009, based on Philippine Institute for Development Studies "A Profile of the Philippine Pharmaceutical Sector" by Reyes et al, published on May 2011)***

6. INFORMATION ON YOUR HOSPITAL PHARMACY

Philippine General Hospital caters to about 1, 500 patients. There are 9 Pharmacy dispensing areas in the hospital catering to the different needs of patients namely: 1) Charity in-patient Pharmacy 2) Pay In-patient Pharmacy 3) Outpatient Pharmacy 4) Main Pharmacy 5) Ophthalmology Pharmacy 6) Obstetrics and Gynecology Pharmacy 7) Operating Room Pharmacy 8) Cancer Institute Pharmacy 9) Central Intensive Care Unit Pharmacy

Organization Chart of the Pharmacy Department



1. Number of section chief: **1 (Chief Pharmacist)**

   Number of deputy chiefs: **3 (division heads)**

   1) Training, Research, and Clinical Services

   2) Drug Supply and Management Services

3) Drug Dispensing Services

Number of managers: **5 senior pharmacists**

2. Number of staff **(as of June 6, 2017)**

    a. Number of pharmacists: **75**
    b. Number of clinical pharmacists: **5**
    c. Number of technicians: **96**

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

    a. Oral medicine: **284**
    b. Injections: **227**
    c. Medicines for external use: **21**

4. Number of prescriptions dealt in your pharmacy per day (as per average daily prescriptions received on April 2017)

    a. For inpatients: **22,108**
    b. For outpatients: **261**

5. Equipment of the pharmacy in your hospital

    a. Does your hospital have a dispensary room? **YES.** We have 9 dispensary rooms.
    The dispensary rooms vary from as large as **126** square meters to as little as **50** square meters. We also have 2 warehouses for medications measuring approximately **242** square meters and **122** square meters. We have another warehouse solely for intravenous fluids measuring approximately **90** square meters.

    b. Does the pharmacy have a clean room or laminar flow hood? **YES**
    We have 2 cleanrooms in the Pharmacy. One is located at the Laboratory Section of the Pharmacy Department wherein 2 laminar flowhoods are housed to cater to the parenteral nutrition needs of the inpatients in the hospital. The other clean room is located at the Oncology Pharmacy with also 2 laminar flow hoods and these laminar flow hoods are utilized to prepare oncologic medications both for inpatients and outpatients.

    c. Does the pharmacy have computers? **YES**
    Computers in the pharmacy are mainly used for inventory management, identification of patients, and for the charging of medications to patients. However, in the Training, Research and Clinical Services Division of the Pharmacy Department, computers are mainly used to aid in the provision of information about drugs and drug therapy to patients and other healthcare professionals.

    d. Do you implement Therapeutic Drug Monitoring (TDM) in your hospital? **NO**

    e. Do you prepare Total Parenteral Nutrition (TPN)? **YES**

f. Can you use internet in the Pharmacy? **YES**
Internet is used primarily in the Pharmacy to check patient data and for charging of costs of medications to patients. Internet connection is also used by pharmacists for answering drug information inquiries.

7. EDUCATION AND LICENSE OF PHARMACISTS IN YOUR COUNTRY

1. *Number of years in primary, secondary and high school education*
Primary: **6 years**
Secondary: **4 years**
High School: **2 years**

2. *Number of years/weeks in the following categories during university or college*
University/college: **5 years**
Professional education: **NA**
Practical Training: **NA**
Duration of Training by each facility: **NA**
Hospital pharmacy: **200 hours**
Community pharmacy: **200 hours**
Pharmaceutical company: **200 hours**
Others: **360 hours major internship at either hospital pharmacy, community pharmacy or pharmaceutical company**
Age at graduation: **approximately 23 years old**

3. *Are there national examinations for pharmacists in your country?* **YES**
Academic Exams: **2 days**
Clinical Exams: **NA**

4. *Which of the following must you fulfill to obtain a pharmacist's license?*
Practical training: **NA**

5. *Number of pharmaceutical university or college graduates:* **2,7840 people (based on number of Pharmacy Licensure examinees last June 2016)**

Alumni placement rate: ***Data based on "Issues and Concerns on Utilization of Pharmacy Workforce in the Philippines" by Loquias and Robles published in 2012***
Hospital: **15%**
Community Pharmacy: **77%**
Government Organizations: **less than 1%**
Enterprise: **7%**
Others: **less than 1%**

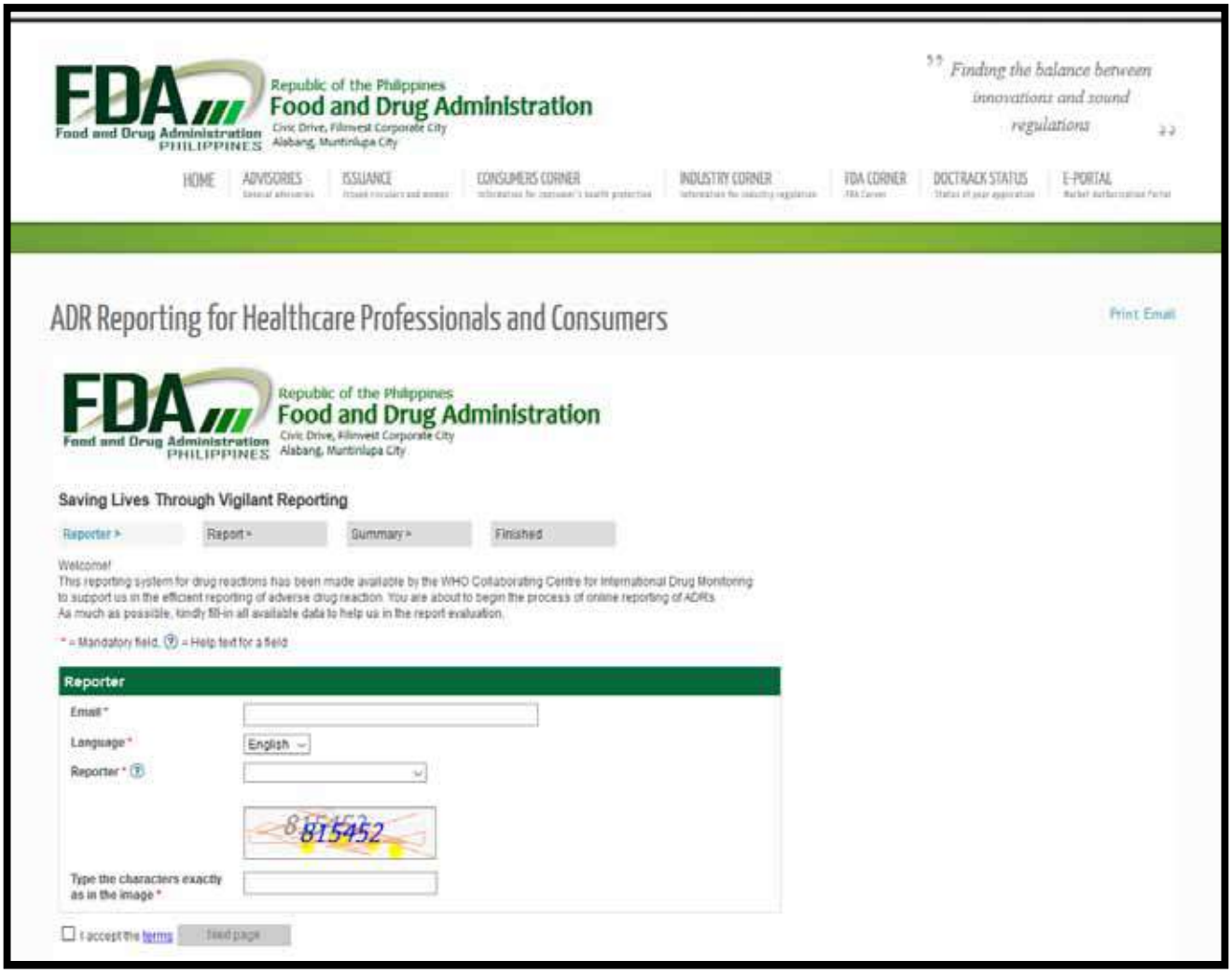
8. SIDE EFFECT REPORT

The national agency involved in the side effect reporting system is the Food and Drug Administration. All healthcare professionals as well as consumers are enjoined to report adverse

drug events to the agency. Few years ago, FDA has an ADR form that is downloadable from their website which any healthcare professional can accomplish and submit the form to the office of the agency. However, just a few years ago, the FDA has designed a user-friendly application in their website to report adverse drug reactions which even the consumers of medications can easily accomplish.

The FDA then collates all adverse drug reaction reports and submits them to World Health Organization (WHO).

However, in some hospitals like in our institution, we have the Medication Safety Subcommittee which is under the Drug and Therapeutics Committee which is in charge of monitoring and reporting adverse drug reactions encountered by our patients. The nurses who are responsible for the direct care of the patients are the ones who will report the adverse drug reactions to the resident-in-charge of the patient and collects the medical supplies used in the administration of drugs. The resident-in-charge of the patient then accomplishes ADR form after stabilizing the patient. The Accomplished ADR form together with the medical supplies used to administer the drug will be turned over to the Pharmacy. All ADR forms will be submitted to the Medication Safety Subcommittee to discuss appropriate actions and recommend policies which will emanate from the discussions of the committee. Any policy regarding the concerned drug will be elevated to the hospital administration to communicate with the national authority which is the FDA.



PHILIPPINES

PHILIPPINE GENERAL HOSPITAL L

Philippine General Hospital (PGH)

- tertiary state-owned hospital administered and operated by the University of the Philippines Manila (UP)
- largest government hospital administered by the university, and is designated as the National University Hospital.
- biggest hospital in the country with a 1,500-bed capacity.
- with 1,000 beds for indigent patients and 500 beds for private patients.

Pharmacy Department

- Consists of 9 Pharmacy dispensing areas and 2 major warehouses, and 1 special service division
- Training, Research and Clinical Services Division

All about me

- Started working in PGH on Sept 2005
  - Liaison officer drugs not locally available through coordination with FDA
  - Member of the subcommittee that evaluates of drugs prior to admission in the Pharmacy
  - Secretariat of Drug and Therapeutics Committee
  - Senior pharmacist of the Unit Dose Drug Distribution System (UDDDS)
  - Drug Information provider
  - Patient Medication counselor

Roles and Position of Pharmacists in the Philippines

- Mainly responsible for the inventory, filling of prescriptions and dispensing of medications to patients
- Clinical pharmacists involved in the provision of pharmaceutical care to patients

Good Practice

- Collaboration with the University of the Philippines College of Pharmacy to train students on
  - ward clinical pharmacy
  - patient medication counseling
  - drug information provision
- Continuing Education Provider
- Antimicrobial stewardship system
- Screening of drugs prior to admission in the Pharmacy

Difficulties/ Lessons Learned from the Past

- Out-of-stock drugs

  - unpredicted increase in consumption of certain drugs, undelivered drugs from distributors due to payment issues, unavailability in the local market

- Inadequate hospital funding

  - charity patients decked in the wards are only allocated with P1,000 worth of drugs

- Emerging antibiotic resistance

  - no regulatory measure for antibiotics

Difficulties/ Lessons Learned from the Past

- Lack of manpower
  - Cannot provide clinical pharmacists in the wards
- Difference in priorities between administration and the department
  - Pharmacists are to serve patients by dispensing drugs as per administration's point of view while the department wants pharmacists in the wards functioning as clinical pharmacists

Interests

- To see the differences in the system of distribution of drugs in different countries and identify which among the systems are applicable in the Philippine setting
- To be able to identify best practices in procurement of drugs without compromising the quality and efficacy of drugs

Interests

- Collaboration with other pharmacists from different countries to be updated with the current trends in the Pharmacy procurement and distribution systems

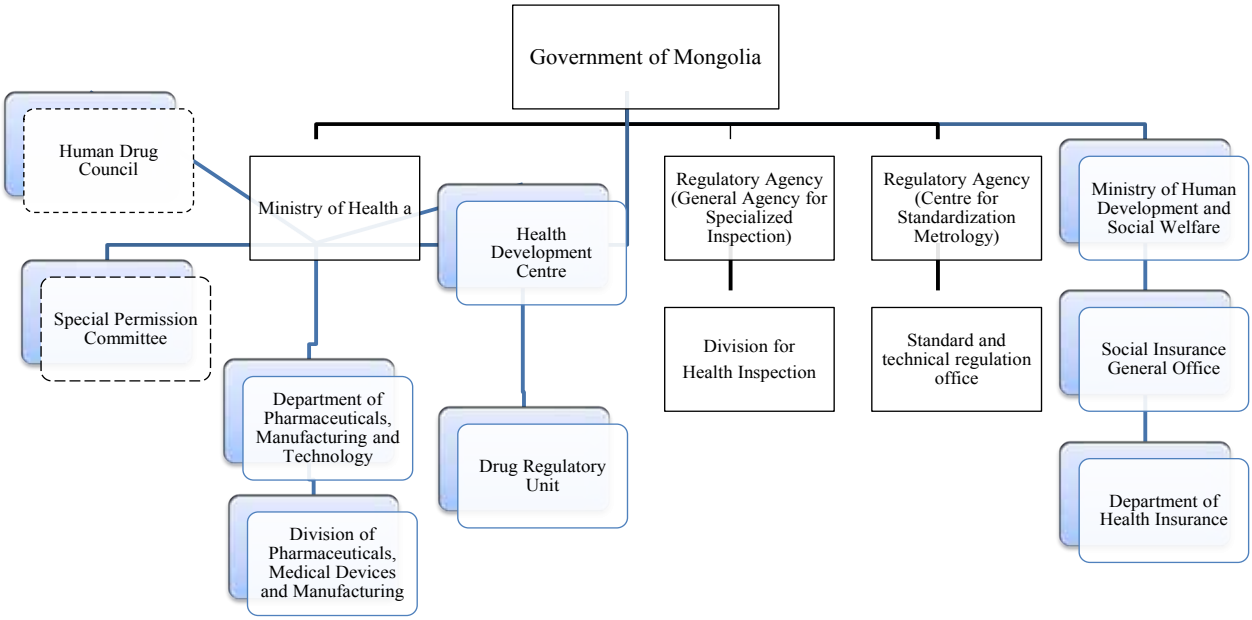
Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

MONGOLIA

Roles of Regulatory Systems and Pharmacists on Ensuring Proper Access to Quality Assured Medicines (JFY 2017)

Course title and number: J1704206
Country: Mongolia
Organization: Mongolian National University of Medical Sciences, Mongolia- Japan Teaching Hospital

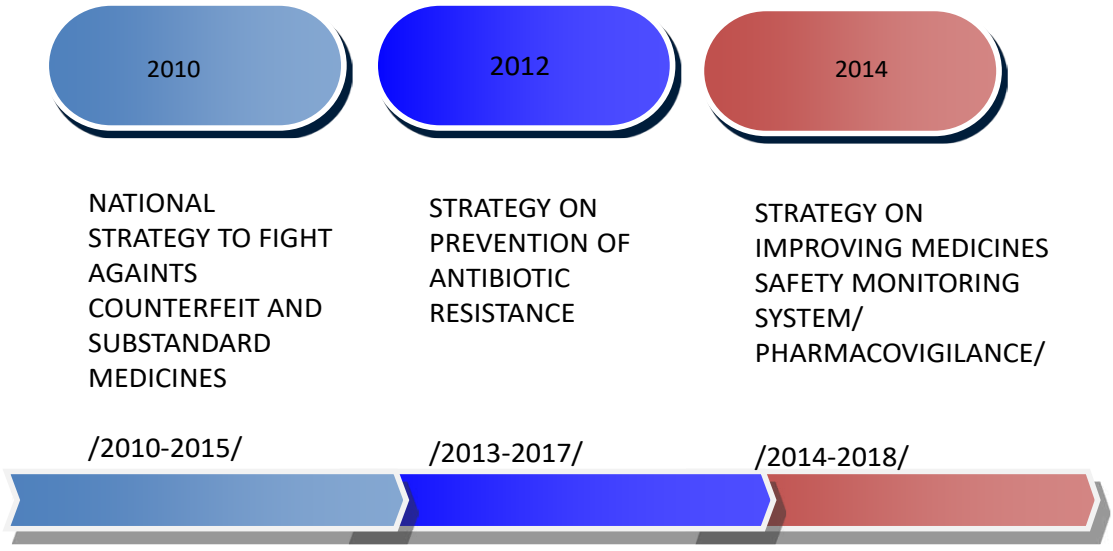
Organizational chart



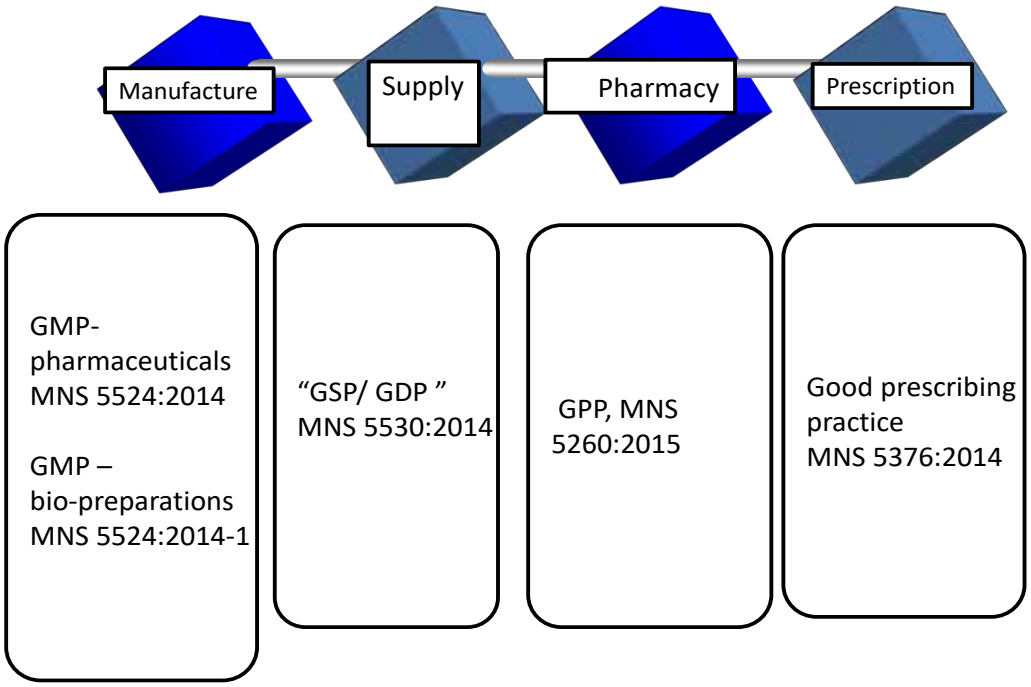
Legislation on pharmaceutical administration

- National level: yes
- Local level: yes
- PIC/S: no (as of 06/2017)

Regulatory services: NMPM



National standards



Drug Pricing

- The price of medicines has not been regulated by the Government since 1997 and a 10% value-added- tax (VAT) was introduced in 1999. Taxes, duties and other government charges applied to medicines include 5% customs duty for imported medicines.
- Registration fees do not differ between originator brands and generic equivalents. However, registration fees are lower for locally produced than for imported medicines; hence the government encourages local production.
- There are no public pharmacies, except those located in public hospitals whose service is limited to inpatients. Furthermore, the government controls dispensing fees for reimbursed essential medicines and some data are available to support the insurers view on the dispensing fee.
- Until 2014, there were no price control mechanisms specific to generic drugs, however the latest revision of the NDPM indicates that the maximum price of essential medicines shall be regulated by the Government.(*Dorj et al, Drug pricing and reimbursement decision making systems in Mongolia, JPPP, 2017)*

Statistic data

1. Number of pharmacists: 1575 (2016)
2. Number of GMP inspectors (National & local): 8
3. Number of pharmaceutical manufacturers/ manufacturing sites: 33
4. Number of traditional medicine manufacturers/ manufacturing sites: 6
5. Number of pharmaceutical importers: 210
6. Number of pharmaceutical wholesalers: 210

Health indicators of Mongolia, HDC, MOH, 2016

MNUMS, Mongolia-Japan Teaching Hospital Pharmacy

(1) Organization:

a. Number of section chiefs : 3

b. Number of deputy chiefs: 2

c. Number of managers: 4

(2) Number of staff:

a. Number of pharmacists: 12

b. Number of clinical pharmacists: 7

c. Number of technicians: 2

(3) Number of drugs: 1673

a. Oral medicine: (689, 41.2%)

b. Injections: (490, 29.3)

c. Medicines for external use: (494, 29.5%)

(4) Number of prescriptions

a. Inpatients: 104 beds (2018)

b. Outpatients: 10-15 per days (2018)

(5) Equipment

a. Dispensary: 12 m2

b. Clean room or laminar flow: Aseptic room / laminar flow*

c. Computers: 5

d. TDM: in planning

e. TPN: no (as of 2018)

f. Internet: yes

Education and License of Pharmacists

(1) Number of years in primary, secondary and high school education: 1-5 year, 6-9 year, 10-12 year

(2) Number of years/ weeks during university or college:

University: 5 years

Professional education: 6 months (postgraduate training)

Practical training: 2 credits

Duration of training by each faculty:

Hospital &Community pharmacy: 2 credits (64 hours)

Pharmaceutical company: 2 credits (64 hours)

Others (Pharmacognosy): 3 credits (88 hours)

Age at graduation: 22 years old

(3) **National examinations**:

Academic Exams: 2-3 days

Clinical Exams: 1 day

(4) Pharmacists license: Exam

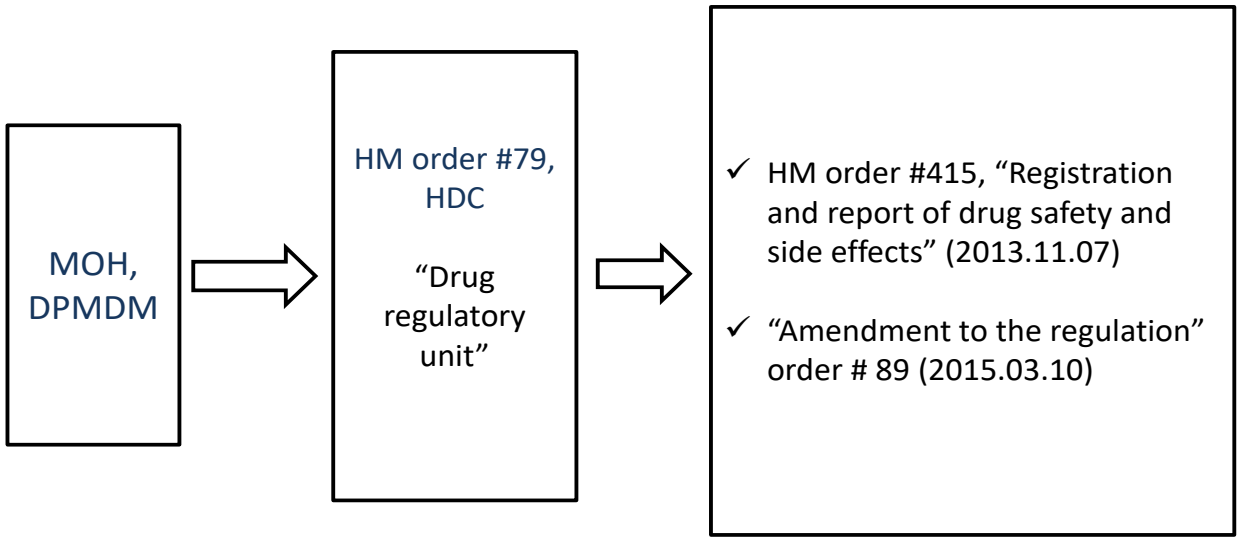
(5) Number of pharmaceutical

University graduates: 252 pharmacist/ 124 technicians (2016)

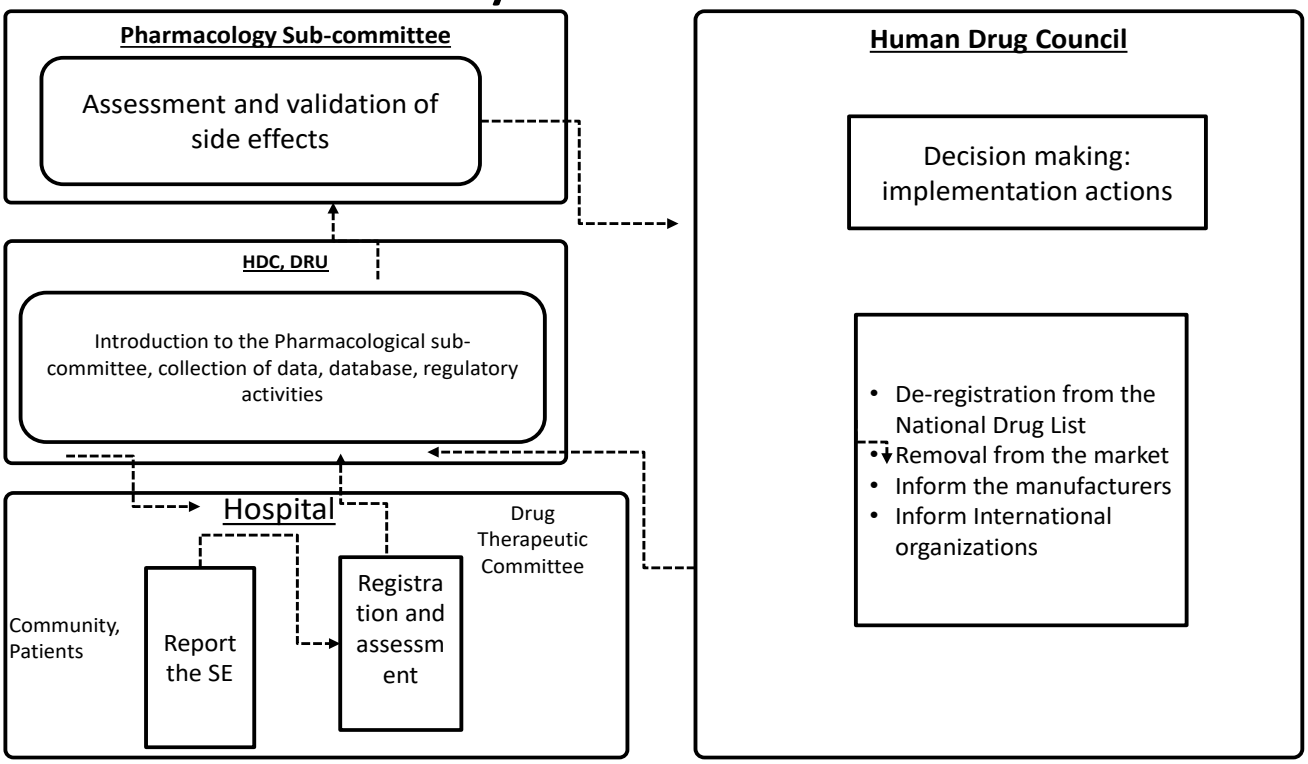
Alumni placement rate (%)

a. Hospital: 20%
b. Community pharmacy: 41%
c. Government organization: 7%
d. Enterprise: 25%
e. Others: 7%

Side effect report



Registration and reporting of drug safety and side effects



Country:
Mongolia
Organization:
Mongolian National University of Medical Sciences, Mongolia – Japan Teaching Hospital

Introduction of work

- Mongolian National University of Medical Sciences, Mongolia- Japan Teaching Hospital
- Pharmacy manager

Good Practice

- Implementation of the Antimicrobial stewardship programme at selected hospitals of Mongolia
- GMP, GLP implementation in Mongolia

Difficulties

- Resources
- Education
- Lack of political stability

My interests

- Drug regulation in Japan and other countries
- Hospital pharmacy in Japan and other countries
- Health Technology Assessment, assurance of quality, safe and cost-effective medicines

Roles of Regulatory Systems and Pharmacists

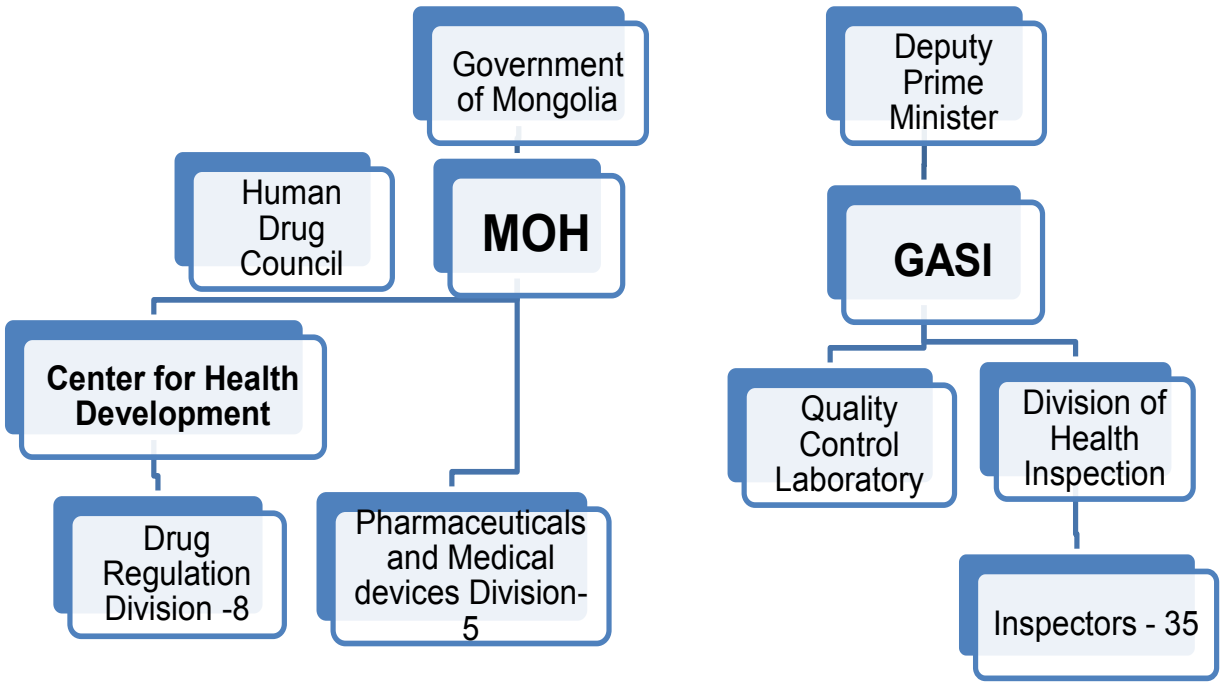
on Ensuring Proper Access to Quality Assured Medicines (JFY 2017)

Name: Tsetsensanaa Gungaajav

Country: Mongolia

Organization/Department/Division: Pharmaceutical and Medical Device Division, Center for Health Development, Ministry of Health of Mongolia

① Organizational chart



② Legislation on pharmaceutical administration

- National Level
  - State Policy on Health (2017) Parliament
  - National Medicines Policy (revised in 2014, integrated into newly adopted

National Health Policy in 2017) Parliament

- Law on Medicine and medical devices (revised 2010 and currently under revision) Parliament
- Law on Health Parliament
- Health ministerial orders Government

➢ Local Level

- Decree and orders of Governor and Head of the local Health Departments (within the implementation of national level legislation)

③ Regulatory services

➢ Pharmaceutical Manufacturing

- Licensing of pharmaceutical manufacturers is administered by the Ministry of Health according to Law on Licensing of Private Enterprises /2001/, Law on Medicine and Medical Devices /2010/, Law on Health /2011/, Regulation on Licensing of health activities /#145-2013/. There are 38 pharmaceutical manufacturers /2 of them complied with GMP/ as of 2016. GMP certificate is also issued by the Ministry of Health based on GMP inspector's conclusion.
- "General requirements on pharmaceutical manufacturing" MNS 5524:2014
- "General requirements on primary packaging materials for pharmaceuticals" MNS 6622:2016

➢ Drug import/export

- Wholesalers and importers who are permitted by the Ministry of Health are allowed to conduct import and export of pharmaceuticals and medical

devices. Center for Health Development issue import and export license for medicines and medical devices according to the "Regulation on import and export licensing" of 2011.

Resolution of the Government of Mongolia №73 of 2011 states that all pharmaceuticals and medical devices should be imported through 4 border points - Buyant-Ukhaa, Sukhbaatar, Altanbulag and Zamiin-Uud.

- Marketing Authorization
  - Mongolia started to register medicine to be marketed in 1994 in order to provide population and healthcare organizations with quality, safe and effective medicine. Medicine registration is regulated by the "Law on Medicine and Medical devices" /2010 and currently under revision/ and "Regulation on registration of pharmaceuticals and biologically active products" approved by the ministerial order №13 of 2015.
- Drug Distribution
  - Distribution of medicine conducted by manufacturers, wholesalers, pharmacies /community and hospital/.
  - Licensing of Medicine wholesalers /importers is administered by the Ministry of Health according to Law on Licensing of Private Enterprises /2001/, Law on Medicine and Medical Devices /2010/, Law on Health /2011/, Regulation on Licensing of health activities /#145-2013/. Private pharmacies act as community pharmacies, whereas hospital pharmacies are run by Government from the state budget. Licensing of private pharmacies conducted by the Local Health Departments.

- "General requirements on storage and distribution of medicine and medical devices" MNS 5530:2014
- "General requirements for pharmacy" MNS 5260:2015
- "General requirements on drug prescription and prescribing" MNS 5376:2014
- ADB project on "Improving access of affordable medicines in public hospital" is being implemented aiming to conduct centralized procurement in public hospitals, to establish outpatient pharmacy system in public hospital, to strengthen the regulatory activities

➢ Medicine Safety

- Strategy for strengthening the medicine safety monitoring and assessment system (Pharmacovigilance) /2014-2018/
- Regulation on registration and reporting of medicine adverse effects and safety issues /Ministerial order #415 of 2014/
- Regulation on Post Marketing Surveillance /Ministerial order #33 of 2014/
- Implementation of the Medicine safety information e-system is included in the Government Action Plan (2016-2019) which consists of four components, Registration and Import, Distribution and Logistics, E-prescription, Adverse Drug Reactions

➢ Relief System for Adverse Drug Reactions

- Medicine Regulatory Agency /Center for Health Development/, Human Drug Council-Pharmacology sub Council, Drug and Therapeutic Committees of hospitals, Suppliers /wholesalers, pharmacies/

- Strategy for strengthening the medicine safety monitoring and assessment system (Pharmacovigilance) /2014-2018/; Regulation on registration and reporting of medicine adverse effects and safety issues /Ministerial order #415 of 2014/
- To create database for drug adverse events, to detect serious adverse signal, to take appropriate regulatory action, to send signals to Vigiflow database of UMC, to provide healthcare organizations with information, to conduct trainings

④ Drug Pricing

- 50-90 percent of medicine included in the List of Discounted medicine are covered by Health Insurance Fund.
- Weak price regulation for Essential Medicine /price of drugs tends to grow depending on currency rate raises/
- 7th Essential Medicine List /8th is under revision/
- There is no formulated policy that regulates medicine's price

⑤ Statistic Data /year of 2016/

1.	Number of pharmacists	1586
2.	Number of pharmacy technicians	1790
3.	Number of GMP inspector (National and Local)	10
4.	Number of pharmaceutical manufacturers/manufacturing sites	38

5. Number of traditional medicine manufacturers/manufacturing sites 7
6. Number of pharmaceutical importers/wholesalers 210

⑦ Education and License of Pharmacists in your country

Mongolia already has its own education system for under- and postgraduate training in pharmaceutical field. Approximately, 8,4 percent of graduates of medical schools are pharmacists. As of 2016, there were total 1586 pharmacists 1790 pharmacy technicians who were working in public and private healthcare sectors.

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

- Primary education 5 years
- Secondary education 9 years
- High school education 12 years

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

a. College education /pharmacy-technician/: 3 years

b. University education /pharmacist/: 5 years

c. Professional education /postgraduate/: 6 months

– Clinical pharmacy
– Pharmaceutical analysis
– Pharmaceutical technology
– Pharmaceutical administration
– Pharmacist of Traditional medicine

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

Yes

Academic exams: All pharmacists should obtain a license in order to conduct pharmaceutical

activities. License is issued or extended every 5 years.

Clinical exams /to obtain professional grade/:

- Senior after 8 years
- Leader after 5 years of senior grade
- Advisor after 5 years of leader grade

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

Pharmacists should be involved in continuous training in order to collect 6 credits each year, totally 30 credits per 5 years to extend the license within the valid period of license. Otherwise, he/she is required to take license exam to obtain the license.

There is no mandatory subject of continuous training required to extend the license.

(5) Number of pharmaceutical university or college graduates:

There are 8 universities that have pharmaceutical faculty of which 1 is public university. Students can get college/diploma degree of pharmacy-technician in those universities completing 3 years of study.

On average, approximately 250 pharmacists and 300 pharmacy-technicians graduate pharmaceutical universities per year.

According to statistics of 2011-2015, the alumni's placement rate (%)

a.	University or college	2
b.	Research institute	2.4
c.	Government organizations, including government hospitals	9.8
d.	Enterprise, including wholesale companies and community pharmacies	59.2
e.	Representatives of foreign companies	1.6

f.	Not in pharmaceutical sector	5.7
g.	Continuously studying	6.5
h.	Indefinite or unemployed	12.65

PAPUA NEW GUINEA

Roles of Regulatory Systems and Pharmacists
on Ensuring Proper Access to Quality Assured Medicines （JFY 2017）

Name: Doreen Dalle

Country: Papua New Guinea

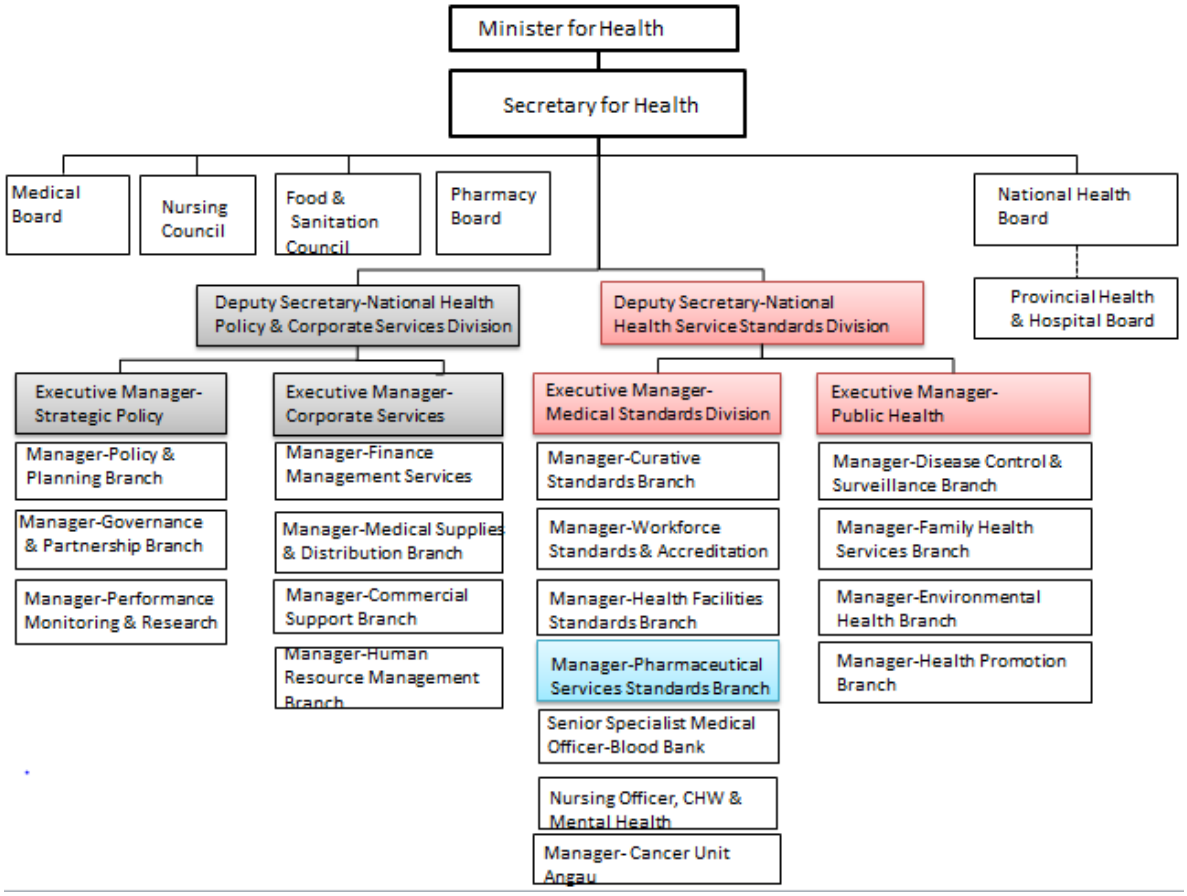
Organization/Department/Division: National Department of Health, Pharmaceutical Services Standard Branch

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.

Organizational Chart: The National Department of Health



The National Department of Health (NDoH) is the National Drug Regulatory Authority in Papua New Guinea. The Pharmaceutical Services Standard Branch within NDoH is responsible for regulatory functions in relation to pharmaceuticals and medical devices regulation. The Pharmaceutical Services Standard Branch executes these functions:

i. Product Registration- marketing authorization of pharmaceuticals, medical devices, cosmetics.

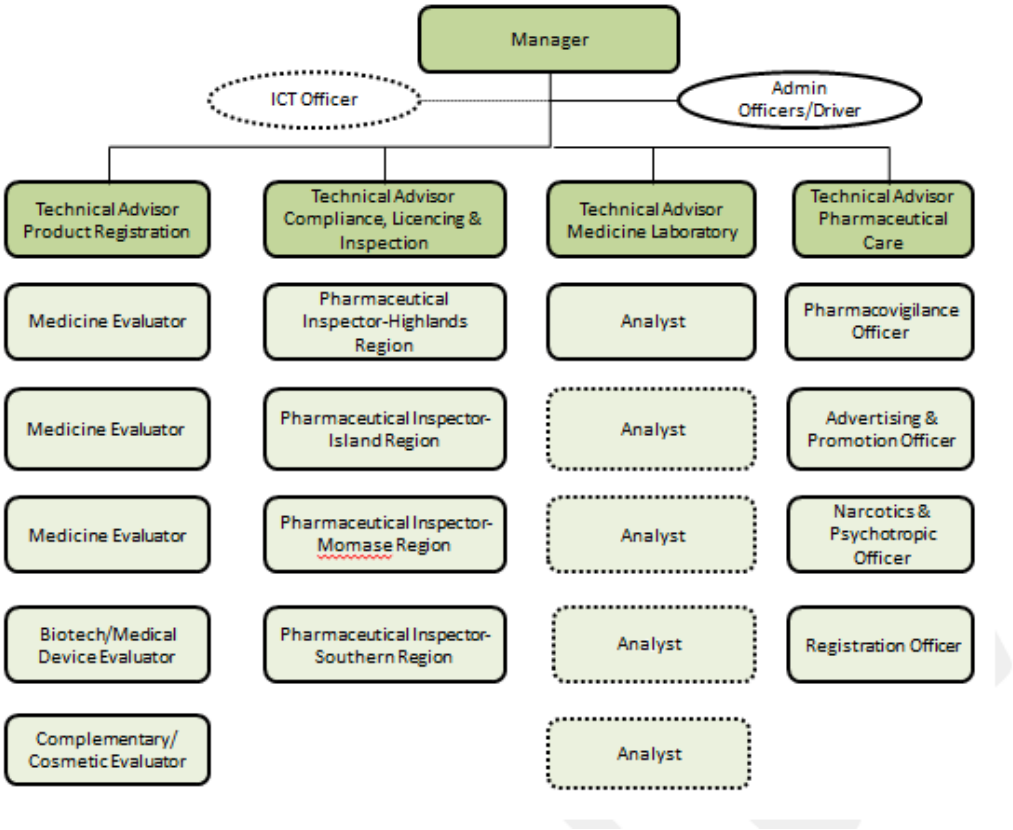
ii. Compliance, Licensing and Inspection-inspection of pharmaceutical facilities to ensure compliance to

regulation and standards. Process and inspects application for new establishments and renewals. Ensure compliance to the Medicines and Cosmetic Act, 1999 and post marketing monitoring.

iii. Pharmaceutical Care-responsible for pharmacovigilance and drug advertisement and promotion. The unit is also responsible for coordinating training of pharmacists and provides secretariat to Pharmacy Board of Papua New Guinea.

iv. Medicines Laboratory Unit-responsible for quality control testing of medicines. The National Department of Health is establishing a National Quality Control Laboratory and should be completed by the end of this year (2017).

Organizational Chart: The Pharmaceutical Services Standard Branch



NB: The Officers marked with dotted lines are contracted through health support grants that is WHO and DFAT grants. This is to support human resources in the regulatory branch.

※Hospital pharmacy only

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

② Legislation on pharmaceutical administration

−Please briefly bulletined major laws/acts

◆National Level

- Medicine & Cosmetic Act, 1999 administered by National Department of Health
- Dangerous Drug Act, 1952 administered by Narcotics Control Bureau

◆Local Level

- Medicine & Cosmetic Act, 1999 administered by National Department of Health
- _____ administered by _____

◆PIC/S

Yes _____ OR No √

If yes, joined when

③ Regulatory Services

−Please describe pharmaceutical regulatory services of your country in response to each topic described below.

−It is recommended to add supplemental information such as systems, regulations, responsible administrators, since you are expected to explain them to other participants.

◆Pharmaceutical Manufacturing

・Systems, Regulations, etc.

Papua New Guinea imports 100% of all pharmaceuticals and medical devices used in the country. However, the National Department of Health is implementing GMP clearance process to ensure manufacturers of pharmaceutical products coming in comply with GMP standards. The Department received technical assistance from Indonesia to assist in developing the Guideline and setting up the process.

- Medicines & Cosmetic Regulation, 2001 administered by National Department of Health
- _____ administered by _____

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

◆Drug Import/Export

・Systems, Regulations, etc.

・Good Distribution Practice administered by National Department of Health

・Good Pharmacy Practice administered by National Department of Health

Good Storage Practice administered by National Department of Health

◆Marketing Authorization

・Systems, Regulations, etc.

The National Department of Health is implementing marketing authorization process this year. Registration Guideline and Roadmap has been developed to guide the implementation process of this regulatory function.

・Good Review Practice administered by National Department of Health (just this year conducting training).

・Good Submission Practice administered by National Department of Health (conducting training for the applicants.

※Example: Good Quality Practice

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

・Systems, Regulations, etc.

・ Drug Procurement, Selection and Sale for the government facilities administered by National Department of Health, by Medical Supplies Procurement and Distribution Branch.

・Public Finance and Management Act, 1995administered by Department of Finance and Treasury.
Medicines & Cosmetic Act, 1999 administered by National Department of Health.

◆Medicine Safety (post-marketing)

・Systems, Regulations, etc.

The National Department of Health (NDoH) is slowly implementing this process. Currently, NDoH is advocating for all government hospitals to set up Medicines Therapeutic Committees (MTCs) within hospitals. The MTCs will consist of pharmacists of the hospitals pharmacies as well as other members within the hospital and the terms of reference include reporting of ADRs.

・ The National Department of Health is yet to develop Guidelines on this process.

・ 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.

Drug pricing is not regulated in Papua New Guinea. The price of other commodities is regulated by another government agency; Independent Consumer and Competition Commission (ICCC).

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 218 (2017)
2. Number of GMP inspector (National & Local) 1 (2017)
3. Number of pharmaceutical manufacturers / manufacturing sites 0 (2017)
4. Number of traditional medicine manufacturers / manufacturing sites 0 (2017)
5. Number of pharmaceutical importers 51 (2017)
6. Number of pharmaceutical wholesalers 56 (2017)

※Hospital pharmacy only

⑥ Information on your hospital pharmacy

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

a. Number of section chiefs:

b. Number of deputy chiefs:

c. Number of managers:

（２） Number of staff

a. Number of pharmacists:

b. Number of clinical pharmacists:

c. Number of technicians:

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

a. Oral medicine:

b. Injections:

c. Medicines for external use:

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

a. For inpatients:

b. For outpatients:

（５） Equipment of the pharmacy in your hospital

a. Does your hospital have a dispensary room?

If "Yes", how large is it?

Yes _____ ㎡ No

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

Yes / No

If "Yes", please describe it in detail

Detail: _____

c. Does the pharmacy have computers?

Yes / No

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

Purpose: _____

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

Yes / No

e. Do you prepare TPN (Total Parental Nutrition)

Yes / No

f. Can you use Internet at the pharmacy?

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

Yes / No

Purpose: _____

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

⑦ Education and License of Pharmacists in your country

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

Primary 8 years

Secondary 2 years

High school 2 years

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

University / college: 4 years

Professional education: 4 years

Practical training: 1 year

Duration of training by each facility: years

Hospital pharmacy: 16 weeks

Community pharmacy: 9 weeks

Pharmaceutical company: Not Applicable weeks

Others: 9 weeks Government Warehouse or Pharmaceutical Wholesaler's Warehouse and 8 weeks at Regulatory Services National Department of Health.

Age at graduation: 20 to 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.

Practical Training is mandatory to obtain a pharmacist's license.

The training period is one (1) year. Practical training consists of the training at the designated sites by which supervisors will sign a log book that is issued to intern pharmacists at the beginning of the training and provide a report whether or not the intern pharmacist completed the training satisfactorily. In addition, the intern pharmacist is required to do a research paper project on a subject topic in the area of pharmaceutical and submit the project to the Pharmacy Board of Papua New Guinea for assessment and approval of license.

* If practical training is optional, give the reasons.

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

There is national exam for training pharmacist and registered pharmacist (on-job pharmacists).

（５） Number of pharmaceutical university or college graduates:

More than 20 people (varies annually) / per year.

The alumni's placement rate (%)

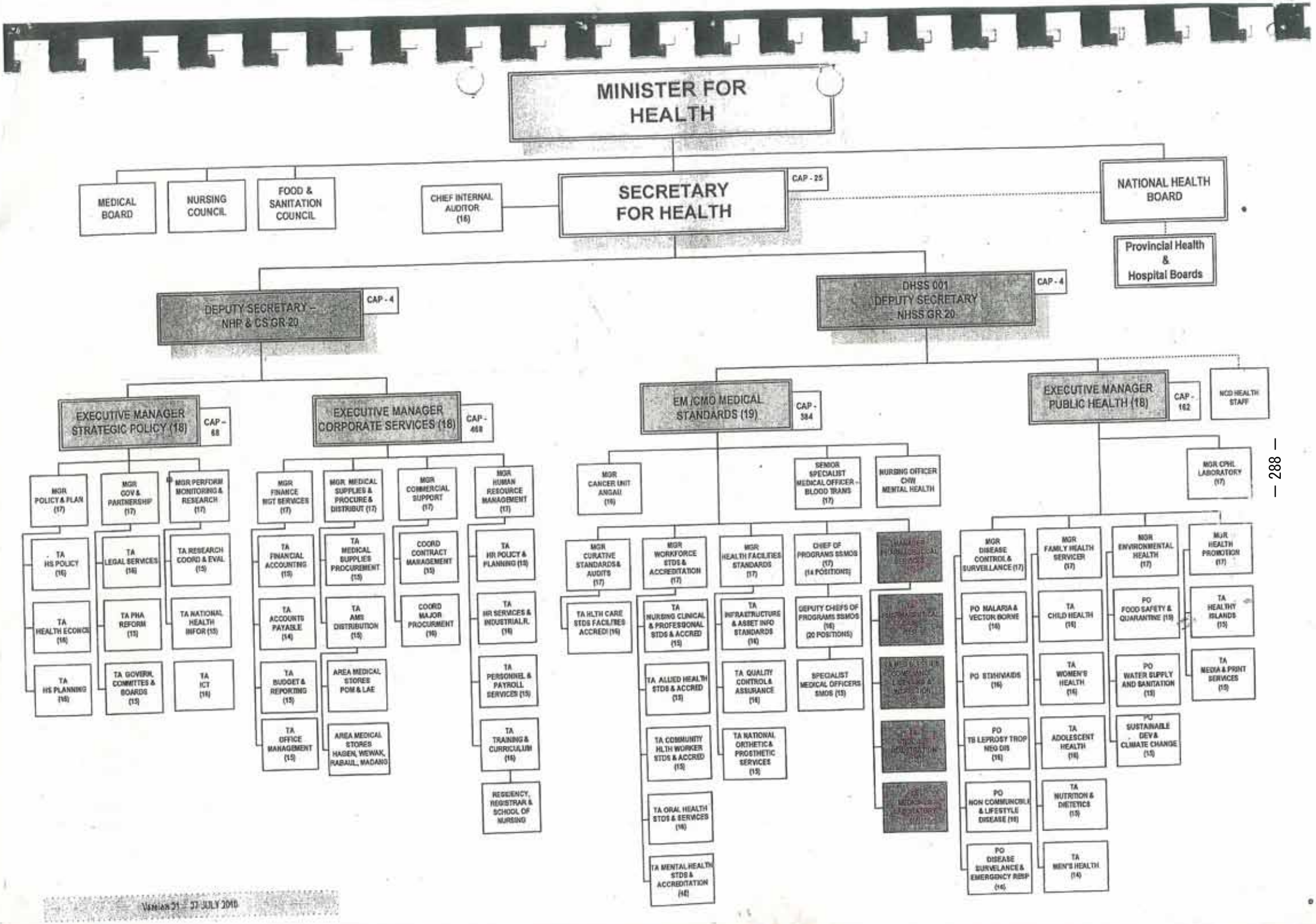
a. Hospital: 25 % estimated

b. Community Pharmacy: 50 % estimated
c. Government Organization: 10 % estimated
d. Enterprise: 10 % estimated
e. Others: 5 % (NGOs) estimated

⑧ **Side effect report**

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

The National Department of Health is implementing this process slowly. However, the current practice is whereby; upon the complain of a patient or medical officer or specialist due to a particular product issue, the pharmacist fills out the ADR Reporting Form and sends it to the National Department of Health immediately. The National Department of Health verifies this information by requesting a stop on the use of this product and investigates to see whether similar cases are experienced in other hospitals. Samples of this product are also requested for quality control testing to verify the content of the product. Upon confirmation of results by Quality Control Laboratory Unit, the particular batch of product may be recalled back to the Warehouses for disposal. The pharmaceutical importer and distributor that imported and distributed this product are also informed of this ADR report. Depending on the nature of the ADR penalties can be applied to the importer and distributor.


MINISTER FOR HEALTH
MEDICAL BOARD
NURSING COUNCIL
FOOD & SANITATION COUNCIL
CHIEF INTERNAL AUDITOR (16)
SECRETARY FOR HEALTH
CAP - 25
NATIONAL HEALTH BOARD
Provincial Health & Hospital Boards
DEPUTY SECRETARY – NHP & CS GR 20
CAP - 4
DHSS 001 DEPUTY SECRETARY NHSS GR 20
CAP - 4
EXECUTIVE MANAGER STRATEGIC POLICY (18)
CAP - 68
EXECUTIVE MANAGER CORPORATE SERVICES (18)
CAP - 468
EM /CMO MEDICAL STANDARDS (19)
CAP - 384
EXECUTIVE MANAGER PUBLIC HEALTH (18)
CAP - 162
NCD HEALTH STAFF
MGR POLICY & PLAN (17)
MGR GOV & PARTNERSHIP (17)
MGR PERFORM MONITORING & RESEARCH (17)
TA HS POLICY (16)
TA HEALTH ECONOMICS (16)
TA HS PLANNING (16)
TA LEGAL SERVICES (16)
TA PHA REFORM (15)
TA GOVERN. COMMITTEES & BOARDS (15)
TA RESEARCH COORD & EVAL (15)
TA NATIONAL HEALTH INFOR (15)
TA ICT (16)
MGR FINANCE MGT SERVICES (17)
MGR MEDICAL SUPPLIES & PROCURE & DISTRIBUT (17)
MGR COMMERCIAL SUPPORT (17)
MGR HUMAN RESOURCE MANAGEMENT (17)
TA FINANCIAL ACCOUNTING (15)
TA ACCOUNTS PAYABLE (14)
TA BUDGET & REPORTING (15)
TA OFFICE MANAGEMENT (15)
TA MEDICAL SUPPLIES PROCUREMENT (15)
TA AMS DISTRIBUTION (15)
AREA MEDICAL STORES POM & LAE
AREA MEDICAL STORES HAGEN, WEWAK, RABAUL, MADANG
COORD CONTRACT MANAGEMENT (15)
COORD MAJOR PROCUREMENT (16)
TA HR POLICY & PLANNING (15)
TA HR SERVICES & INDUSTRIAL R. (16)
TA PERSONNEL & PAYROLL SERVICES (15)
TA TRAINING & CURRICULUM (16)
RESIDENCY, REGISTRAR & SCHOOL OF NURSING
MGR CANCER UNIT ANGAU (16)
SENIOR SPECIALIST MEDICAL OFFICER - BLOOD TRANS (17)
NURSING OFFICER CHW MENTAL HEALTH
MGR CURATIVE STANDARDS & AUDITS (17)
TA HLTH CARE STDS FACILITIES ACCRED (16)
MGR WORKFORCE STDS & ACCREDITATION (17)
TA NURSING CLINICAL & PROFESSIONAL STDS & ACCRED (15)
TA ALLIED HEALTH STDS & ACCRED (15)
TA COMMUNITY HLTH WORKER STDS & ACCRED (15)
TA ORAL HEALTH STDS & SERVICES (16)
TA MENTAL HEALTH STDS & ACCREDITATION (16)
MGR HEALTH FACILITIES STANDARDS (17)
TA INFRASTRUCTURE & ASSET INFO STANDARDS (16)
TA QUALITY CONTROL & ASSURANCE (16)
TA NATIONAL ORTHETIC & PROSTHETIC SERVICES (15)
CHIEF OF PROGRAMS SSMOS (17) (14 POSITIONS)
DEPUTY CHIEFS OF PROGRAMS SSMOS (16) (20 POSITIONS)
SPECIALIST MEDICAL OFFICERS SMOS (15)
MGR DISEASE CONTROL & SURVEILLANCE (17)
PO MALARIA & VECTOR BORNE (16)
PO STI/HIV/AIDS (16)
PO TB LEPROSY TROP NEG DIS (16)
PO NON COMMUNICBLE & LIFESTYLE DISEASE (16)
PO DISEASE SURVELANCE & EMERGENCY RESP (16)
MGR FAMILY HEALTH SERVICES (17)
TA CHILD HEALTH (16)
TA WOMEN'S HEALTH (16)
TA ADOLESCENT HEALTH (16)
TA NUTRITION & DIETETICS (15)
TA MEN'S HEALTH (14)
MGR ENVIRONMENTAL HEALTH (17)
PO FOOD SAFETY & QUARANTINE (15)
PO WATER SUPPLY AND SANITATION (15)
PO SUSTAINABLE DEV & CLIMATE CHANGE (15)
MGR HEALTH PROMOTION (17)
TA HEALTHY ISLANDS (15)
TA MEDIA & PRINT SERVICES (15)
MGR CPHL LABORATORY (17)

and Pharmacists on Ensuring Proper Access to Quality Assured Medicines

Course No: J17-042016

Country: Papua New Guinea
Organisation: National Department of Health

Introduction

- National Department of Health is the National Drug Regulatory Authority in Papua New Guinea.
- Worked for National Department of Health in the Pharmaceutical Services Standard Branch.
- The Pharmaceutical Services Standard Branch performs or executes the regulatory functions of National Department of Health.
- The Pharmaceutical Services Standard Branch has 27 staffs of which 22 are pharmacists working in this section.
- The Pharmaceutical Services Standard Branch has 4 units:

i. *Product Registration*
ii. *Compliance, Inspection & Licensing*
iii. *Pharmaceutical Care*
iv. *Medicine Laboratory*

- My Job Tenure:

✓ *Worked with Product Registration Unit as a Medicine Evaluator.*
✓ *Assessment of product registration dossiers mostly generics medicines submitted to National Department of Health for product registration (marketing authorization).*

Roles and Position of Pharmacists in Papua New Guinea

General duties of a pharmacist (Medicines & Cosmetic Regulation 2001)

1. A pharmacist who carries on a business as such or who is in charge of dispensary shall:
(a). Ensure that the premises in which the business is carried on or dispensary, is adequately locked and otherwise secured at all times, when the business or dispensary is not normally open to the public; and
(b). Maintain the business or dispensary in a clean, hygienic and orderly condition; and
(c.) Provide and maintain in good order and condition such equipment, necessary for full and proper conduct of the business or the dispensary; and
(d) Provide and maintain adequate stocks of all medicinal products as are reasonably required for full and proper practice of the profession and as maybe prescribed by the medical practitioner, veterinary surgeon or a dentist; and
(e) Keep prominently displayed at all times at the premises so as to be readily visible to the public, a notice a notice setting out the normal trading hours of the business or dispensary; and
(f) Have legibly printed or written, and continually so maintained in a conspicuous place on the front of the business premises; Name, Professional qualification and "Pharmacist in charge" and
(e) Provide advice on rational drug use to the public and medical profession
(F) Maintain professional knowledge in order to provide quality pharmaceutical care and services; and
(g)At all times have regard to laws and regulations applying to medicinal products and pharmaceutical practices and maintain a high standard of professional conduct.

Roles and Position of Pharmacists in Papua New Guinea

- Pharmacist profession is still young in the country.
- Generally pharmacists are now working in these areas:

i. Public and private Hospitals dispensary
ii. Retail shops outlets and pharmaceutical establishments
iii. Warehouses
iv. Regulatory at the national level
v. Procurement of pharmaceuticals at the national level
vi. Non-government organizations (Churches and humanitarian organizations)

- Generally most pharmacist practicing in the dispensary are involved in dispensing practices.
- Workload is often high and often pharmacists are so busy that proper drug counselling is often lacking.
- Pharmacist to Patient Ratio on average is 1:250.
- NDoH has captured in its Strategic Implementation Plan for hospitals to create more positions for pharmacists with improved employment conditions.
- Continuous training for registered pharmacist is also lacking as employers often don't support their staff as it is deem unnecessary. Pharmacist are often advised to resign if they want to pursue training.
- Although most pharmacists maintain a high standard in their practice and code of conduct, there is still some pharmacists who have less value in their profession.

Good Practices

❖ **Good Practices in relation to product registration.**

- ✓ Developing guidelines and Standard Operating Procedures (SOPs) has prove to be a good practice in this process as it guides NDoH as well as those involved (pharmaceutical companies) on this process.
- ✓ Developing a roadmap is very helpful-how the process will be implemented phase by phase.
- ✓ Continuous meeting with applicants helps them to understand this process and also assist NDoH to understand their challenges and how both parties can worked together to implement this process.
- ✓ Keeping the higher management of NDoH inform of the process the pharmaceutical Services Standard Branch is carrying out is important for their support in terms of funding and training of the staffs.
- ✓ Strategic Planning in relation to process, resources and tools is vital for a successful outcome for Papua New Guinea.

Difficulties & Lesson Learnt from Past Experiences

❖ **Setting up a database system for Product Registration as well as other regulatory functions is still a challenge for National Department of Health.**

❖ **Limited resources is a big challenge.**

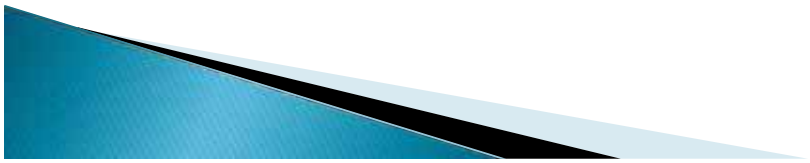
❖ **Making a good review or sound scientific judgement on the dossier of generic medicine that has not been registered by another regulatory authority is still a challenge for the Product Registration Unit.**

❖ **Implementing a effective and efficient regulatory system is still a major challenge for Papua New Guinea.**

My interest and what I hope to learn:

- Marketing authorisation of generic medicines and Japanese system of drug approval.
- GMP process and clearance of manufacturers .
- Good Distribution Practices of Japan
- Clinical trial clearance process and systems of Japan.
- Post marketing measures of drugs on the market.

With limited resources and capacity, what can be done and how best it can be done to ensure access to quality assured medicines for Papua New Guineans .



Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

MYANMAR

Roles of Regulatory Systems and Pharmacists
on Ensuring Proper Access to Quality Assured Medicines （JFY 2017）

Country: Republic of the Union of Myanmar
Organization/Department/Division: Ministry of Health and Sports/ Department of Food and Drug Administration/Drug Control Division

Ministry of Health and Sports (MOHS)

Ministry of Health and Sports is the main organization which is taking responsibility for providing comprehensive health care services covering activities for promoting health, preventing diseases, providing effective treatment and rehabilitation to raise the health status of the people. The head of the Ministry is the Union Minister. There are altogether seven departments under Ministry of Health and Sports and each department is headed by Director General. They are-

1. Department of Medical Services
2. Department of Public Health
3. Department of Medical Research
4. Department of Health Professional Resources Development and Management
5. Department of Traditional Medicine
6. Department of Food and Drug Administration
7. Department of Sports and Physical Education

The objectives of the Ministry of Health and Sports are

1. To enable every citizen to attain full life expectancy and enjoy longevity of life
2. To ensure that every citizen is free from diseases.

To realize these objectives, all health activities are implemented in conformity with the following strategies:

1. Widespread disseminations of health information and education to reach the rural areas.
2. Enhancing disease prevention activities
3. Providing effective treatment of prevailing diseases.

Department of Food and Drug Administration (FDA)

The Food and Drug Administration was established in 1995 as one of the divisions under the Department of Health, Ministry of Health. The Food and Drug Administration was upgraded to a separate department in August 2013 as Department of Food and Drug Administration. It was extended to States/ Regional levels and border areas such as Muse, Tachileik, Tamu, Myawaddy etc. It is further extended to district levels in 2017. The head office is situated in Nay Pyi Taw, the capital city of Myanmar.

The aim of the department is to ensure the safety and quality of Food, Drugs, Medical Devices and Cosmetics in the country. The department is headed by Director General and constitutes six divisions as follows;

1. Administrative Division
2. Planning and Auditing Division
3. Drug Control Division
4. Food Control Division
5. Medical Devices and Cosmetic Control Division
6. Laboratory Division

Organizational Chart

The organization chart of the Department of Food and Drug Administration is attached in Annex-1.

Pharmaceutical Administration in Myanmar

Pharmaceutical administration in Myanmar is mainly done by Drug Control Division of FDA. It controls both pre market and post market activities. The main functions are;

- Marketing authorization for new products, renewal registration and variation of existing products
- Good Manufacturing Practice inspection and licensing of drug manufacturers
- Good Storage and Distribution Practice inspection of importers and distributers
- Random sampling and testing
- Adverse Drug Reaction Monitoring
- Training and Health Education

There are about 15000 drugs are registered in Myanmar. About 95% of them are imported drugs.The documentations required for product registration are according to ASEAN Common Technical Dossier (ACTD) format which is harmonized among ASEAN member countries. The quality control tests for registration samples are done at Laboratory Division of FDA. The three main laboratories of FDA are situated in Nay Pyi Taw, Yangon and Mandalay. The Pharmaceutical Chemistry Laboratory in Nay Pyi Taw has achieved ISO/IEC 17025: 2005 Accreditation Certificate in December, 2016. The approval or rejection of product registration is decided by Drug Advisory Committee (DAC).

FDA issues Drug RegistrationCertificate (DRC) for product registration, Drug Manufacturing Licence for local drug manufacturers and Drug Importation Approval Certificate (DIAC) for drug importers.The Post Market Surveillance (PMS) activities are regularly done by not only in head office (Central) but also in States/ Regional levels and District levels. FDA controls and takes the action on illegal drug importers, manufacturers, distributors and drug sellers. FDA also notifies the counterfeit, substandard, falsified and unregistered drugs to the public and health care professionals through the media and FDA website (http://www.fdamyanmar.gov.mm).

The States/ Regional levels and District levels of FDA inspect the pharmacies in their respective areas to comply with Good Pharmacy Practice. They also do the regular PMS activities according to their action plans and health advocacy to the public. The States/ Regional FDA and border FDA perform the screening test for some medicines with mini laboratory facilities in order to detect the substandard and counterfeit drugs. The suspected drugs are sent to the head office for confirmatory test. Mini laboratory facilities have also been set up at FDA offices in 12 States/Regions and border areas. Mini laboratories can perform identification and screening test for about 60 items of drugs including anti‐malaria, anti‐tuberculosis, anti‐microbial and some analgesics.

The border FDA checks the drugs at border areas coming from neighboring countries in coordination with Custom Department.

FDA also closely collaborates and cooperates with other relevant agencies such as Department of Trade, Myanmar Police Force, Custom Department and City Development Committee to ensure the quality, efficacy and safety of drugs which could be consumed in confidence by the public.

Legislation on pharmaceutical administration

◆National Level

・ National Drug Law (1992), updated in 2014 administered by Ministry of Health and Sports

◆Local Level

・ administered by

◆PIC/S

~~Yes~~ OR ☑No

Regulatory Services

◆Pharmaceutical Manufacturing

Pharmaceutical Manufacturing is regulated by Ministry of Health's Notification 4/93. The inspection team including officials from Central and States/ Regional FDA and members of respective Food and Drug Supervisory Committee inspect the manufacturing sites of local pharmaceutical manufacturers in order to comply with Good Manufacturing Practice (GMP). For oversea inspection, FDA only does for special cases such as anti-malarial drug manufacturers and only for the case requested by manufacturers. FDA issues Drug Manufacturing Licence for local pharmaceutical manufacturers that conform to GMP with the validity of three years.

◆Drug Import/Export

Drug importation is regulated by Ministry of Health's Notification 5/93. When the drug importer applies the importation for registered drugs in Myanmar, FDA inspects this importer's warehouse to comply with Good Storage Practice (GSP) and Good Distribution Practice (GDP) and issues Drug Importation Approval Certificate (DIAC) with the validity of three years.

◆Marketing Authorization

The product registration is regulated by Ministry of Health's Notification 3/93. The applicant has to submit the pharmaceutical dossiers in line with ASEAN Common Technical Dossier (ACTD) format and samples. After the decision of Drug Advisory Committee (DAC) with the complete set of

documentation and good quality control test result, FDA issues Drug Registration Certificate (DRC) for approved product with the validity of five years.

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

The distributors must get the authorized letter from marketing authorization holder and apply the wholesale licence for distribution that concern for private. For public sector, the distribution system is concerned with Department of Medical Services.

◆Medicine Safety (Post-marketing)

Post Marketing Surveillance activities are regularly done by Central, States/ Regional and District FDA.

◆Relief System for Adverse Drug Reactions

Adverse Drug Reaction (ADR) Reporting form is uploaded on FDA web page.There is an ADR reviewing committee in Department of Medical Services. The Department of Food and Drug Administration is one of the members of this committee.

Drug Pricing

The drug pricing is not controlled by Ministry of Health and Sports. The Ministry of Commerce checks the difference of price between import drug price and drug price in market for both wholesales and retails.

Statistic Data

1.	Number of pharmacists	3810	(2017)
	(Ph.D– 2, M. Pharm – 148, B. Pharm –3660)		
2.	Number of GMP inspector (National & Local)	15	(2016)
3.	Number of pharmaceutical manufacturers / manufacturing sites	9	(2016)
4.	Number of traditional medicine manufacturers / manufacturing sites	-	
5.	Number of pharmaceutical importers	214	(2016)
6.	Number of pharmaceutical wholesalers	> 600	(2016)

Education and License of Pharmacists in your country

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

Primary 5 years
Secondary 4 years
High school 2 years

（２）Number of years / weeks in the following categories during university or college
University / college: 4 years
Professional education: 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: about 22 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.
NA

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

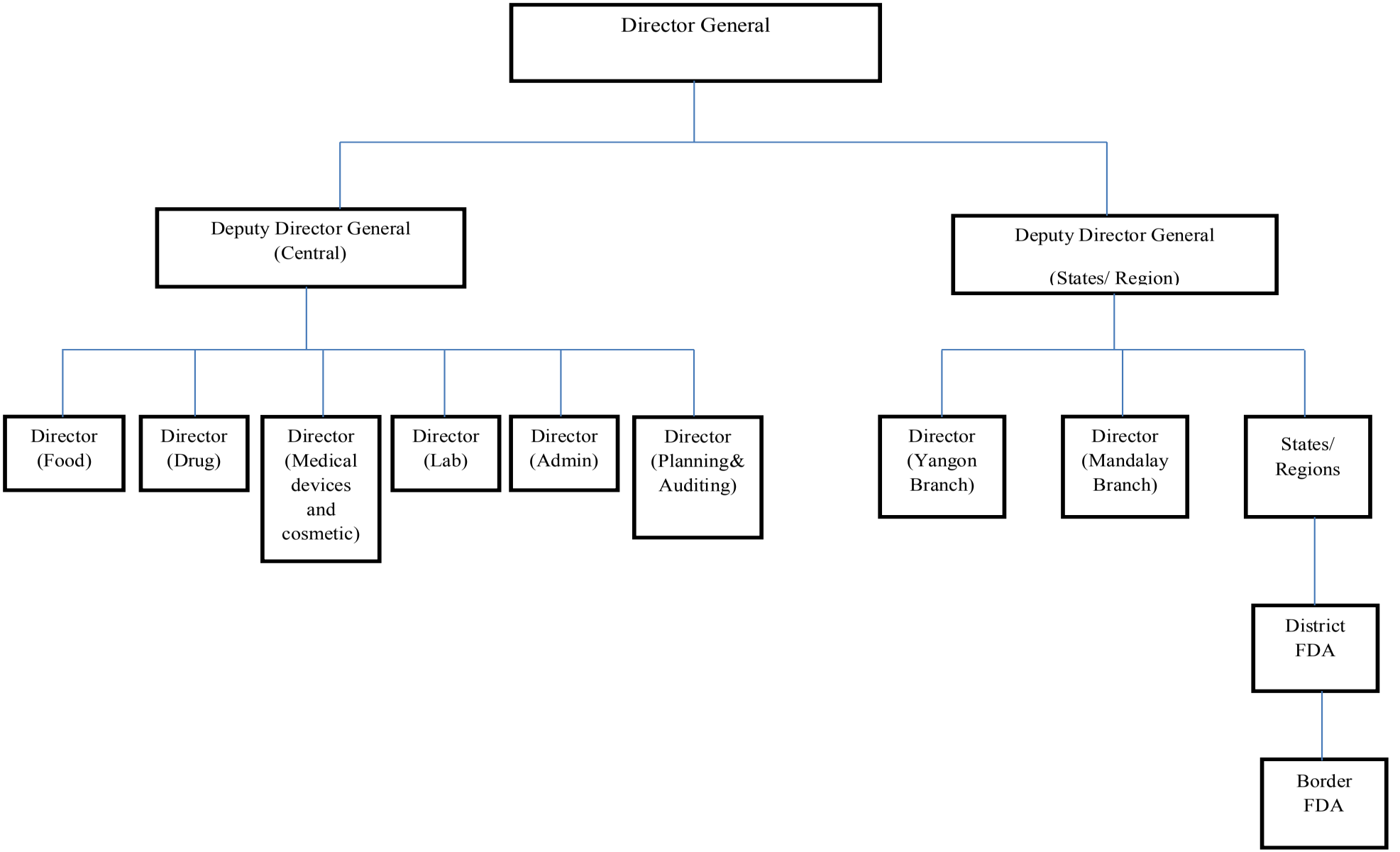
（５）Number of pharmaceutical university or college graduates:
about 250/ per year

The alumni's placement rate (%)
a. Hospital: 10%
b. Community Pharmacy: 5%
c. Government Organization: 30%
d. Enterprise: 40%
e. Others: 15%

Side effect report

Adverse Drug Reaction (ADR) form is uploaded on FDA webpage. The serious cases can be directly reported to Director General of FDA by filling in ADR form by any health care professionals.

Department of Food and Drug Administration - Organization Chart



Republic of the Union of Myanmar
Ministry of Health and Sports
Department of Food and Drug Administration

Pharmaceutical Administration

Ministry of Health and Sports (MOHS)

- Main organization responsible for the health of the people, headed by Union Minister and constitutes seven departments

  - Department of Medical Services
  - Department of Public Health
  - Department of Medical Research
  - Department of Health Professional Resources Development and Management
  - Department of Traditional Medicine
  - Department of Food and Drug Administration
  - Department of Sports and Physical Education

2

FDA, Myanmar

- Established Food and Drug Administration (FDA) in January, 1995 under Department of Health, Ministry of Health
- Became a separate department in August, 2013 as Department of Food and Drug Administration
- Extended to States/ Regional levels and then border areas in 2014
- Further extended to District levels in 2017

➢ Aim - To ensure the safety and quality of Food, Drugs, Medical Devices and Cosmetics in the country

3

Control of Pharmaceuticals

➢ Marketing authorization for new products, renewal registration and variation of existing products

➢ Good Manufacturing Practice inspection and licensing of drug manufacturers

➢ Good Storage and Distribution Practice inspection of importers and distributers

➢ Random sampling and testing

➢ Adverse Drug Reaction Monitoring

➢ Training and Health Education

4

5

Laws and Regulations in Myanmar

To protect the public from unsafe drugs-

- 1972 - Public Health Law
- 1992 October - National Drug Law , Amendment of NDL (April, 2014)
- 1993 August - Notifications for Registration, Manufacturing, Importation, Sales and distribution, Labeling and advertisement
- 2003 March - Order Relating to Control of Narcotic Drugs and Psychotropic substances

6

Roles of Pharmacists in Myanmar

- Regulatory
- Quality Control and Quality Assurance
- Research
- Industry
- Hospital
- Academic
- Pharmaceutical companies

7

Good Practices and Achievements

- Good Manufacturing Practice (GMP), Good Storage Practice (GSP), Good Distribution Practice (GDP) support quality assurance system
- Regulation of supply chain helps to access quality assured medicines
- By coordination and collaboration with Custom Department, Department of Trade, Consumer Protection Association and Stakes holders to eliminate illegal drugs
- By coordination with Interpol and Myanmar Police Force to combat the illegal pharmaceuticals trade through border areas

8

Ongoing projects and Need to be strengthened

- Plan to organize the National workshop for counterfeit medicines
- To update pharmacovigilance guideline
- Need to upgrade local manufacturers to comply with GMP
- Need to control online selling such as food supplements etc. and to educate the public
- Try to improve pharmacies in hard to reach areas and non peace areas

9

My interest

- Pharmaceutical regulatory system in Japan
- Countermeasures against counterfeit medicines
- Site visit to the whole pharmaceutical supply chain

10

Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

INDONESIA

BADAN POM

Drug Regulatory Authority

Badan Pengawas Obat dan Makanan
(Badan POM)

(National Agency Of Drug and Food Control – NADFC)

Republic of Indonesia

Japan, June
2017

Vision and Mission

BADAN POM RI

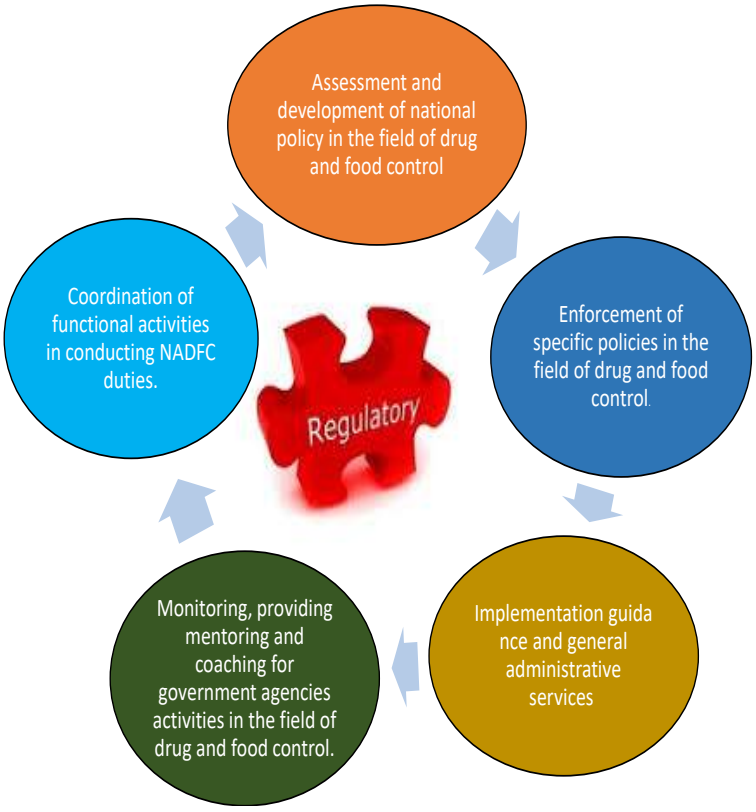
VISION

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

MISSION

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

REGULATORY FUNCTION



Organization and Department

Directorate of Distribution Control of Therapeutic Products, NADFC, consists of 3 Sub Directorates:

1. Surveillance and Risk Analysis of Therapeutic Products
2. Promotion and Labelling Control of Therapeutic Products

3. Inspection and Certification of Distribution Facilities

- Conducting audit and investigation in Distribution and Health Facillities,
- Evaluating inspection's result and taking a follow up action of it
- Evaluating CAPA submitted by the Facillities
- Evaluating inspection's result conducted by NADFC Province via online reporting system
- Providing Quarter report of Distribution and Health Facilities Control
- Conducting Surveillance Audit for Certificate Drug Wholeseller
- Making tools or guidance of Good Distribution Product

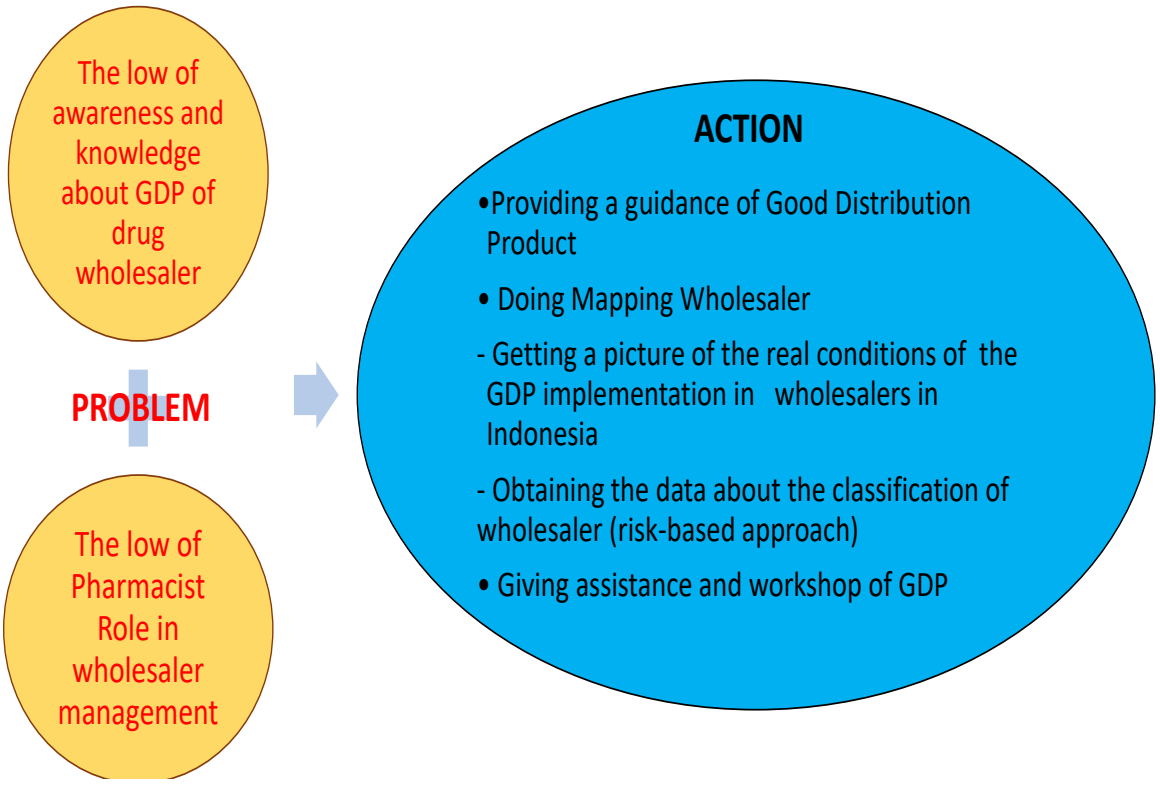
Job Tenure

- Joined with NADFC since 2013
- Placed in Directorate of Distribution Control of Therapeutic Products
- General Staff at Directorate of Distribution Control of Therapeutic Products (2013-2014)
- Inspection Staff of Distribution Control of Therapeutic Products
- Drug and food inspector-first level (2015-now)

Roles and Position of Pharmacists

1. Ensuring and maintaining the implementation of Quality Management System
2. Focusing on all activities of their duty and within their authority
3. Supervising the training program for personnel related with distribution activities
4. Supervising the product's recall and the product's complaint
5. Doing the qualification of customer and suppliers
6. Having a role in Contract Cooperation
7. Conducting self inspection

The Implementation of Good Distribution Practices



IMPLEMENTATION

ON GOING PROJECT

- Routine inspection to Wholesaler
- GDP Certification (Mandatory Planning)
  - Ensuring the consistency of GDP implementation
  - Ensuring the consistency of medicines quality according to approved specifications.
- Conducting Surveillance Audit
- Conducting GDP Technical Meeting for NADFC Province
- Providing Guidance of Follow up Action
- Conducting Desk CAPA Evaluation

ACHIEVEMENT

- Improvement wholesaler's awareness and knowledge in GDP
- The increase of role and responsibility of Pharmacists
- The increase of drug safety
- Ensuring drug quality distributed in society
- The increase of GDP compliance by wholesaler

Current Issue and Challenge

Current Issue

The low of role and lack of competency of Pharmacists in health Facilities

The increase of the counterfeit drug distributed in our society

The lack of coordination among NADFC and other related sectors, primarily in giving authorization and revoking the licence

Challenge

- The breaking out of Drug selling via online
- The low of punishment given to businessmen
- The low of authority to follow up the drug inspection result

Interest and Expectation

a. Acquiring information about:

•The regulatory management in Japan for access to quality medicines including the inspection system

•The actual operations both in govermental and medical institutions for ensuring quality of medicines

•Lectures on countermeasures against counterfeit medicines

b. Doing observation at pharmaceutical company and pharmacy

Through this programme, I hope to be able to:

-improve my knowledge in roles of Regulatory System and Pharmacists in Ensuring Proper Access to Quality Assured Medicines.

-Handle and take countermeasures against counterfeit medicines

Republic of Indonesia
National Agency of Drug and Food Control

独立行政法人 国際協力機構

INTRODUCTION OF THE WORK

ORGANIZATION

National Agency of Drug and Food Control in Surabaya

DEPARTMENT

Certification and Customer Information Service

JOB TENURE

2,5 years in current position; 13,5 years overall

REGULATORY SERVICES

- Drafting drug and food control plans and programs.
- Implementing laboratory examination, testing and assessing quality of therapeutic products, narcotics, psychotropic, addictive substances, traditional medicines, cosmetics, complementary products, food and hazardous substances.
- Implementing laboratory examination, testing and assessment of the microbiological quality of the product.
- Implementing local inspection, sampling and inspecting production facilities and distribution.

REGULATORY SERVICES (continued)

- Investigating crime cases in the field of Drug and Food control.
- Implementing certification of products, production and distribution facilities imposed by the Head of NADFC
- Implementing consumer information services.
- Evaluating and drafting Drug and Food testing report.
- Implementing administrative affairs.
- Implementing other duties in the respective field, set by the Head of NADFC.

ROLES OF PHARMACIST IN INDONESIA

- Management of Pharmaceutical Supplies (Supervisor, Manager, Director)
- Pharmaceutical Services (Pharmacist in Charge)
- Development of Drug, Drug substance and Traditional Medicine (Analyst, Supervisor, Manager, Director)

GOOD PRACTICES

Almost no noticeable achievement in drug monitoring

DIFFICULTIES/LESSONS LEARNED FROM PAST EXPERIENCE

- The challenges from the health programme (neglected tropical diseases, contraceptive drugs), new technology medication (NCE, biosimilar, blood product, stem cell) or drugs on un-communicable diseases (cancer, diabetes mellitus, hipertension)
- Drugs appear to be safe and well-tolerated, but the safety in the 'real world' is unclear (the fact about chronically/repeatedly use of drugs, and drug interaction)

DIFFICULTIES/LESSONS LEARNED FROM PAST EXPERIENCE (CONTINUED)

- Drug safety in vulnerable groups is unknown (pregnant women, breastfeeding mother, elderly and young children)
- Patient genotype, phenotype, social and economic conditions are markedly distinct, so we can't extrapolate data from developed countries
- Numbers of counterfeit drugs

INTERESTS

1. Detecting drug counterfeits
2. Pharmacovigilance reporting
3. Pharmaceutical care

Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

SRI LANKA

Roles of Regulatory Systems and Pharmacists on Ensuring Proper Access to Quality Assured Medicines (JFY 2017)

Country: Sri Lanka

Organization: National Medicines Regulatory Authority

1. Overview of country and organization

Sri Lanka is a beautiful island around 65,000 sq. km in the Indian Ocean, also famous as 'Isle of Serendipity' and 'Ceylon' in all over the world in the Past. It lies between northern latitudes 5^0 55' and 9^0 50' and eastern longitudes 79^0 42' and 81^0 52'.Travellers from deferent countries attracted to my mother land due to the natural beauty of the country given by sea beaches, nature reserves, wild life and variety in climate, landscape and rich cultural heritage. As such Sri Lanka introduce as a 'Pearl of the Indian Ocean".

Democratic Socialist Republic of Sri Lanka has a parliamentary democratic system of government in which, legislative powers are vested in parliament. The executive authority is exercised by a Cabinet of Ministers, presided over by an Executive President. The President and Members of the Parliament are elected directly by the people.

Sri Lanka's population is about 21 million and population growth is about 1.2% per year according to the government estimation.

Sri Lanka is Multinational and Multicultural country. The largest ethnic groups in Sri Lanka are the Sinhalese that around for 72% and others included Hindus, Muslims, Christians & other minor communities. As such three languages are used mainly Sinhala, Tamil and English. Buddhism is the dominant creed of the largest ethnic group. Other religions like Hindu, Islam & Christians also available. Although all Sri Lankans are live peacefully in the country.

Agricultural side is highly developed in Sri Lanka. The chief crop is rice with which the country is almost self-sufficient. Tea, rubber and coconut are also important agricultural crops, with tea being a major foreign exchange earner well known as “Ceylon tea”. In addition, other crops of importance are cocoa and spices such as cinnamon, cardamom, nutmeg, pepper and cloves. Fruit and vegetables, native to both tropical and temperate regions, grow well in Sri Lanka.

The last three decades have seen tourism emerge as an important industry. There has also been a rapid growth in manufacturing industries, which offer a wide range of export goods such as petroleum products, leather goods, ready-made garments and electronic equipment in minor level.

Health Care System

Sri Lanka is a country known to the world for providing cost effective healthcare free of direct cost to the patient. As such Gross national income per capita (PPP international $, 2014) was 10270. Total expenditure on health per capita (Intl $, 2014) was 308 and the total expenditure on health as percentage of gross Domestic product (GDP) (2014) around 3.

The maternal mortality ratio, neonatal mortality rate, life expectancy at birth and many more health indicators are comparable with those of the developed world. As per the Annual health bulletin 2014, life expectancy among male and female 72.0 and 78.6 years respectively, According to 2014 statistics from registrar general department, the midyear population the crude birth rate was 16.9/1000 population and crude death rate was 6.2/1000 population (5). Based on 2014 data, maternal mortality ratio per 100,000 live births was 19.3.

As per the, update data there were 1085 medical institutions with inpatient facilities. There were included 20 teaching Hospitals 21 DHPs 487 Primary Health Care Unit and 337 Medical Officer of Health (MOH) areas in Sri Lanka. The number of beds in the hospitals increased to 76,781 in 2014 and the hospital beds per 1,000 populations is 3.7.

The total number of medical officers was 15,910 in 2012. Accordingly, medical officers per 100,000 populations were 78. The total numbers of nurses were 36,486 in 2012. This was 180 nurses per 100,000 populations. A shortage of qualified paramedical staff, such as pharmacists, medical laboratory technicians, radiographers, physiotherapists and electrocardiogram (ECG) technicians still exists.

Total pharmacists employed at public hospitals by 2012 was around 1200, that is 6.7 pharmacists per 100, 000 population . Almost all of them were with diploma in Pharmacy qualification.

Although these Sri Lankan indicators are the best in the region, much has to be done to ensure quality and safety in the delivery of healthcare, especially in hospitals

2. Organizational chart of Ministry of Health, Nutrition and Indigenous Medicine

Ministry of Health Nutrition and Indigenous Medicine appointed by the President and govern by the Health Minister who is responsible for the vital heath care system of the country. Organization chat is complex attached with Annexure 01.

In order to ensure proper drug management system of the state sector an organizational frame work exists within the Ministry of Health. However Organization system related to the pharmaceutical administration can be summarized as follows:

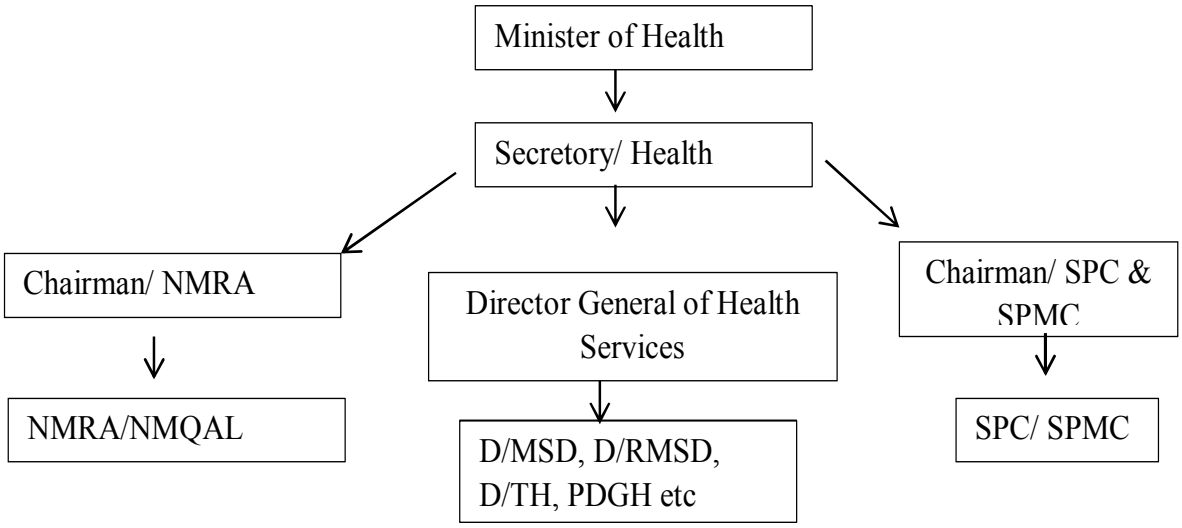


Figure 1: Organizational chart of Pharmaceutical administration

- Minister of Health- responsible Policy making, such as introducing necessary amendments to the act and making regulations appointed by the President.
- Secretory /Health- Responsible for all administration and support to the Minister.
- SPMC- Procurement of Pharmaceuticals to the Public sector
- SPM- Drug manufacturing by state sector
- NMRA; Regulation of Pharmaceuticals
- NMQAL: Quality Assurance of Pharmaceuticals
- DGHS,D/MSD, D/RMSD- Distribution of Pharmaceutical locally through state Hospitals.

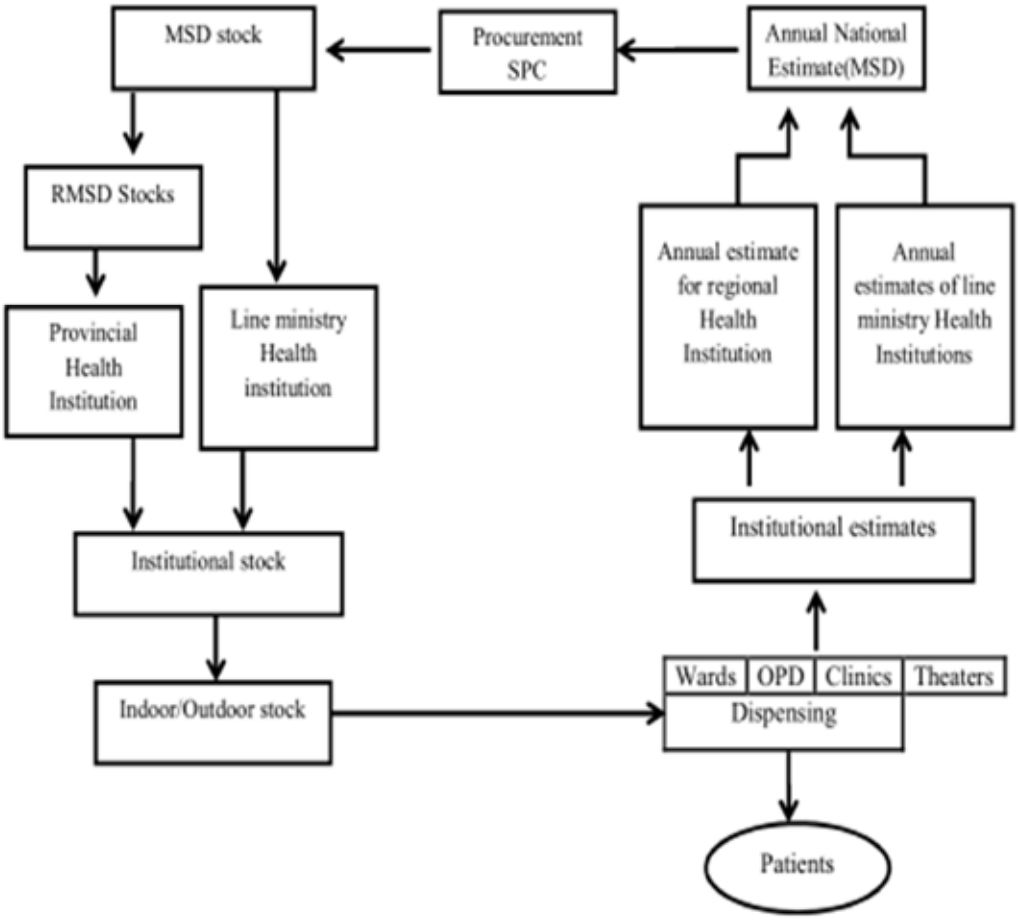


Figure 2: Procurement & distribution of Pharmaceuticals at state sector

2. Legislation Govern the Pharmaceutical Administration in Sri Lanka.

I. NMRA Act

National Medicines Regulatory Authority Act no.5 of 2015 and regulations made under the provisions of this act is responsible for the regulation and control of registration, licensing, manufacture importation and all other aspects pertaining to medicines, medical devices, and borderline products and conducting of clinical trials in a manner compatible with national medicines policy. This act was come into operation from 19th March 2015.

The Act controls:
Registration, Manufacture, Importation, Transportation, Sale (Retail and Wholesale) & Distributions, Labeling & Advertising, Testing, Disposal of outdated or spoilt drugs Medicines, Devices, Borderline Products, Clinical Trial regulations, Pharmacovigilance, Research and Education on Pharmaceuticals etc.
Under the above the act establishment of new NMRA was done in 2015 including following structure.

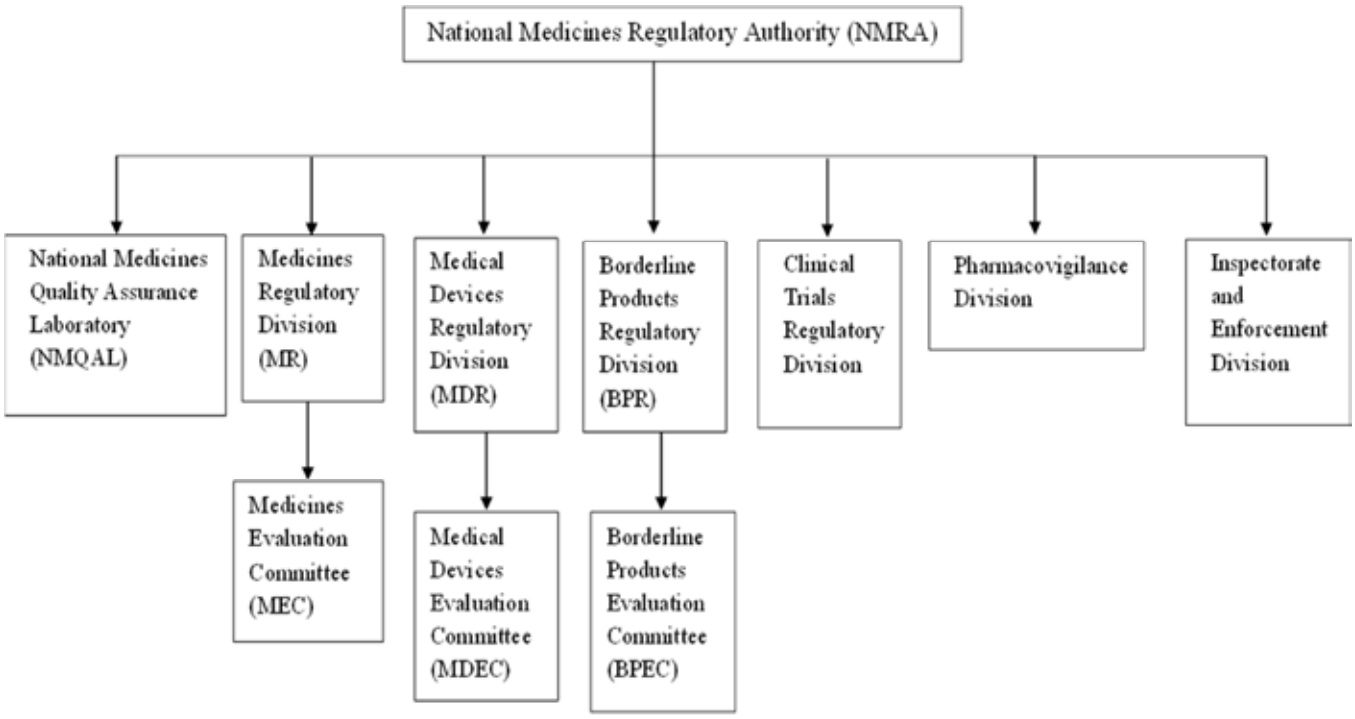


Figure 3: Organizational structure of NMRA

(ii) Poisons, Opium and Dangerous Drugs (Amended) Act.

Poisons, opium and dangerous drugs ordinance (Chapter 218) as amended by Act No 13 of 1984 regulates,

- Importation
- Storage
- Distribution and
- Use of Poisons, opium and dangerous drugs

III. Other Act : Pesticides Act, Consumer Affairs Act, Food Act

3. <u>Regulatory Service</u>

NMRA provide following regulatory services

- Regulation of Medicines, Medical Devices and Borderline Products used in Sri Lanka through a market authorization scheme and a post marketing surveillance system.
- Inspection of manufacturing premises for compliance of Good Manufacturing Practices (GMP).
- Inspection and licensing of retail and wholesale establishments of pharmaceuticals and vehicles used to transport pharmaceuticals.
- Monitoring of suspected adverse drug reactions.
- Recalling of Medicines, Medical Devices and Borderline Products from the market on safety grounds.
- Control of advertisement on medicinal drugs.
- Control of Narcotics, Psychotropic substances, and Precursors used as medicines, industrial chemicals or used for other scientific purposes.
- Regulation of clinical trials.
- Development of guidelines and manuals on medicines and related practices.
- Training of healthcare professionals and their students with related to Cosmetics,
- Devices and Drugs Act and its regulations. Awareness programs for the general public.

Pharmaceutical Manufacturing

The Sri Lankan pharmaceutical industry comprises 15% of the local market as there are few pharmaceutical manufactures in Sri Lanka. Some of the local pharmaceutical manufacturers include State Pharmaceutical Manufacturing Corporation (SPMC), Astron Ltd, Interpharm (Pvt) Ltd, J. L. Morison Son and Jones (Ceylon) PLC, GlaxoSmithKline Pharmaceuticals Ltd, Ceylinco Pharmaceuticals Ltd, Gamma Pharmaceuticals (Pvt) Ltd and Unical (Ceylon) (Pvt) Ltd.

All of these are members of Sri Lanka Pharmaceutical Manufacturers Association which was founded in 1963 with the mission of collectively lobbying with its stakeholders for the benefit of local manufacturers of pharmaceuticals in making their ventures successful.

Though more than 200 pharmaceutical products are being locally manufactured all most all of them are belong to oral liquid or solid dosage forms or topical dosage forms. The State Pharmaceutical Manufacturing Corporation (SPMC), which was established in 1987 based on a grant aid received from the Japanese government through **JICA** (Japan International Cooperation Agency), is the largest oral solid dosage form (tablets and capsules) manufacturer in Sri Lanka .

SPMC is the only state owned pharmaceutical manufacturer in the country. It actively produced 40 drugs during the year 2012 out of its total of 63 products. Every section of the SPMC conforms to the current GMP (cGMP) requirements under the guidelines of the WHO . SPMC maintains British (BP) and United State (USP) Pharmacopeial quality standards. Some of other manufacturing industries are maintaining Indian Pharmacopeial quality standards as well.

Importation

Imports of Pharmaceuticals are done by both Public and Private Sector. SPC is the whole local agent for State sector. All the drug imports to Sri Lanka should be registered under Medicines Regulatory Division (MR Division) established under NMRA.

- **Marketing Authorization**

Marketing authorization is either taken by the manufacturer to market the products manufactured or by importers. All these functions are monitored and authorized by the Regulatory Divisions under NMRA.

- **Drug Distribution**

For the public sector, drug distribution is mainly controlled and monitored by the Medical Supplies Division (MSD). This is a centrally located government organization under Ministry of Health, and there are provisional supplies divisions to supply medicines to other regional hospitals. MSD is responsible for procuring medicines, surgical items and devices for government sector hospitals, for procuring private sector hospitals and pharmacies there is no such distribution channel operating at the moment. (Figure: 2)

Private hospitals can procure their requirements directly from available drug manufacturers or suppliers. Apart from this there is government owned pharmacies known as "Osusalas" managed by the State Pharmaceuticals Corporation (SPC). SPC is responsible in supplying medicines and other additional pharmaceutical products for all the pharmacies ("Osusala") located island wide. All these functions are monitored and authorized by the NMRA.

- **Medicines Safety**

National Medicines Quality Assurance Laboratory (NMQAL) is responsible to conduct post marketing surveillance program and check the quality of all the drugs in the market Sri Lanka, Quality testing done for Registration and Complain Samples as well. Samples collected by the food and drug inspectors also tested at NMQAL. Most of the test done as per the BP and USP specifications, and in case by case basis in-house methods also has been followed. Maintenance of GLP is highly considered within the laboratory and focusing of ISO Accreditation is the main target in 2017.

- **Relief System of Adverse Drug reaction**

In an event of an adverse drug reaction a doctor or the patient can submit the details of adverse drug reactions to the Pharmacovigilance unit located at the Department of Pharmacology, Faculty of Medicine, University of Colombo, Where details of serious adverse drug reactions are

collected from government hospitals and government medical institutions, private medical institutions and from the patients and provided investigation reports. Meanwhile Safety of drugs and risk evaluation Sub-Committee (SAFRESC) under NMRA investigate and make recommendations on adverse drug reactions reported. As per the decisions taken by the committee the drugs are subject to withhold, withdraw. (Decisions based on quality testing by the NMQAL as well).

4. Drug Pricing

Drugs for public sector in Sri Lanka are free of charge. They procure drugs, according to government tender procedures. Therefore, those who bid for the tenders will govern the prices. However, apart from that the government also procures drugs directly from the State Pharmaceuticals Manufacturing Corporation. Prices for these drugs are negotiated between the two government organizations. In the case of the private sector, there are now fixed prize drugs are available in different prices in the market. However as per the new act NMRA introduced price regulation system for pharmaceuticals in 2016.

4. Statistical Data

Category	Data	Year
a) Number of government pharmacists	1386	2015
b) Number of GMP inspectors (Pharmacists do inspections)	26	2016
c) Number of pharmaceutical Manufacturers (Medicines, Borderline Products)	38 (Small scale-28 and large scale 10)	2016
d) Number of pharmaceutical Manufacturers (Devices)	57	2016
e) Number of traditional medicine manufacturers	Statistical data not available	
f) Number of pharmaceutical importers	1500	2016
g) Number of pharmaceutical whole sellers	299	2016

Table 1: Statistical Data on Pharmacy Practice

6) Education and License of Pharmacists

Pharmacy training was first introduced in Sri Lanka in the early 1950's. By 1957, a full time pharmacy certificate course was introduced (16). Since then, three types of pharmacy certificates have been developed: A certificate of proficiency in pharmacy, a certificate of efficiency in pharmacy and a diploma of pharmacy.

A Bachelor of Science (Special in Pharmacy) degree course commenced at the University of Colombo in 1999. The Bachelor of Pharmacy (B. Pharm) program was introduced in 2006 at the University of Peradeniya (UP) in Central part of Sri Lanka and University of Sri Jayewardenepura (USJ) in Colombo and University of Jaffna (UJ). Followed by, University of Ruhuna (2010) in Galle Southern province, Open University of Sri Lanka (2013) and Kotelawala Defense University (2014) in Colombo have also started B. Pharm degree programs at their respective universities.

So far no local university is providing postgraduate programs in pharmacy.

Currently approximately around 100 graduate Pharmacists are produced from local public universities. Some students after their Advanced Level examination get some scholarship and study B. Pharm or Pharm.D in overseas specifically in South Asian Countries.

Category	Duration		
	Graduate Pharmacist	**Diploma Pharmacist (Hospital)**	**Diploma Pharmacist (Community)**
University/ college	Four years	Three years	Three years
Professional training	Three years	Two years	Two years
Duration of training by each facility	One year	One year	Two years
Hospital pharmacy			
Community pharmacy			
Pharmaceutical company			
Other (Regulatory Authority)			
Age of graduation	24- 26 years old	23 years old	Depends age started

Table 2: Statistical Data on Pharmacy Education

Table 3: Universities offering pharmacy degree program

University/institute	Year of establishment	Number of years of study	Number of students enrolled / year	Degrees offered	Ownership
University of Colombo	1999	2 yrs BSc and Pharmacy special 2 yrs	10	BSc Pharmacy	Government
University of Sri Jayewardenepura	2006	4	10-20	B. Pharm	Government
University of Peradeniya	2006	4	11-30	B. Pharm	Government
University of Jaffna	2006	4	3-16	B.Pharm	Government
University of Ruhuna	2010	4	15-20	B.Pharm	Government
Kotelawala Defense University	2013	4	25	B.Pharm	Government
Open University of Sri Lanka	2013	4	100	B.Pharm	Government

National Examinations for Pharmacists

The Sri Lanka Medical council (SLMC)conducts the National Examination for Diploma pharmacists and it has one day Academic Exam and one day Clinical Exam.

Pharmacist's license

SLMC is registered qualified Pharmacist on who completed any of the above three category of Pharmacy education successfully and provided Pharmacist License.

To obtain a pharmacist license practical training is mandatory for both of graduate or diploma pharmacists. The overall knowledge on following areas is mandatory in practical training.

Forensic Pharmacy- Study the laws applicable to running any kind of pharmacy (retail /wholesale), business laws applicable to the pharmacy and study the role of authorized officers.

Prescription based learning- Read and understand prescriptions,enter the details of the prescriptions in prescription book,dispense prescriptions with proper patient advice

Packaging and labeling requirements- check the labels and packagings whether they comply with regulations.

Management and Storage- Arrangement of stocks in the pharmacy,study inventory control systems in pharmacy and how to handle expiry and quality failed drugs.

Dosage forms- Classify dosage forms in pharmacy, prepare and dispensing of immediate preparations.

Quality assurance- Organoleptic detection of deterioration of dosage forms, detection of particles and microbial spoilage in small and large volume parental preparations.

8) Challenges in the pharmacy practice

In Sri Lanka, practice of pharmacy is one of the neglected areas of health services and medical practice.

In many government sectors including Ministry of Health, government hospitals and NMRA, there are only few or no graduate pharmacists are employed.

At present, in Sri Lanka the clinical pharmacy service is minimal or almost neglected; this is perhaps due to professional isolation, lack of qualified clinical pharmacists and lack of recognition of the role of clinical pharmacists within the healthcare system.

Students had limited exposure to clinical placements during their undergraduate years, this is

may be due to lack inter medical professional understanding towards the goal of health profession.

Sri Lankan academics were concerned about gaps in clinical pharmacy expertise and so approached Australian pharmacist academics to collaborate to develop and teach the clinical pharmacy subject.

Migration of pharmacy professionals also remains high, adding further strain on the industry.

On a separate note, intensifying competitive pressures over the medium to longer term could Challenge the existing players.

Community pharmacy practice should be improved in Sri Lanka, law enforcement regarding dispensing prescription and controlled drugs should be strengthened. In the current practice, almost everyone can get any drug from most of the private community pharmacies in Sri Lanka. Pharmacy institutions in the country are facing problem with lack equipment's and laboratory facilities to conduct pharmacy related practical's during their undergraduate pharmacy training. There are no different categories of qualified pharmacist's registration process among external Apprentice pharmacists, diploma pharmacists and graduate pharmacists.

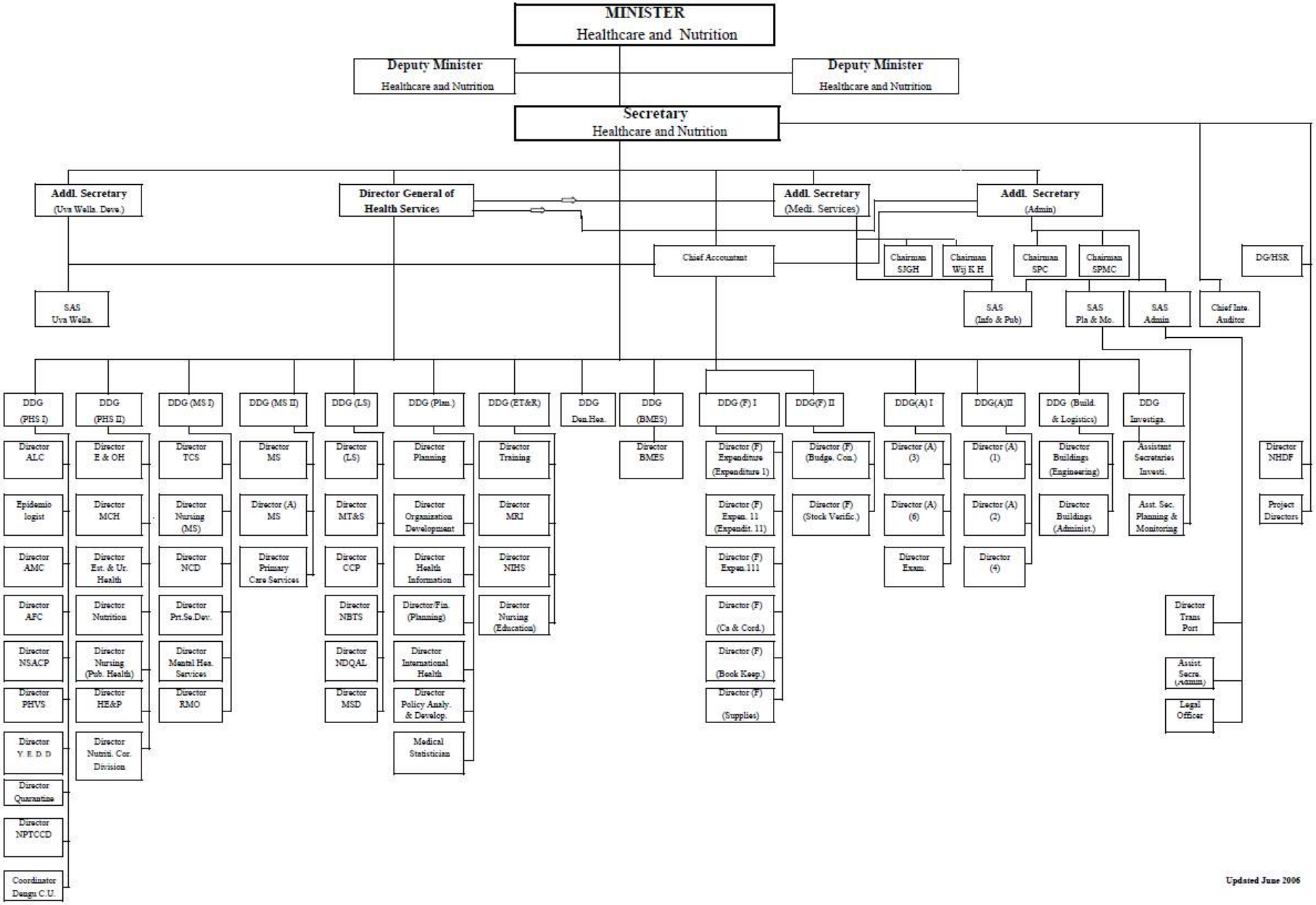
There is no separate carder for graduate pharmacists in government sector. Both diploma and graduate pharmacists are recruited in the same salary scale.

And also there are less in service training available to update Pharmacist knowledge in their professional field,

References:

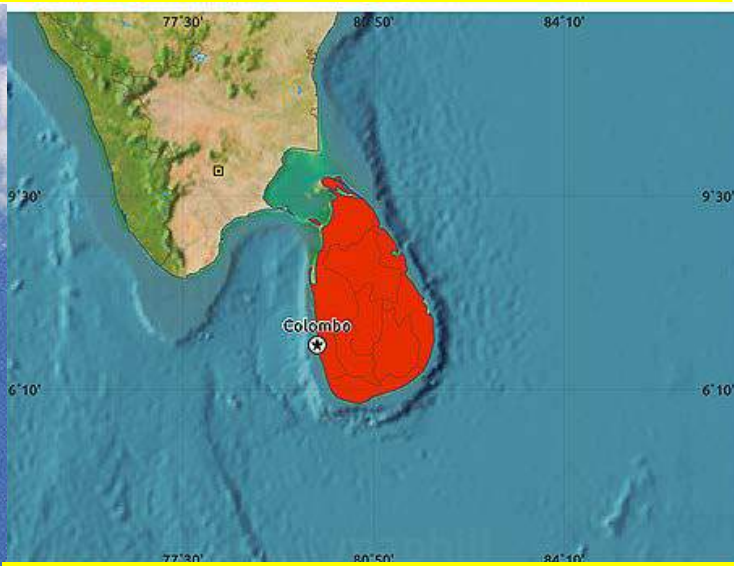
1. Annual Health Bulletin, Sri Lanka ,2014
2. National Medicines Regulatory Act, 2015
3. Manual of Drug Management System, 2008
4. Book Chapter: Pharmacy practice in Sri Lanka; Shukry Zawahir, Dhakshila Niyangoda,Nadeesha Lakmali.

ORGANIZATION CHART - MINISTRY OF HEALTHCARE AND NUTRITION

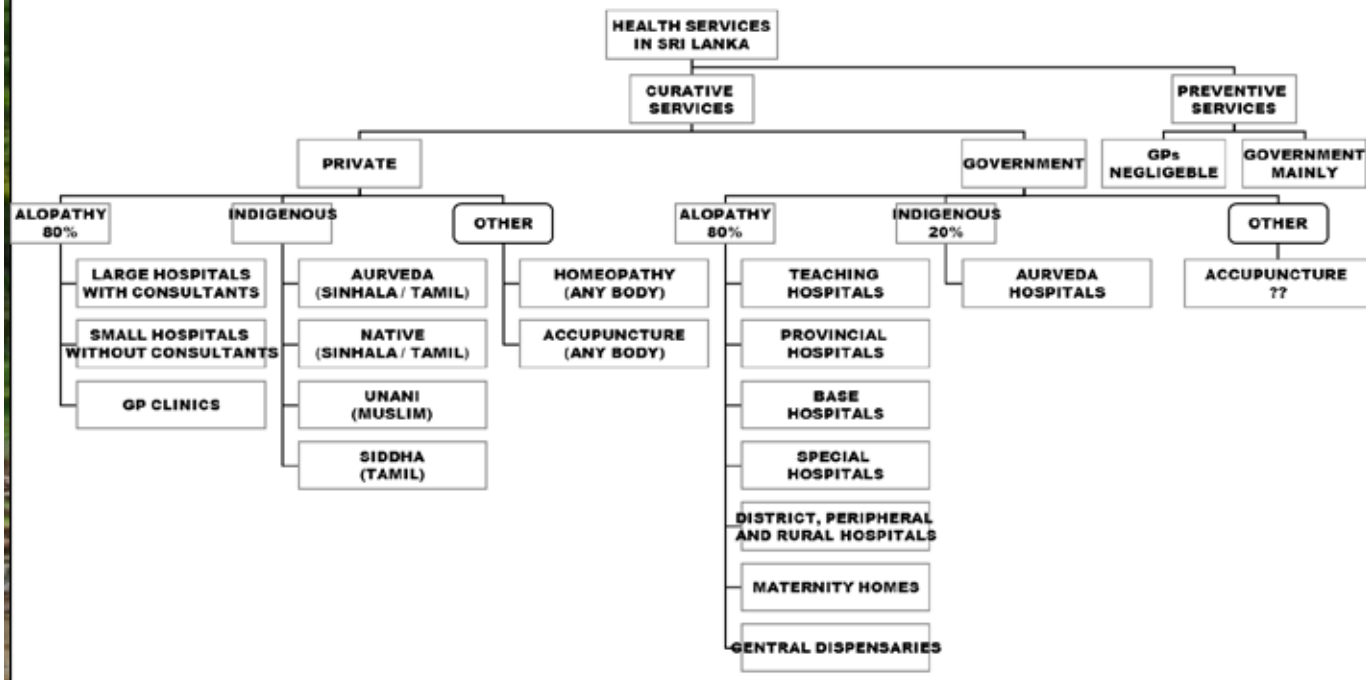


Updated June 2006

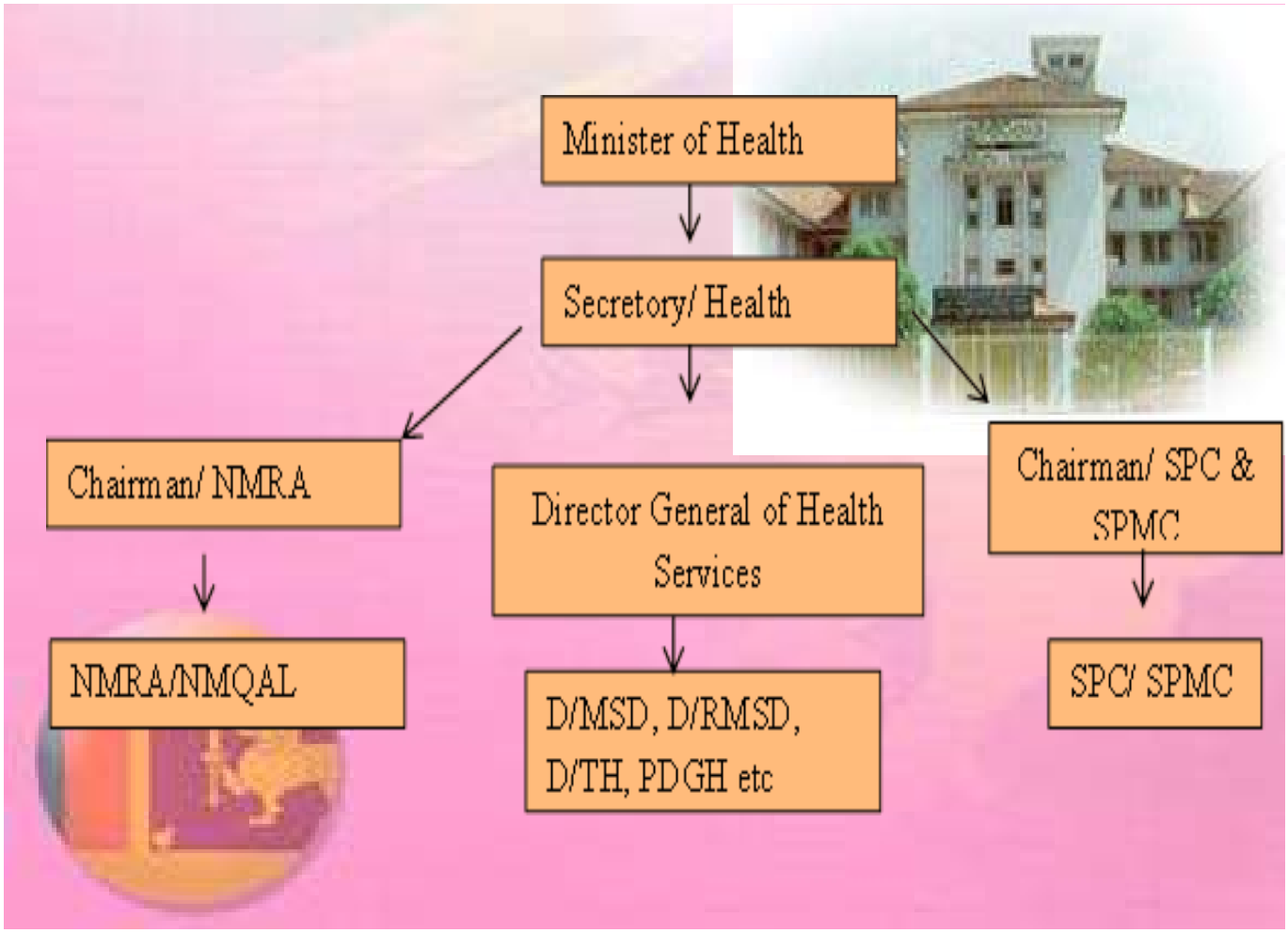
“CEYLON”/ SRI LANKA



Mihinthale hospital was built in the 9th century



Government expenditure as per GMP	3%
Number of Hospitals	622
Number of Hospitals beds per 1000	3.9
Medical officer per 100000	84.8
Nurses per 100000	185.1
Pharmacist per 100000	6.7
Life expectancy Male	72
Life expectancy Female	78.6



Pharmacy Practice

Category	Data	Year
Number of government pharmacists	1386	2015
Number of GMP inspectors (Pharmacists do inspections)	26	2016
Number of pharmaceutical Manufacturers (Medicines, Borderline Products)	38 (Small scale-28 and large scale 10)	2016
Number of pharmaceutical Manufacturers (Devices)	57	2016
Number of traditional medicine manufacturers	Statistical data not available	
Number of pharmaceutical importers	1500	2016
Number of pharmaceutical whole sellers	299	2016

Pharmacy Education

Category	Duration		
	Graduate Pharmacist	Diploma Pharmacist (Hospital)	Diploma Pharmacist (Community)
University/ college	Four years	Three years	Three years
Professional training	Three years	Two years	Two years
Duration of training by each facility	One year	One year	Two years
Hospital pharmacy			
Community pharmacy			
Pharmaceutical company			
Other (Regulatory Authority)			
Age of graduation	24- 26 years old	23 years old	Depends age started

NMRA

Vision, Mission, Objective and Strategies of NMRA

VISION	MISSION
To achieve a healthier nation by ensuring the provisions of safe, quality and efficacious medicinal products.	To regulate and control the manufacture, Importation, sale, storage and distribution of medicines, medicinal devices, including nutraceuticals and borderline devices efficiently and effectively while ensuring rational usage.

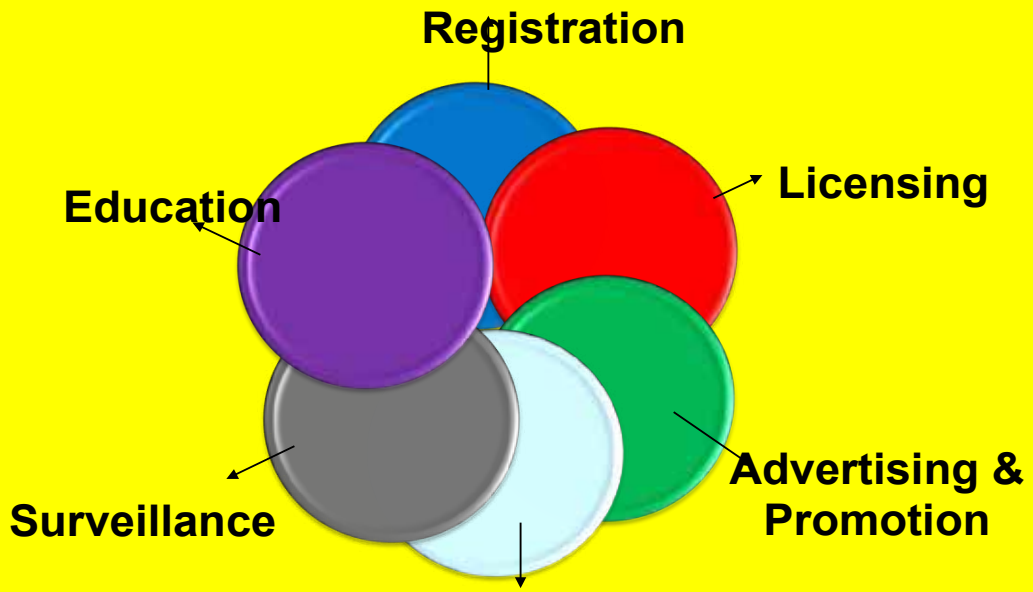
OBJECTIVE

- To ensure that all the Medicines, medicinal devices and borderline products
- available in Sri Lanka are of safe, efficacious and acceptable quality.
- To ensure uninterrupted availability of cosmetics, devices and drugs
- To ensure rational usage.

STRATEGIES

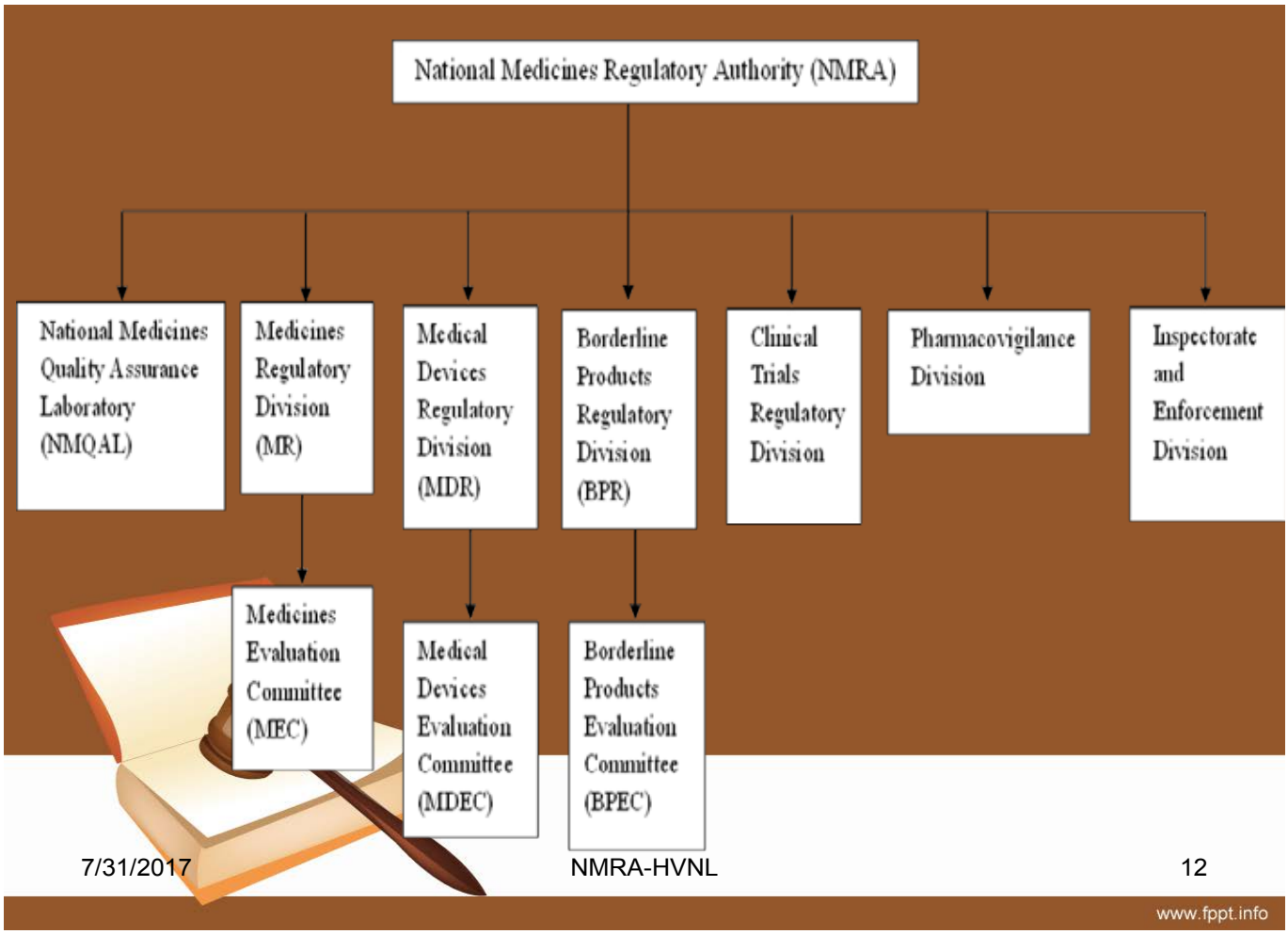
Ensure organisational efficiency and effectiveness	Strengthen enforcement activity	Ensure continuous mutual understanding and cooperation between regulatory bodies and private sector	Upgrade personnel potential and expertise	Attain a dedicated and fully committed work force	Strengthen research activities and upgrade facilities	Create a conducive working environment

National Medicines Regulatory Authority Act no.5 of 2015



Expectations

Patients	• Expect treatment using new medical innovations • Timely access to new drugs • Accountability • Trust
Prescribers	• Expect drugs to be reviewed and approved in a judicious manner • Expect drugs to be of quality, efficacious, safe • Timely access • Flexibility • Responsiveness • Confidence
Industry	• Reduction in bureaucratic procedures • Harmonization of standards and technical requirements • Predictability



Achievements

- Establishment of new Act
- CDDRA NMRA
- Implementation of Price regulation for Medicines

NATIONAL MEDICINES REGULATORY AUTHORITY ACT

A regulatory authority responsible for

- Regulation and Control
- Registration
- Licensing
- Manufacture
- Importation
- All aspects pertaining to medicines, medical devices, borderline products and for the conducting of clinical trials.

Members of the Authority

Ex-officio members

- Director-General of Health Services
- Secretary to the Treasury or his nominee
- Chief Executive Officer of the Authority functions as Secretary to the Authority.

CEO will be a person who holds a post graduate degree in Medicine, Pharmacology, Pharmacy or any other related discipline from a recognized University with at least five years management experience at senior executive level.

Health Minister Appointed members

Four specialist clinicians attached to the Ministry of Health, representing the following clinical disciplines, nominated by their respective professional bodies:

- General Medicine
- General Surgery
- Paediatrics
- Gynaecology and Obstetrics

- A Professor in Pharmacology of any University in Sri Lanka.
- A Professor or Senior Lecturer in Pharmacy of any University in Sri Lanka.
- Four professionals, who have gained eminence in the fields of management, law, accountancy or health respectively.

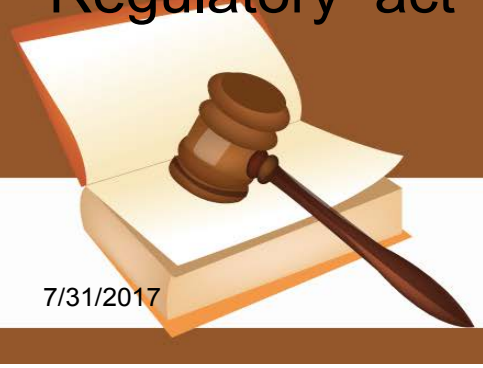
Sources: National Medicines Regulatory Authority Act *ST Graphic by Indramurthi Jayasuriya*

Solutions for past problems

- GMP inspection of manufacturing facilities.
- Regulation of API manufacturers.
- Registration of Similar Bio therapeutic products according to the format recommended by the WHO.
- Making bioequivalence studies mandatory for registration
- Implementation of novel recall procedure.
- Prequalification of supplier

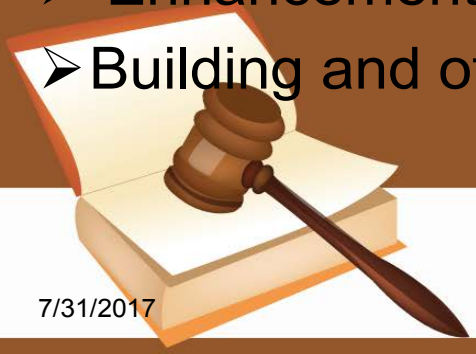
Ongoing projects to deal with current problems

- NDQAL / MT&S
  ↓ ↓
  NMQAL/ NMRA
- Implementation of new Clinical Trial Regulatory act



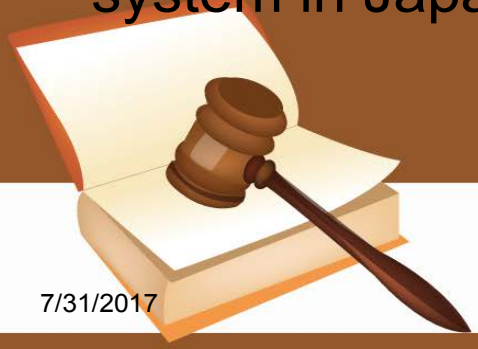
Difficulties / Lessons leaned from Past experience

- Human Resources-
- Qualified Pharmacist (Limited number of staff)
- In-service training
- Enhancement of Laboratory Facilities
- Building and other facilities



Interest in KCCP/JICA

- Local and international recognition
- Harmonizing the regulation processes with other countries.
- Understanding Health care & regulatory system in Japan



State Pharmaceuticals Manufacturing Corporation

- SPMC- 1987 By JICA
- Manufacture quality, effective and safe medicinal drugs.
- First proposed in the Bibile - Wickramasinghe Report published in March 1971.
- Only state owned pharmaceutical manufacturer in Sri Lanka.
- Total products 70.
- Active products 58 drugs (2016)

Vision.....

To be an internationally recognized, model manufacturing and marketing organization for pharmaceuticals and health care products in South Asia.

Mission.....

To manufacture safe, effective and affordable medicinal drugs of good quality up to international standards to the local and international markets.

SPMC

Formulation, Research and Development Department

I have been working in this department since April, 2015.

As a chemist,

- Involve in formulation development
- Conducting analysis of developed formulas according to the official monographs
- Manufacturing and quality assurance of pharmaceutical solid oral dosage forms

SPMC

The regulatory services which I engaged,

- ✓Prepare documentation on formulation approval and drug registration.
- ✓Designing labeling and packaging according to the regulations.
- ✓Handling stability testing and determining the shelf life of generic products

Good Practice

- Reduced the products cost by implementing new manufacturing process, such as alcohol coating method replaced by aqueous coating method.
- Established a regulatory committee which represent each department to smoothly flow of drug registration and regulatory activity on timely.
- Join collaboration with professional bodies to carry out clinical trials of the pharmaceutical products which we manufacturing.

Difficulties/ Lessons Learned from Past Experience

- The major issue is finding good quality raw materials at reasonable prices.
- During the recent past trend was seen that frequent drug shortages occur due to quality failures of the imported products.
- How to do SPMC expansions without compromising GMP standards.
- Job fluctuations and lack of trained persons.

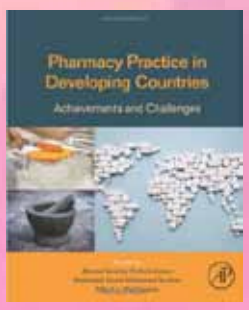
Interests

- Current trends in drug manufacturing and regulatory affairs in Japan.
- Current Good Manufacturing Practice (CGMP)
- To get understand about pharmaceutical inspection system

References

- Annual Health Bulletin, Sri Lanka 2014
- Manual on management of drugs 2nd revision 2008 by Ministry of healthcare and nutrition.
- NMRA act.
- Chapter 5 : Pharmacy practice in developing countries.

(Shukry Zawahir,Dhakshila Niyangoda, Nadeesha Lakmali)



Roles of Regulatory Systems and Pharmacists on Ensuring Proper Access to Quality Assured Medicines (JFY 2017)

Country : Sri Lanka
Organization : State Pharmaceutical Manufacturing Corporation of Sri Lanka

1. Overview of country and organization

Sri Lanka is a South Asia country with a Population about 21 million and 65610 Km^2 land. Politically, it is a country governs by parliament Democracy and headed by the Executive President.

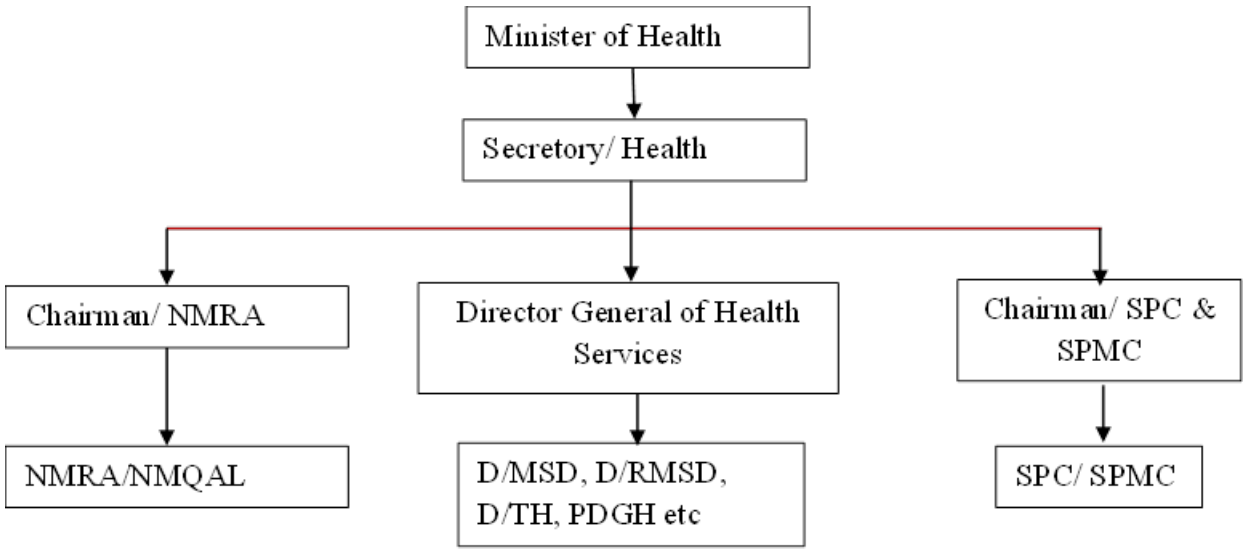
In Sri Lanka, both public and private sectors provide health care. The public sector provides free Healthcare System which is providing Healthcare to people irrespective of their wealth, income or social status. Ninety five percent of inpatient care is provided by the public sector. The private sector provides mainly curative care of the outpatient and is largely concentrated in the urban and suburban areas.

Western, Ayurvedic, Unani, Siddha and Homoeopathy systems of medicine are practiced in Sri Lanka. Of these, western medicine is the main sector catering to the needs of a vast majority of the people. The public sector comprises Western and Ayurvedic systems, while the private sector consists of practitioners in all types of medicine.

As per the Annual health bulletin 2014, life expectancy among male and female 72.0 and 78.6 years respectively, According to 2014 statistics from registrar general department, the midyear population the crude birth rate was 16.9/1000 population and crude death rate was 6.2/1000 population. Based on 2014 data, maternal mortality ratio per 100,000 live births was 19.3

As per the, update data there were 1085 medical institutions with inpatient facilities. There were included 20 teaching Hospitals 21 DHPs 487 Primary Health Care Unit and 337 Medical Officer of Health (MOH) areas in Sri Lanka. The number of beds in the hospitals increased to 76,781 in 2014 and the hospital beds per 1,000 populations is 3.7

Organizational chart of Ministry of Health, Nutrition and Indigenous Medicine



- **Minister of Health**- Policy making, such as introducing necessary amendments to the regulatory act and making regulations.

- **Secretory /Health-** Responsible for all administration and support to the Minister.

- **Director General of Health Services**- DGHS is the "Drug Authority" of the country responsible for forming Drug Therapeutic Committees. Functions of the committee would be to monitor supply, distribution and consumption of drugs at national, provincial, and institutional levels. Similarly, there are Drug therapeutic Committees for both provincial levels and regional levels.

- **Director/Medical Supplies Division (MSD)**-The MSD of the Ministry of Health Nutrition & Indigenous Medicine is responsible for the consolidation of annual requirements of drugs for the institutions under the Central Ministry and the Provincial Councils. Director, MSD and his staff periodically visit and monitor the activities in relation to drug management in the respective provinces / institutions.

- **Director/Regional Medical Supplies Divisions (RMSD) -** MSD functions as the sole supplier of all the medicinal items to the public sector and these items are distributed via the RMSD'S located in 26 Divisions Island wide.

- **National Medicines Regulatory Authority (NMRA) -** Regulation body of pharmaceuticals.

- **National Medicines Quality Assurance Laboratory (NMQAL)-**The primary function of the NMQAL is to conduct laboratory tests necessary for determining compliance with product safety and quality requirements. Quality testing of drug products is carried out on samples collected on a random basis at different points of the distribution; namely at pre-marketing and post marketing stages, and issue reports/recommendations based on the analyses/evaluations.

- **State Pharmaceuticals Corporation (SPC) -** The SPC has been designated as the sole procurement agency for pharmaceuticals and surgical consumable items required by the government health institutions. These items are imported or locally purchased and supplied to the MSD of the Department of Health Services from where they are distributed to government healthcare institutions.

- **State Pharmaceuticals Manufacturing Corporation (SPMC) -** The State Pharmaceutical Manufacturing Corporation (SPMC), which was established in 1987 based on a grant aid received from the Japanese government through **JICA** (Japan International Cooperation Agency), is the largest oral solid dosage form (tablets and capsules) manufacturer in Sri Lanka .

  SPMC is the only state owned pharmaceutical manufacturer in the country. It actively produced 58 drugs during the year 2016 out of its total of 70 products. Every section of the SPMC conforms to the current GMP (cGMP) requirements under the guidelines of the WHO . SPMC maintains British (BP) and the United State (USP) Pharmacopeial quality standards. Some of other manufacturing industries are maintaining Indian Pharmacopeial quality standards as well.

2. Legislation Govern the Pharmaceutical Administration in Sri Lanka.

National Medicines Regulatory Authority Act no.5 of 2015 and regulations made under the provisions of this act is responsible for the regulation and control of registration, licensing, manufacturing, importation and all other aspects pertaining to medicines, medical devices, borderline products and conducting of clinical trials in a manner compatible with national medicines policy. This act was come into operation from 19th March 2015.

National Medicines Regulatory Authority (NMRA) was the body corporate established under this act and has following objectives.

(a). Ensure the availability of efficacious, safe and good quality medicines, medical devices and borderline products to the general public at affordable prices

(b). Function as the central regulator for all matters connected with the registration, licensing, cancellation of registration or licensing, pricing, manufacture, importation, storage, transport, distribution, sale, advertising and disposal of medicines, medical devices and borderline products.

(c). Ensure that all activities related to registration, licensing and importation of medicines, medical devices, borderline products and investigational medicinal products are carried out in a transparent, sustainable and equitable manner.

(d). Encourage the manufacturing of good quality medicines in Sri Lanka with a view to assuring the availability of essential medicines at affordable prices.

(e). Promote the safe and rational use of medicines, medical devices and borderline products by healthcare professionals and consumers.

(f). Recommend appropriate amendments to relevant laws pertaining to medicines, medical devices and borderline products.

(g). Educate the general public, health care professionals and all stakeholders on medicines, medical devices and borderline products.

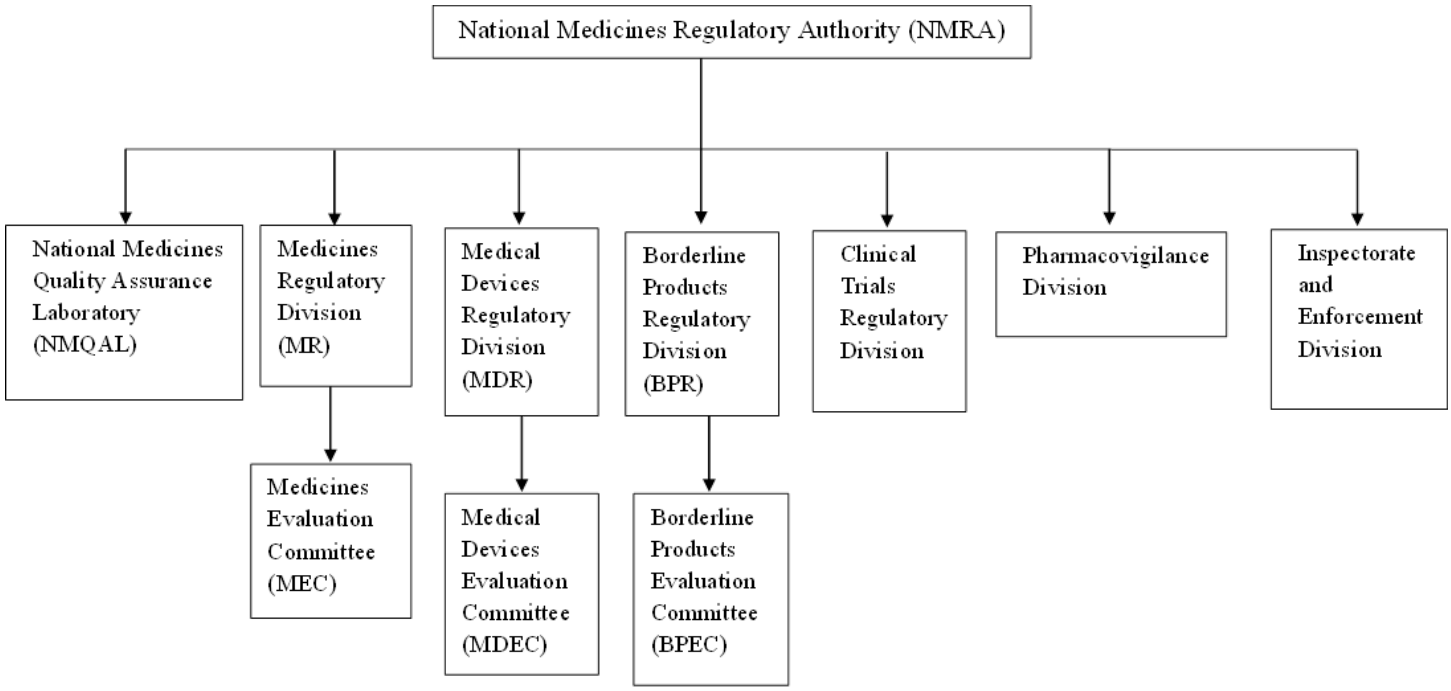
(h). Regulate the promotion and marketing of medicines, medical devices and borderline products.

(i). Regulate the availability of the medicines, medical devices and borderline products.

(j). Conduct post marketing surveillance on quality, safety and adverse reaction of the medicines, medical devices and borderline products.

(k). Regulate all matters pertaining to the conduct of clinical trials in Sri Lanka.

Institutions established under NMRA act



3. Regulatory Service

- **Pharmaceutical Manufacturing**

  Both public and private sectors are involved in pharmaceutical manufacturing in Sri Lanka. Any manufacturer must obtain prior approval (Formulation Approval) to carry out trials to obtain a stable formula from Medicines Regulatory Division (MR Division). The items to be manufactured commercially, should have to obtain separate license for such manufacturing from the Medicines Regulatory Division (MR Division). This license can be provisional which is valid for one year, and can be upgraded to a full registration with time and necessary documentation. Good Manufacturing Practices for manufacturing processes are monitored and given by the Medicines Regulatory Division (MR Division).

- **Drug import**

  Drug import to Sri Lanka can be divided into two categories such as imports to public sector and private sector. For the public sector drugs are imported mainly through the State Pharmaceuticals Corporation (SPC). They procure all the essential drugs, devices, surgical items for the Medical Supplies Division, which lies as the main unit responsible in distributing drugs and related items to government sector hospitals. All the drug imports to Sri Lanka should be registered under Medicines Regulatory Division (MR Division) established under NMRA.

- **Marketing Authorization**

  Marketing authorization is either taken by the manufacturer to market the products manufactured or by importers. All these functions are monitored and authorized by the Medicines Regulatory Division (MR Division) under NMRA act no 5 in 2015.

- **Drug Distribution**

  For the public sector, drug distribution is mainly controlled and monitored by the Medical Supplies Division (MSD). This is a centrally located government organization under Ministry of Health, and there are provisional supplies divisions to supply medicines to other regional hospitals. MSD is responsible for procuring medicines, surgical items and devices for government sector hospitals, for procuring private sector hospitals and pharmacies there is no such distribution channel operating at the moment. Private hospitals can procure their requirements directly from available drug manufacturers or suppliers. Apart from this there are government owned pharmacies known as "Osusalas" managed by the State Pharmaceuticals Corporation (SPC). SPC is responsible in supplying medicines and other additional pharmaceutical products for all the pharmacies ("Osusala") located island wide. All these functions are monitored and authorized by the National Medicines Regulatory Authority act no 5 in 2015.

- **Medicine Safety (Post - Marketing)**

  In Sri Lanka there is no such organized system for post marketing surveillance. But we have an independent laboratory to check the quality of all the drugs manufactured in Sri Lanka and all the drugs imported to Sri Lanka termed National Medicines Quality Assurance Laboratory (NMQAL). They monitor the safety and efficacy of the drugs, prevails within the island.

- **Relief system for adverse drug reactions**

  In an event of an adverse drug reaction a doctor or the patient can submit the details of adverse drug reactions to the Pharmacovigilance unit located at the Department of Pharmacology, Faculty of Medicine, University of Colombo, Where details of serious adverse drug reactions are collected from government hospitals and government medical institutions, private medical institutions and from the patients. As per the decisions taken by the committee the drugs are subject to withhold, withdraw or quality testing by the NMQAL.

4. Drug Pricing

Drugs for public sector in Sri Lanka are free of charge. They procure drugs, according to government tender procedures. Therefore, those who bid for the tenders, will govern the prices. However, apart from that the government also procures drugs directly from the State Pharmaceuticals Manufacturing Corporation. Prices for these drugs are negotiated between the two government organizations. In the case of the private sector, there are now fixed price drugs are available in different prices in the market. However, as per the new act NMRA introduced a price regulation system for pharmaceuticals in 2016.

5. Statistical Data

Category	Data	Year
a) Number of government pharmacists	1386	2015
b) Number of GMP inspectors (Pharmacists do inspections)	26	2016
c) Number of pharmaceutical Manufacturers (Medicines)	38 (Small scale-28 and large scale 10)	2016
d) Number of pharmaceutical Manufacturers (Devices)	57	2016
e) Number of traditional medicine manufacturers	Statistical data not available	
f) Number of pharmaceutical importers	1500	2016
g) Number of pharmaceutical whole sellers	299	2016

6. Education and License of Pharmacists

(1) Primary, Secondary and high school education

In our education system of primary, secondary and high school is not specialized as pharmacists. Those stages, students get the only overall idea about health sciences.

(2) University and College education

Pharmacy training was first introduced in Sri Lanka in the early 1950's. By 1957, a full time pharmacy certificate course was introduced (16). Since then, three types of pharmacy certificates have been developed: A certificate of proficiency in pharmacy, a certificate of efficiency in pharmacy and a diploma of pharmacy.

A Bachelor of Science (Special in Pharmacy) degree course commenced at the University of Colombo in 1999. The Bachelor of Pharmacy (B. Pharm) program was introduced in 2006 at the University of Peradeniya (UP) in Central part of Sri Lanka and University of Sri Jayewardenepura (USJ) in Colombo and University of Jaffna (UJ). Followed by, University of Ruhuna (2010) in Galle Southern province, Open University of Sri Lanka (2013) and Kotelawala Defense University (2014) in Colombo have also started B. Pharm degree programs at their respective universities.

Table 3: Universities offering pharmacy degree program

University/institute	Year of establishment	Number of years of study	Number of students enrolled / year	Degrees offered	Ownership
University of Colombo	1999	2 yrs BSc and Pharmacy special 2 yrs	10	BSc Pharmacy	Government
University of Sri Jayewardenepura	2006	4	10-20	B. Pharm	Government
University of Peradeniya	2006	4	11-30	B. Pharm	Government
University of Jaffna	2006	4	3-16	B.Pharm	Government
University of Ruhuna	2010	4	15-20	B.Pharm	Government
Kotelawala Defense University	2013	4	25	B.Pharm	Government
Open University of Sri Lanka	2013	4	100	B.Pharm	Government

Statistical Data on Pharmacy Education

Category	Duration		
	Graduate Pharmacist	**Diploma Pharmacist (Hospital)**	**Diploma Pharmacist (Community)**
University/ college	Four years	Three years	Three years
Professional training	Three years	Two years	Two years
Duration of training by each facility	One year	One year	Two years
Hospital pharmacy			
Community pharmacy			
Pharmaceutical company			
Other (Regulatory Authority)			
Age of graduation	24 years old	23 years old	Depends age started

(3) National Examinations for Pharmacists

The Sri Lanka Medical council conducts the National Examination for Diploma pharmacists and it has one day Academic Exam and one day Clinical Exam.

(4) To obtain a pharmacist's license

To obtain a pharmacist license practical training is mandatory for both of graduate or diploma pharmacists. The overall summary of subjects in practical training.

- **Forensic Pharmacy-** Study the laws applicable to running any kind of pharmacy (retail /wholesale), business laws applicable to the pharmacy and study the role of authorized officers.
- **Prescription based learning-** Read and understand prescriptions,enter the details of the prescriptions in prescription book,dispense prescriptions with proper patient advice
- **Packaging and labeling requirements-** check the labels and packagings whether they comply with regulations.
- **Management and Storage-** Arrangement of stocks in the pharmacy,study inventory control systems in pharmacy and how to handle expiry and quality failed drugs.
- **Dosage forms-** Classify dosage forms in pharmacy, prepare and dispensing of immediate preparations.
- **Quality assurance-** Organoleptic detection of deterioration of dosage forms, detection of particles and microbial spoilage in small and large volume parental preparations.

(5) Number of Pharmaceutical University or college graduates

Graduate Pharmacists 100 people per years
Diploma Pharmacists 250 people per years
There are no data available on the alumni's placement rate for the industry.

7. Side effect or adverse drug reaction report

In an event of a severe Side effect case a doctor or the patient can submit the details of adverse drug reactions to the Pharmacovigilance unit located at the Department of Pharmacology, Faculty of Medicine, University of Colombo, Where details of serious adverse drug reactions are collected from government hospitals and government medical institutions, private medical institutions and from the patients. As per the decisions taken by the committee the drugs are subject to withhold, withdraw or quality testing by the NMQAL.

References:

1. Annual Health Bulletin, Sri Lanka ,2014
2. National Medicines Regulatory Act, 2015
3. Manual of Drug Management System, 2008
4. Book Chapter: Pharmacy practice in Sri Lanka; Shukry Zawahir, Dhakshila Niyangoda,Nadeesha Lakmali.

Roles of Regulatory Systems and Pharmacists on Ensuring Proper Access to Quality Assured Medicines Inception Report

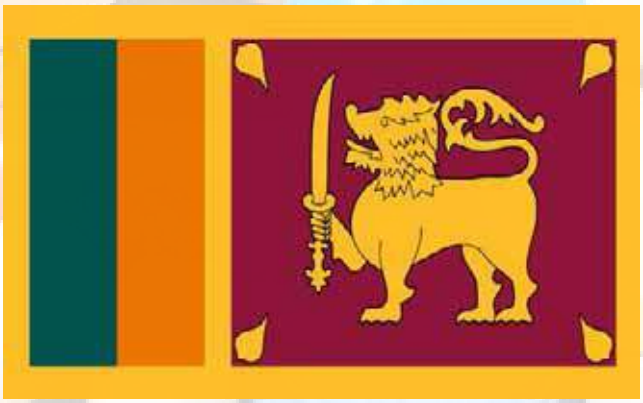
Country : Sri Lanka
Organization : State Pharmaceutical Manufacturing Corporation

Over view of Sri Lanka

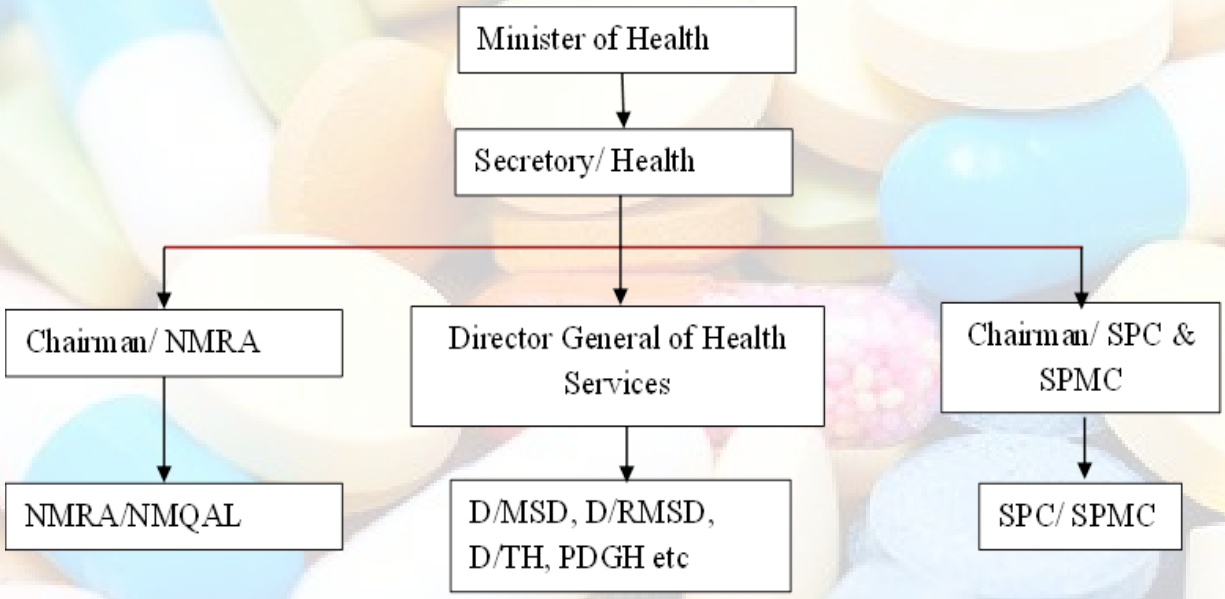
- **Democratic Socialist Republic of Sri Lanka**
- **South Asian country**
- **Multi national and multi religious country**

Over view of Sri Lanka

- Population around 21 million
- **Ethics groups**
  Sinhalese - 75%
  Tamils – 15.3%
  Muslims – 9.2%
  Others – 0.5%
- Major religion
  Buddhism others are Hindu, Islam and Christian



Organizational chart of Ministry of Health, Nutrition and Indigenous Medicine



Health Care System

- Sri Lanka is a country known to the world for providing cost effective healthcare free of direct cost to the patient.
- life expectancy among male and female 72.0 and 78.6 years
- crude birth rate was 16.9/1000 population and crude death rate was 6.2/1000 population.
- maternal mortality ratio per 100,000 live births was 19.3
- Medical institutions with inpatient facilities - 1085.
- Teaching Hospitals- 21
- District/Base Hospitals - 577
- Primary Health Care Unit- 487
- Medical Officer of Health (MOH) - 337 areas in Sri Lanka.
- The number of beds in the hospitals increased to 76,781 in 2014 and the hospital beds per 1,000 populations is 3.7

Legislation Govern the Pharmaceutical Administration in Sri Lanka

- National Medicines Regulatory Authority Act no.5 of 2015
- National Medicines Regulatory Authority (NMRA) was the body corporate established under this act
- There are eleven objectives of this authority such as control of registration, licensing, manufacturing, importation and all other aspects pertaining to medicines, medical devices, borderline products and conducting of clinical trials in a manner compatible with national medicines policy

Regulatory Services of Sri Lanka

- **Pharmaceutical Manufacturing**

  Both public and private sectors are involved in pharmaceutical manufacturing in Sri Lanka.
- **Drug import**

  Drug import to Sri Lanka can be divided into two categories such as imports to public sector and private sector. For the public sector drugs are imported mainly through the State Pharmaceuticals Corporation (SPC).
- **Marketing Authorization**

  monitored and authorized by the Medicines Regulatory Division (MR Division) under NMRA act no 5 in 2015.
- **Drug Distribution**

  For the public sector, drug distribution is mainly controlled and monitored by the Medical Supplies Division (MSD) to government hospitals. The government owned pharmacies known as "Osusalas" managed by the State Pharmaceuticals Corporation (SPC).
- **Medicine Safety (Post - Marketing)**
- **Relief system for adverse drug reactions**

  In an event of an adverse drug reaction a doctor or the patient can submit the details of adverse drug reactions to the Pharmacovigilance unit

Statistical Data

Category	Data	Year
a) Number of government pharmacists	1386	2015
a) Number of GMP inspectors (Pharmacists do inspections)	26	2016
a) Number of pharmaceutical Manufacturers (Medicines)	38 (Small scale-28 and large scale 10)	2016
a) Number of pharmaceutical Manufacturers (Devices)	57	2016
a) Number of traditional medicine manufacturers	Statistical data not available	
a) Number of pharmaceutical importers	1500	2016
a) Number of pharmaceutical whole sellers	299	2016

Education and License of Pharmacists

Category	Duration		
	Graduate Pharmacist	**Diploma Pharmacist (Hospital)**	**Diploma Pharmacist (Community)**
University/ college	Four years	Three years	Three years
Professional training	Three years	Two years	Two years
Duration of training by each facility	One year	One year	Two years
Hospital pharmacy			
Community pharmacy			
Pharmaceutical company			
Other (Regulatory Authority)			
Age of graduation	24 years old	23 years old	Depends age started

Education and License of Pharmacists cont….

- The Sri Lanka Medical council conducts the National Examination for Diploma pharmacists and it has one day Academic Exam and one day Clinical Exam.
- To obtain a pharmacist license practical training is mandatory for both of graduate or diploma pharmacists.
- The area covered by practical training.
  - **Forensic Pharmacy**
  - **Prescription based learning**
  - **Packaging and labeling requirements**
  - **Management and Storage**
  - **Dosage forms**
  - **Quality assurance**

Roles of Regulatory Systems and Pharmacists on Ensuring Proper Access to Quality Assured Medicines

State Pharmaceuticals Manufacturing Corporation Sri Lanka

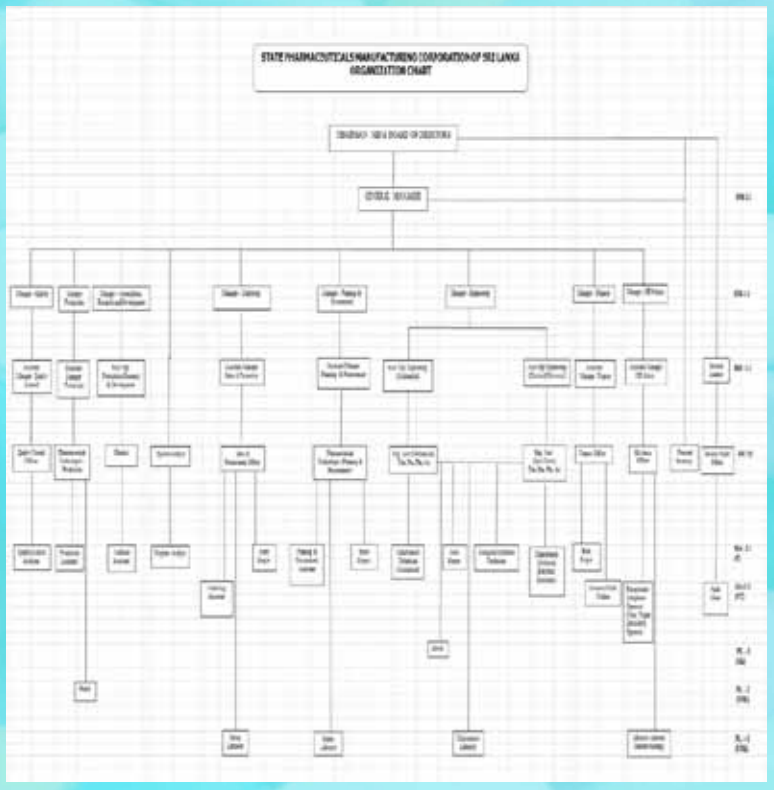
SPMC

01 Introduction of the work

The State Pharmaceutical Manufacturing Corporation (SPMC) was established in the year 1987 based on a grant aid received from the Japanese government through JICA (Japan International Cooperation Agency) with a commitment to manufacture quality, effective and safe medicinal drugs. This far-sighted decision was first proposed in the Bibile - Wickramasinghe Report published in March 1971.

SPMC is the only state owned pharmaceutical manufacturer in the country. It actively produced 58 drugs during the year 2016 out of its total of 70 products.

SPMC



Vision.....

To be an internationally recognized, model manufacturing and marketing organization for pharmaceuticals and health care products in South Asia.

Mission.....

To manufacture safe, effective and affordable medicinal drugs of good quality up to international standards to the local and international markets.

SPMC

Formulation, Research and Development Department

I have been working in this department since April, 2015.

As a chemist,

- Involve in formulation development
- Conducting analysis of developed formulas according to the official monographs
- Manufacturing and quality assurance of pharmaceutical solid oral dosage forms

SPMC

Roles and position of pharmacists in Sri Lanka

- Pharmacists are in charged with dispensing and compounding medicines as prescribed by the doctors.
- Patient counseling with regards their medications to ensure compliance and prevent drug misuse.
- Pharmacist are also highly engaged in the regulatory sector where they ensure companies manufacturing medicines both internationally and locally, which compliance with current GMP while adhering to a set of guidelines and regulations as provided by the National Medicinal Regulatory Authority(NMRA) of Sri Lanka.

SPMC

The regulatory services which I engaged,

- ✓Prepare documentation on formulation approval and drug registration.
- ✓Designing labeling and packaging according to the regulations.
- ✓Handling stability testing and determining the shelf life of generic products

SPMC

02 Good Practice

- Reduced the products cost by implementing new manufacturing process, such as alcohol coating method replaced by aqueous coating method.
- Established a regulatory committee which represent each department to smoothly flow of drug registration and regulatory activity on timely.
- Join collaboration with professional bodies to carry out clinical trials of the pharmaceutical products which we manufacturing.

SPMC

03 Difficulties/ Lessons Learned from Past Experience

- The major issue is finding good quality raw materials at reasonable prices.
- During the recent past trend was seen that frequent drug shortages occur due to quality failures of the imported products.
- How to do SPMC expansions without compromising GMP standards.
- Job fluctuations and lack of trained persons.

SPMC

04 Interests

- Current trends in drug regulatory affairs in Japan.
- Current Good Manufacturing Practice (CGMP)
- To get understand about pharmaceutical inspection system

AFGHANISTAN

Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

MOLDOVA

Roles of Regulatory Systems and Pharmacists
on Ensuring Proper Access to Quality Assured Medicines（JFY 2017）

Country: Republic of Moldova
Organization/Department/Division: Ministry of Health, Medicines and medical devices dept.

1 Organizational Chart

Pharmaceutic system in Republic of Moldova:
Regulatory authorities:
Ministry of Health – bears responsibility to elaborate policy in the area of medicines and pharmaceutical activities.
Medicines and Medical Devices Agency – bears responsibility of the following procedures management:

- drugs authorization,
- pharmacovigilance system,
- announces and monitors clinical trials,
- register manufacturer's price of medicines and manages national Register of prices,
- authorization of drugs import,
- quality control of autohtonous and imported drugs (by means of Laboratory of quality control),
- control and monitoring of pharmaceutical activities of pharmaceutical units and institutions; control of implementation and adherence to GMP and GDP.

Locally:
Pharmaceutical units and institutions are:

- drug manufacturers
- importers/distributors
- pharmacies:
  a) public/community pharmcy
  b) closed-type pharmcy (hospital pharmcy)

2 Legislation on pharmaceutical administration

−Please briefly bulletined major laws/acts

◆National Level

- *Law on Pharmaceutical Activity no 1456-XII dated 25.05.1993;*
- *Law on Drugs no 1409-XIII dated 17.12.1997;*

◆Local Level

- Government decrees
- Laws of the Ministry of Health

◆PIC/S **No**

① **Regulatory Services**

◆Pharmaceutical Manufacturing

Medicines and Medical Devices Agency by means of Inspectorate GMP and GDP bears responsibility for:

- management and execution of GMP inspections of manufacturers which produce drugs for human use and control of drug manufacturing activities, according, suspension and revoking certificates for manufacturing of drugs / medicinal compounds as well as GMP certificates, offering conciliation and management of eventual defects in quality .

Legal framework:

Activities in the area of manufacturing drugs for human use

Order of the Ministry of Health nr. 309 of 26.03.2013 regarding approval of GMP guidelines for drugs for human use

Order of theMMDA nr. 24 of 04.04. 2013 regarding approval of GMP guidelines for drugs for human use

Order of the Ministry of Health nr. 1024 of 25.09.2013 regarding authorization of manufacturing of medicines for human use in Republic of Moldova

Before implementation of GMP guidelines there were 26 drug manufaturers in Moldova.
Implementation of GMP guidelines startedin 2013, 6 manufacturers have been certfied.
Information is available on Drug Agency site:
http://amed.md/sites/default/files/attach/201504_List.fabr_.certif.GMP_.pdf

◆Drug Import/Export

Import authorization by Medicines and Medical Devices Agency is a permission issued by the state for an economical agent in order to perform external commercial activity (import) for a definite period, on a scale as specified in the authorization.

MMDA Order nr. 1 of 16.01.2006 "Regarding authorization of import – export of medicines, other pharmaceutical and parapharmaceutical products"

- Import authorization for imported medicines
- Permission for import of medicinal products and other pharmaceutical products for preclinical studies, bioequivalence trials and clinical trials.
- Permission for import of medicines and other pharmaceutical products for advertisement and promotion during an exhibition, congress, conference, symposium etc.

It is settled by law that in state of emergency (natural disaster, catastrophe, epidemics, epizootics, mass poisoning other cases of health-threatening situations; absence of analogs or substituents on pharmacy market), Medicines and Medical Devices Agency is authorized to grant permission for import, distribution and medical use of medicines, other pharmaceutical and medical devices and medicinal raw material which are not authorized in the Republic of Moldova, but being authorized in the country of origin.

The procedure is defined by ***Order of the Ministry of Health nr. 820 of 15 October 2015 "Guidelines regarding import authorization of medicines, other pharmaceutical and parapharmaceutical products and medicinal raw***

material which are not authorized in the Republic of Moldova,

◆Marketing Authorization

- Medicines for human use may be commercialized in the Republic of Moldova only after Medicines and Medical Devices Agency issued certificate of registration of a medicine**.**
  - Medicines and Medical Devices Agency uses all reasonable efforts in order a certificate of registration of a medicine to be issued within at most 210 days**.**
  - Medicines and Medical Devices Agency performs expertise of a medical product and accompanying documentation, makes reports based on its results and takes decision during drug committee sessions.
  - On the base of positive reply of drug committee Medicines and Medical Devices Agency elaborates draft of order for authorization of medical products which will be subsequently approved by the Ministry of Health.
  - Medicinal products, listed in the MoH order are considered to be included in State Registry of medicinal products, authorized in the Republic of Moldova, starting with the effective date of respective order.

Legal framework:

Order of the Ministry of Health no. 739 of 23.07.2012 "Regarding regulation of authorization of medicinal products for human use and introduction post-authorization changes"

Order of the Medicines and Medical Devices Agency no. 309 of 28.12.2015 "On the approval of the necessary Guidance for authorization of medicinal products for human use and introduction post-authorization changes"

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

Regulatory Authority: Medicines and Medical Devices Agency

Coordinating and conducting inspections of Best Practice for the Distribution

Legal framework:

Order of the Minister of Health no. 1400 of 09.12.2014 on the testing of the Good Practice of Distribution of Medicines (GDP) for human use.

List of certified GDP distributors:

http://amed.md/sites/default/files/inspectorat/Lista%20distribuitorilor%20din%20Moldova%20certificati%20GDP%20GDP.pdf

The procurement of medicines.

Regulatory Authority: Center for Centralized Public Procurement in Health

Legal framework:

Law on Public Procurement no. 131 of 03.07.2015

Government Decision No.1128 of 10.10.2016 on Center for Centralized Public Procurement in Health

Missions of the Center for Centralized Public Procurement in Health

- Planning of procurement procedures for medicines, other medical products and medical devices;
- Carrying out procurement procedures for medicines, other medical products and medical devices;
- Coordination of public procurement processes for the needs of the health system;
- Supervising and monitoring the execution of public procurement contracts for the procurement of medicines, other medical products, medical devices.

Task: Tendering or price negotiation of medicines. Pharmacotherapeutic Committees of public health facilities and medical institutions determine the need for medicines for the planned period (the next year), taking into account the Institutional Pharmacotherapeutics Formulary, dosage, pharmaceutical form of medicines, clinical protocols approved by MoH, the amount needed to treat one patient, stocks of drugs in institutions, and provide this information to Center. MoH determine the necessary amount of medicines for National vertical and special Programs. Criteria: Requirements for each batch of medicines are evaluated separately. The tender prices are benchmarked against the registered price in the National Catalogue.

Beneficiaries: 371 medical institutions at republican, municipal, rayon level.

Institutional Pharmacotherapeutic Committees:

Task: Decision on introduction of medicines in the needed for procurement list of medicines Criteria: eligibility for diseases, efficiency, safety, cost criteria. VEN and ABC analysis.

The hospitals purchase the medicines from the winning bidder. The cost of medicines is included in the DRG price. High cost medicines are reimbursed separately by the National Health Insurance Company (surfactant, chemotherapeutics).

At the same time, the Ministry of Health procures vaccines from the National Immunization Program through UNICEF and through UNDP procures medicines and medical devices for some national and special health programs.

Pricing in the in-patient sector

◆Medicine Safety (post-marketing)

The system of pharmacovigilance - the state system created for the storage, scientific evaluation and control of information about adverse reactions of drugs and other pharmaceuticals, for the purpose of undertaking appropriate measures at the stage of clinical trials and at the stage of their use in medical practice.

In the Republic of Moldova, responsible for collecting data on adverse drug reactions, is the Pharmacovigilance Department of the Agency for Medicines and Medical Products.

Legal framework:

Order of the Minister of Health no. 358 of 12.05.2017 Concerning the approval of the Regulation on performing pharmacovigilance activities

◆Relief System for Adverse Drug Reactions

Process description of managing of Adverse Drug Reactions

1. **Receiving the Adverse Drug Reaction/Ineffectiveness Reporting Form, reported by healthcare professionals and patients**

Adverse Drug Reaction/Ineffectiveness Reporting Form for healthcare specialists and for patients are transmitting to Pharmacovigilance Department by phone, fax, paper support, e-mail or E-Reporting.

Reports of suspected cases of ADR on medicinal products can be completed by doctors and other healthcare professionals (pharmacists, nurses, etc.) within the healthcare institutions, manufacturers / manufacturer authorization holders (MAH) or their official representatives and patients.

Reports of suspected cases of ADR are received by responsible person from Pharmacovigilance Department and recorded in Register, maintained electronically.

2. **Validation of Adverse Drug Reaction's Reports (ADR Report)**

The ADR reports are validated on the basis of the validation criteria. Reports that do not contain the description of the adverse reaction or the name of the medicine are not validated.

Invalid reports are recorded in the database. The report classified as invalid will be validated only after the insufficient data will be filled in, further requested from the rapporteur.

The reports are identified by a reference number generated in the VigiFlow program.

3. Primary assesment of Adverse Drug Reaction's Reports

After validation, reports of unexpected or serious adverse drug reactions are being followed with caution in order to obtain additional information from the original rapporteur or other available sources

4. Specialized assesment of Adverse Drug Reaction's Reports

On this stage, the ADR is classified by different criteria.

The type of ADR is established taking into account several unique or combined criteria as follows:

- frequency;
- severity;
- latency and duration;
- the mechanism underlying their appearance;
- predictability; Dose, time, susceptibility (DoTS classification).

After establishing and identifying the type of ADR, according to the above-mentioned criteria, the WHO-ART classification, ADR reports are evaluated for severity, predictability to assess the causality.

Data of ADR or drug ineffectiveness are recorded in the national database (Vigi Flow), maintained on electronic support and in the ADR register. Subsequently, they are transmitted (electronically) to UMC, the Uppsala Monitoring Centre, Sweden.

In dependence of case, the response will be sent to the rapporteur.

② **Drug Pricing**

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

PRICING at ex -factory price level:

All type of medicines (Rx and OTC) authorised and included in the State Medicines Nomenclature.

Regulatory Authority: Bureau of Price, from Medicines and Medical Devices Agency.

Task: Calculation of average price of the lowest three prices of the reference countries: Romania, Greece, Bulgaria, Serbia, Croatia, Czech Republic, Slovakia, Lithuania and Hungary; generic medicine price does not exceed 75% of the original medicine; medicines price that cannot be found in the reference countries must be equal to the average of InternationalNon-proprietaryName (INN) recorded in the Register.

Criteria: External reference pricing.

The manufacturer price of medicines is approved for a period of one year, calculated from the date of issuing the Agency order. The price is declared by the applicant in the national currency (Moldavian lei) and foreign currency. If there is no price information in the reference countries, the manufacturer price for medicines is compared with:

a) the price in the country of origin, with a copy of the Catalogue of the prices of medicines on the pharmaceutical market of the country of origin of the medicine;

b) the manufacturer's price, recorded in the National Prices Catalogue of Producer's for similar medicines according to the ATC code (anatomicaltherapeutic-chemical);

c) the average import price for the previous years for the given pharmaceutical product, if it was imported.

PRICING at wholesale and pharmacy price level:

Pricing in the out-patient sector:

Medicines distributed via wholesale and pharmacy, regressive mark-up.

Purchase price (MDL)	Final margin	Wholesale ark-up	Pharmacy mark-up	For reimbursed medicines Pharmacy mark-up
0-30,00	≤40%	≤15%	≤25%	≤15%
30,01-60,00	0 ≤32%	≤12%	≤20%	≤15%
60,01- 120,00	≤26%	≤10%	≤16%	≤15%
120,01- 240,00	≤21%	≤8%	≤13%	≤13%
>240,01	≤16%	≤5%	≤11%	≤11%

Annotation: The average exchange rate in May 2017: 1 EUR = 20.6037 MDL

VAT for all types of medicines: 8 %

Reimbursement:

Reimbursement in the out-patient sector

Council of reimbursed medicines from compulsory health insurance funds

Task: Decision on reimbursement status and rate of International Non-proprietary Name.

Criteria: eligibility for priority diseases, efficiency, safety, pharmacoeconomic criteria.

List of medicines for sustained (long-term) treatment in ambulatory care

• Reimbursed rate:

➢100% (full price);

➢50% and 70% from median retail price (from 50 community pharmacies).

87 INN for:

✓Cardiovascular diseases; Digestive diseases; Endocrine diseases (inclusive Diabetes mellitus (100%); Bronchial asthma; Anaemias in pregnant women (100%); Some diseases of children up to 18 years (100%); Epilepsy (100%); Parkinson diseases (100%); Psychical diseases (100%); Some autoimmune diseases (100%); Some rare diseases (100%) etc.

List of medicines for episodic treatment in the day hospital/day care room, procedures room and at home treatment, of diseases commonly found in the practice of family physician

Reimbursed rate:

➢100% (full price) for children up to 18 years;

➢70% from median retail price (from 50 community pharmacies).

• 47 INN for:

✓ Respiratory system diseases: Pneumonia; Chronic bronchitis; COPD, Bronchial asthma; Digestive system diseases: Chronic hepatitis; Fibrosis and liver cirrhosis; Chronic pancreatitis, Ulcerative disease; Mental diseases: Multiple sclerosis; Myelopathy; Cerebrovascular disease; Encephalopathy; Osteoarticular diseases: Rheumatoid arthritis; Reactive arthritis; Psoriatic arthritis; Gout; Back pain; Endocrine diseases: Diabetes mellitus + diabetic neuropathy; Diabetes + angiopathies; Diabetic Nephropathy; Infection diseases: Acute Respiratory Viral Infection (on children

③ Statistic Data

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

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

1. Number of pharmacists ___ (year)
2. Number of GMP inspector (National & Local) 2 (2017)
3. Number of pharmaceutical manufacturers / manufacturing sites 6 (2017)
4. Number of traditional medicine manufacturers / manufacturing sites - (year)
5. Number of pharmaceutical importers/ Number of pharmaceutical wholesalers 7 GDP certified and 15 GDP-free, if by 2017 they will not have GDP in 2018 they will not be active (2017)

④ Education and License of Pharmacists in your country

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

Primary 4 years

Secondary 5 years

High school 3 years

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

Pharmaceutical frames:

University - 5 years, pharmacists

Postuniversity - 2 years, (mangement, pharmacists - clinicians, technologists)

College - three years, lab farmaişti

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

Yes

Pharmacists graduating from a university hold a state examination, composed of practical and theory. If they fail to take the exam, they do not get the activity license

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

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

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

（5）Number of pharmaceutical university or college graduates: 120 people / per year

The alumni's placement rate (%)

a. Hospital: 3 %
b. Community Pharmacy: 70 %
c. Government Organization: 3 %
d. Enterprise: 20 %
e. Others: 4 %

⑤ Side effect report

5. Management of a serious adverse drug reaction

If an adverse drug reaction is assessed as serious, the following actions will be taken:

- contacting the reporter by phone and / or the specialists from pharmacovigilance department are moving at the scene to take samples of drug, collect the patient's history, analyze the patient's observation sheet (if applicable), get to know the patient's dynamics;
- samples of drug are taking by Inspectors / Pharmacists from Laboratory for Quality Control/ Pharmacovigilance specialists from Medicines and Medical Devices Agency, according to the sampling procedure, with their transmission to Laboratory for Quality Control;
- After receiving and evaluating the laboratory results, it is preparing the report including the description of the data (anamnestic, clinical, laboratory, etc.);
-The report - Report of serious adverse drug reaction evaluation is submitted to the Medicine's Committee
- Medicine's Committee takes a decision, and on the basis of this decision, are taken necessary actions.

Examples of decisions: withdrawal of medicine from market/suspension, including variations in SmPC (Summary Product Characteristics)

Part Ⅱ Presentation format

REPUBLIC of MOLDOVA

MINISTRY OF HEALTH

Maria Lapteanu

独立行政法人 国際協力機構

Organizational Chart

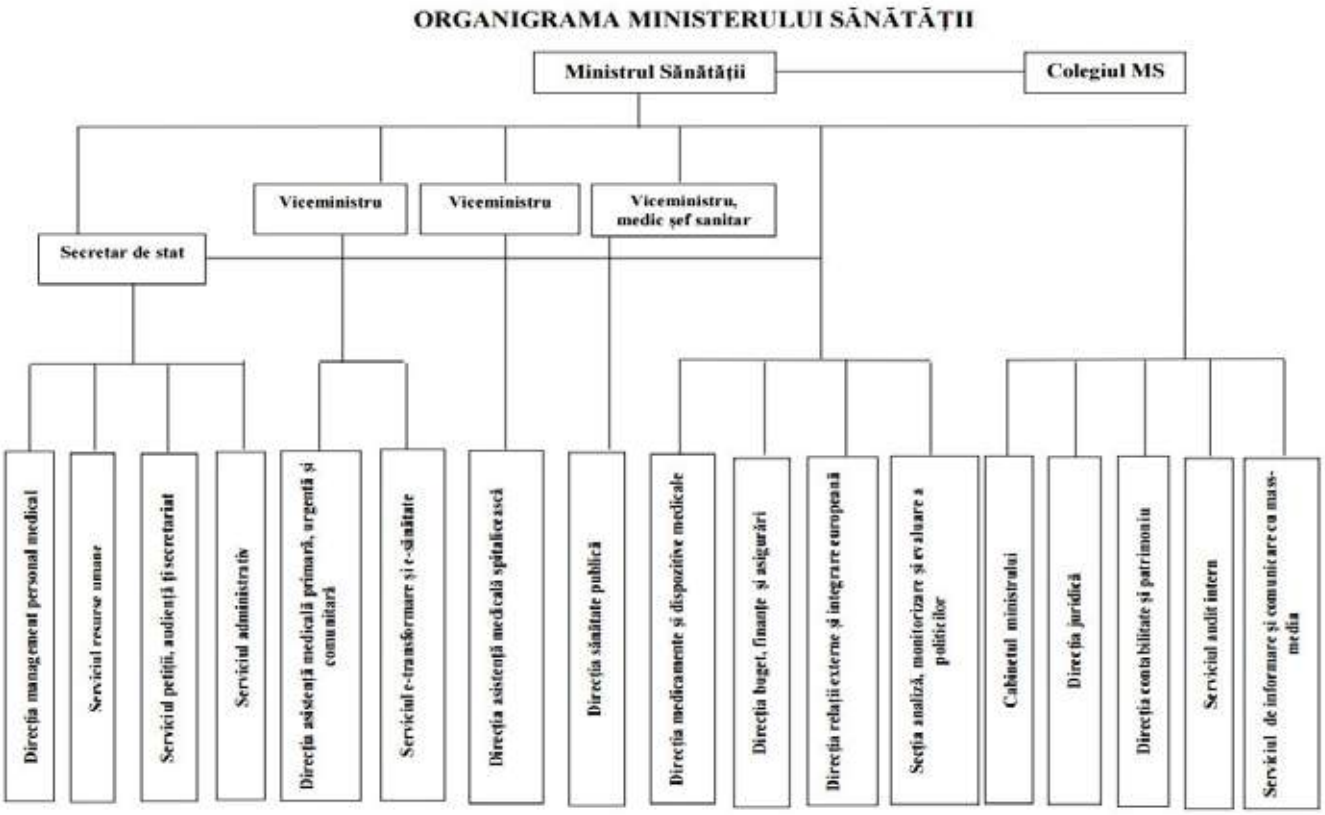
Minister
Deputy Ministers
State Secretary
The Cabinet of the Minister
Department:
- Primary, Emergency and Community Care
- Hospital care
- Medical Personnel Management

Medicines and Medical Devices

- Budget, finance and insurance
- Legal
- External Relations and European Integration
- Accounting and heritage

Policy Analysis and Monitoring Section
E-transformation and e-health service
Human resources service
The information and communication service with the media
Internal audit service, petitions, audience and secretariat service

1. Organizational Chart



1. Introduction of the work

Currently Republic of Moldova is in the process of joining EU, and all the areas of work and development are under continuous improvement. The medicines and medical devices field is one the field is under transformation, in order to develop and implement the best practices.

1. Introduction of the work

- **Plans and carries out reforms of the health sector to ensure the highest level of compliance of the health system to the needs, preferences and expectations of appropriate population, especially of socially vulnerable groups, recognizing and respecting the rights and responsibilities with regard to health.**

1. Introduction of the work

Working with:

State authority:

- **Medicines and Medical Devices Agency**
- **Center for Centralized Public Procurement in Health**

1. Introduction of the work

Pharmaceutical units and institutions are:

- **drug manufacturers**
- **importers/distributors**
- **pharmacies:**

- public/community pharmcy

- closed-type pharmcy (hospital pharmcy)

1. Introduction of the work

Pharmacist is a Qualified Person who deals with the preparation, control and distribution or sale of medicines.

The profession of pharmacist is exercised through the following activities:

- preparation of pharmaceutical forms of medicinal products;
- manufacture and control of medicines;
- drug control in a drug control laboratory;
- storage, preservation and distribution of wholesale medicines;
- preparing, controlling, storing and distributing drugs in pharmacies open to the public;
- preparing, controlling, storing and dispensing medications from hospital pharmacies;
- providing information and advice on medicines.

1. Introduction of the work

The pharmacist, in accordance with his / her university education, is competent to practice other professional activities such as:

- collaboration with the doctor for the establishment and follow-up of the patient's therapy;
- pharmacovigilance;
- manufacture, control, storage, preservation and distribution of herbal products, nutritional supplements, hygienic-cosmetic products, medical devices, veterinary medicines, active and auxiliary pharmaceutical substances;

analyzes in biochemistry, toxicology and hygiene laboratories of the environment and foodstuffs;

- marketing and pharmaceutical management;
- didactic activities or sanitary administration.

1. Introduction of the work

(1) Organization and department that you belong to

(2) Job tenure

(3) Regulatory services that you are engaged in

(4) roles and position of pharmacists in your country1) Organizația și departamentul căruia îi aparțineți

(2) Loc de muncă

(3) Serviciile de reglementare în care sunteți angajat

(4) rolurile și poziția farmacistului din țara dvs.

2. Good Practice

Good Manufacturing Practice:

Before implementation of GMP guidelines there were 26 drug manufaturers in Moldova.

Implementation of GMP guidelines startedin 2013, 6 manufacturers have been certfied.

Good Distribution Practice:

Number of pharmaceutical wholesalers - 7 GDP certified and 15 GDP-free, if by 2017 they will not have GDP in 2018 they will not be active.

3. Difficulties/Lessons Learned from Past Experience

The procurement of medicines.

Procurement of insulin analogues in the context of centralized procurement national/UNDP

No.	International nonproprietary name (INN)	Price per unit paid by MoH in 2016, USD	Price per unit -USD	Savings comparing to MoH prices (previous tenders 2016 vs 2017)
1	Biphasic insulin aspart	22,80	6,44	72%
2	Insulin aspart	12,19	6,37	48%
3	Insulin detemir	22,64	10,08	55%
4	Insulin glargine	16,47	7,92	52%
5	Insulin glulisine	9,64	4,71	51%
6	Insulin lispro	8,37	6,93	17%

Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

MALAWI

Roles of Regulatory Systems and Pharmacists
on Ensuring Proper Access to Quality Assured Medicines　(JFY 2017)

Country: MALAWI

Organization/Department/Division: MINISTRY OF HEALTH, HEALTH TECHNICAL SUPPORT SERVICES-PHARMACEUTICALS.

① Organizational Chart

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

Please briefly describe each role and responsibility on pharmaceutical administration.

※Hospital pharmacy only

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

-Ordering and inventory control of medicines and medical supplies

-Management of distribution of medicines and supplies to wards and health centers

-Drug budget control and monitoring of its usage

-Production of reports on availability of medicines procured and dispensed.

-Supervision of subordinate staff.

-Dispensing of medicines to patients

② Legislation on pharmaceutical administration

Please briefly bulletined major laws/acts

◆National Level

- Pharmacy Medicines and Poisons Board Act administered by the Pharmacy Medicines and Poisons Board
- Procurement Act administered by Office of the Director of Public Procurement (ODPP).
- Supreme Law of Malawi (Constitution of Malawi) administered by the Courts of Malawi

◆Local Level

・Bylaws administered by District Councils/Local Assemblies.

◆PIC/S

Yes　　OR　　No

If yes, joined when

③ Regulatory Services

Please describe pharmaceutical regulatory services of your country in response to each topic described below. It is recommended to add supplemental information such as systems, regulations, responsible administrators, since you are expected to explain them to other participants.

◆Pharmaceutical Manufacturing

・Systems, Regulations, etc.

・ Pharmacy Medicines and Poisons Board of Malawi (PMPB) and is administered by PMPB.
・ Medical Council of Malawi and Nurses Council of Malawi administered by Medical Council and Nurses Council of Malawi respectively.

※Example: Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice (PMPB only)

◆Drug Import/Export

・Systems, Regulations, etc.

・Pharmacy Medicines and Poisons Board of Malawi administered by PMPB.

・Malawi Revenue Authority(MRA) administered by MRA.

◆Marketing Authorization

・Systems, Regulations, etc.

・Pharmacy Medicines and Poisons Board of Malawi administered by PMPB.

※Example: Good Quality Practice

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

・Systems, Regulations, etc.

・ Procurement and distribution of medicines and medical supplies for public sector is mainly done by Central Medical Stores Trust (CMST) on behalf of the Ministry of Health. This is administered by CMST.
・ Some Procurement and distribution services (Antiretroviral drugs and Antimalarial drugs) are outsourced, others are done by Donor Agencies on behalf of Ministry of Health and is administered by the Agencies themselves.

◆Medicine Safety (post-marketing)

・ Systems, Regulations, etc.
・ Pharmacy Medicines and Poisons Board of Malawi administered by PMPB

※Example: Good Pharmacovigilance Practice

◆Relief System for Adverse Drug Reactions

・Systems, Regulations, etc.

・Pharmacy Medicines and Poisons Board of Malawi and is administered by PMPB

④ **Drug Pricing**

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

80-90 percent of medicines and medical supplies used in Malawi are procured from outside the country for both public and private sector. As a result, prices are largely dictated by importation costs and are not very much regulated. Local strategies or deliberate policies are put in place to promote local production through what is known as buy Malawi strategy.

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	10	(2017)
2.	Number of GMP inspector (National & Local)	8	(2017)
3.	Number of pharmaceutical manufacturers / manufacturing sites	4	(2017)

4. Number of traditional medicine manufacturers / manufacturing sites 0 (year)
5. Number of pharmaceutical importers 25 (year)
6. Number of pharmaceutical wholesalers 30 (year)

※Hospital pharmacy only

⑥ **Information on your hospital pharmacy**

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

a. Number of section chiefs:3
b. Number of deputy chiefs: 3
c. Number of managers:1

（2） Number of staff

a. Number of pharmacists: 42
b. Number of clinical pharmacists: 0
c. Number of technicians: 76

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

a. Oral medicine: 150
b. Injections: 36
c. Medicines for external use: 21

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

a. For inpatients: Not applicable

（5） For outpatients: Equipment of the pharmacy in your hospital

a. Does your hospital have a dispensary room?
If "Yes", how large is it?
Yes 40 ㎡ No

b. Does the pharmacy have a clean room or laminar flow hood?
Yes / No
If "Yes", please describe it in detail
Detail: Not Applicable

c. Does the pharmacy have computers?
Yes / No
If "Yes", what is the purpose of using them.
Purpose: Logistics Management Information System (LMIS) and processing of documents and communication from the Pharmacy department to other Departments such as Drug bulletins and drug orders. Keeping records for medicines and medical supplies available in the Pharmacy

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

e. Do you prepare TPN (Total Parental Nutrition)

Yes / No

f. Can you use Internet at the pharmacy?

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

Yes / No

Purpose:

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

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

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

Primary	8 years
Secondary	4 years
High school	0 years

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

University / college:	5 years
Professional education:	5 years
Practical training:	4 years
Duration of training by each facility:	N/A years
Hospital pharmacy:	12 weeks
Community pharmacy:	12 weeks
Pharmaceutical company:	12 weeks
Others:	N/A weeks
Age at graduation:	31 years old

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

Yes

Academic Exams	1 days
Clinical Exams	1 days

No

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

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

To get registered as a pharmacist, you must be a qualified Pharmacist from a recognized University and do internship for a period of 12 months under supervision of a preceptor in a public hospital, Retail/Community Pharmacy and Manufacturing plant. Finally you have to sit for a written examination administered by the Pharmacy Medicines and Poisons Board. If you pass the exam, the Board will register your name and issue a license and registration number to allow you practice but you have to retain your name on the register every year by paying retention fee.

* If practical training is optional, give the reasons.

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

Practical training is mandatory during training at college and internship

（5）Number of pharmaceutical university or college graduates:

20 people / per year

The alumni's placement rate (%)

a. Hospital: N/A %

b. Community Pharmacy: N/A %

c. Government Organization: N/A %

d. Enterprise: N/A %

e. Others: N/A %

⑧ **Side effect report**

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

Malawi

Ministry of Health

Charles Chimenya

From the warm Hear t of Africa

独立行政法人 国際協力機構

1. Introduction of the work

- ✓ Ministry of Health, Directorate of Health Technical Support Services responsible for Pharmaceutical Services.
- ✓ Three departments-Pharmaceuticals, Physical Assets Management and Diagnostics(Laboratory and Radiology)
- ✓ Full time Position –risen through the ranks of the profession and works directly under the Deputy Director

- ✓ Mission HTSS-P: To contribute to the improvement of the health of Malawians through equitable access to and rational use of good quality, safe and efficacious medicines and medical supplies at an affordable cost, with particular attention to vulnerable sections of the populations: Children, women and the poor through well trained , motivated and dedicated personnel

Regulatory services-MOH

- Provides Policy direction for the Pharmaceutical sector both public and private.
- Provides oversight function in the registration of medicinal products, Pharmacy professionals, establishments dealing in pharmaceutical products.
- Selection of medicinal products for use in public health facilities.
- Regulates the training of Pharmacy professionals in the country.

Roles and position of pharmacists

- Pharmacists in public service are either trained locally or abroad
- Primarily they are responsible for managing drug supply in hospitals and even at National level -supply chain management
- Regulatory services - Registration and inspection of pharmaceutical services in public and private sector
- Training institutions
- Private sector-Community/retail/wholesaling Pharmacies, manufacturing plants

2. Good Practice

Until 2006, when Malawi started training its own Pharmacists at College of Medicine, the industry had critical shortage of Pharmacists-only

From 2009, Pharmaceutical sector has seen improvements in the numbers of Pharmacists.

Challenges still remain:

-locally trained Pharmacists are opting to work in the private sector (poor remuneration in civil service)

-lack of specialized training for limited pharmacists to work in public sector.

- Storage space for health commodities

Improving HR Pharmaceutical department – GOM increasing no. of training institutions for lower level Pharmacy Assistants for health centres

Logistics management information system(LMIS) – Data visibility for logistics data expected to improve with introduction of a (web based Open LMIS).

2. Good Practice

- Achievements: establishment of school of pharmacy

- Solutions for past problems: continue with trainings for all Pharmacy cadres to improve on staffing levels and service delivery at HCs-access to quality medicines

- On-going projects to deal with current problems
- -Training of Pharmacy Assistants for H/Cs
- - Installation of web based system for improving data visibility.
  - Infrastructure improvement(SIAB) at lowest level of care

Infrastructure improvement at Health centre : SIAB Unit

3. Difficulties

Challenges struggling to solve-MOH

- Theft and pilferage of medicines and medical supplies in public hospitals.
- Expired medicines –Donations and inventory control management challenges
- Visibility of end user data-accountability of medicines issued out of the pharmacy.
- Infrastructure improvement at lowest level of care

4. My interests

(1) Learn from counterparts from participating countries on how they are handling issues of accountability for medicines in hospitals (Primary, Secondary and Tertiary).

(2) Technology being used in Japan to track products up to patient level

Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

TANZANIA

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY & CHILDREN

INCEPTION REPORT

Roles of Regulatory Systems and Pharmacists
on Ensuring Proper Access to Quality Assured Medicines （JFY 2017 - 04206）

Contents

1. Organisational Chart (Pharmaceutical Administration Only).....2
2. Roles and Responsibilities.....2
3. Legislation on Pharmaceutical Administration.....3
National level.....3
4. Regulatory Services.....4
5. Drug Pricing 5
6. Statistic Data 5
7. Education and License of Pharmacists in your country.....5
8. Side effect report.....7

Roles of Regulatory Systems and Pharmacists

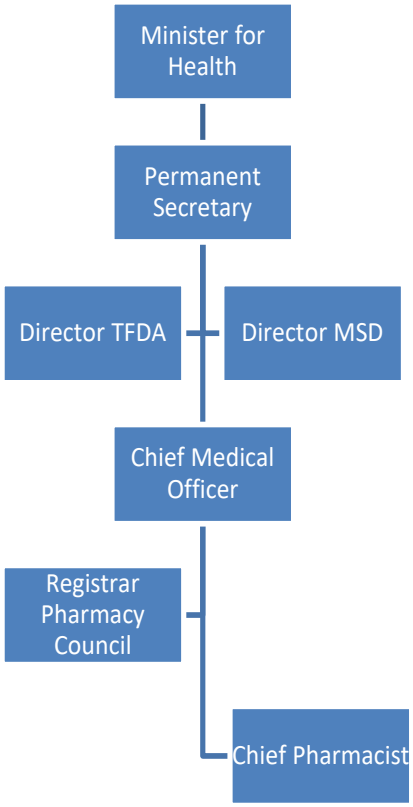
on Ensuring Proper Access to Quality Assured Medicines （JFY 2017 - 04206）

Name: Ambwene R Mwakalobo

Country: Tanzania

Organization: Ministry of Health, Community Development, Gender, Elderly and Children /Pharmaceutical Services Unit

1. Organisational Chart (Pharmaceutical Administration Only)



2. Roles and Responsibilities

Minister for Health is the Minister responsible for Health

The Permanent Secretary is the Chief Executive Officer for the Ministry of Health, Community Development, Gender, Elderly and Children

TFDA is a regulatory body for the products regulated under TFDA act, 2003

Medical stores Department (MSD) is responsible for procurement, storage and distribution of health commodities for the public sector, it is non-profit seeking organisations which is financially self-sustaining

Chief Medical Officer (CMO) is a technical advisor to the Permanent Secretary and all Professional Councils (Nurses, Doctors, Pharmacists etc.) Registrars report to CMO, Directors from all Directorates also reports to the CMO

The Chief Pharmacist / Director of Pharmaceutical Services is responsible for the Pharmaceutical Sector in the Country, it is the technical unit that advises the Ministry regarding all matters related to Pharmaceuticals and Medical supplies as per policy guidelines, Strategic plans, health policies, budgets, supply chain of medicines, regulatory in collaboration with the TFDA, Practice of Pharmaceutical personnel in collaboration with the Pharmacy council, etc.

3. Legislation on Pharmaceutical Administration

National level

Tanzania Food, Drugs and Cosmetics Act, 2003 administered by Tanzania Food and Drugs Authority (TFDA)

The Pharmacy Act No 7 of 2002 administered by The Pharmacy Council

Other related acts for specific items

Local level

At the local level same laws are administered by the above entities in collaboration with the Local Government Authorities.

Tanzania is NOT a PIC/S member

4. Regulatory Services

Pharmaceutical manufacturing systems, regulations etc

Good Manufacturing Practice (GMP) administered by TFDA

Good Laboratory Practice (Private) administered by Private Health Laboratory Board (PHLB)

Good Pharmacy Practice administered by The Pharmacy Council

Good Clinical Practice administered by professional councils' e.g. The Pharmacy Council of Tanzania

Drug Import/Export

Import is administered by the TFDA/TBS/TPRI/TAEC

Marketing Authorization systems, regulations etc

Marketing authorization is administered by TFDA

Drug distribution (including drug selection and procurement) systems, regulations etc

Drug procurement, storage and distribution for public health facilities is administered by The Medical Stores Department

Drug procurement, storage and distribution for private health facilities is administered by Private companies, Non-governmental organisations etc

Drug selection for public health facilities is done centrally at the Ministry of Health, Community Development, Gender, Elderly and Children. The list of National Essential Medicines is created and is normally aligned to the Standard Treatment Guidelines

Medicines safety (Post-marketing) systems, regulations

Pharmacovigilance is administered by the TFDA

Relief System for Adverse Drug Reactions systems and regulations

The current system to capture ADRs is a passive one, where by healthcare workers are supposed to report them through filling pre-paid post forms and patient normally get treated at the respective facilities

5. Drug Pricing

Procurement of health commodities is done centrally through the Medical Stores Department (MSD). That is a semi-autonomous entity established by act no 13 of 1993. Its role is to procure, store and distribute all health commodities to all public health facilities in Tanzania. Thus bulky procurement reduces the transactions costs, they sell these products at a small profit margin. Patient buy drugs from public facilities at a reduced cost as per MoHCDGEC cost sharing guidelines. Normally pricing surveys are conducted to monitor what is happening on the ground. However currently there is no comprehensive drug pricing policy guidelines.

6. Statistic Data

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

1. Number of pharmacists around 1300 (2015)
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)

7. Education and License of Pharmacists in your country

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

Primary 7 years

Secondary 4 years

High school 2 years

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

University / college: 4 years

Professional education: years

Practical training: 1 years

Duration of training by each facility: 4 years

Hospital pharmacy: 52 weeks

Community pharmacy: 26 weeks

Pharmaceutical company: weeks

Others: weeks

Age at graduation: varies years old

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

Yes

Academic Exams 1 days

Clinical Exams nil days

No

（4）Which of the followings must you fulfill to obtain a pharmacist's license? Finish a 4-year University degree, Internship for at least 12 months, Pass a written exam administered by the Pharmacy Council

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

All subjects that relate to pharmaceutical services are covered depending on the field of interest. But mostly it is in a hospital setting.

* If practical training is optional, give the reasons. NOT optional

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

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

The alumni's placement rate (%)

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

8. Side effect report

Currently reporting system for side effects is a passive one, that is once health care notices or is informed by the patients of the side effects, they are supposed to fill in pre-paid yellow forms all the details of the patients and the details of all the medications that the patient is taking. Including the trade names, batch numbers, dosage formulation etc. then the forms needs to be posted to Tanzania Food and Drug Authority. There the forms are entered in a database. In case TFDA find that product unfit for human consumption, it will be banned immediately and reverse logistics applies to recall and destroy the product. At the same time its importation is banned.

Tanzania

Ministry of Health, Community Development, Gender, Elderly and Children

Ambwene R Mwakalobo

独立行政法人 国際協力機構

1. Introduction of the work

- Ministry of Health, Community Development, Gender, Elderly and Children
- Pharmaceutical Services Unit (PSU)
- PSU in collaboration with the TFDA, and IPs and the Pharmacy Council conduct regular inspections, pharmacovigilance and supportive supervisions to both private and public sector

- Roles of pharmacists includes to ensure availability of safe and efficacious drugs and medical supplies to all needy patients in Tanzania

- Also to ensure rational use of medicines

- **To conduct post marketing surveillance of the authorised products in the market**

2. Good Practice

Implementation of the pull system of supply chain for health commodities

Engaging all stakeholders on regulatory matters especially the donors and the local Government Authorities

Improvement of management of health commodities through 5S-KAIZEN-TQM (ongoing)

3. Difficulties/Lessons Learned from Past Experience

Ad-hoc imports that come as donations that sometimes do not comply the regulations

Donation policy guidelines is an important tool that can counter ad-hoc and unplanned donations

Off budget clearing and forwarding costs as well as distribution costs

High valued products that can be bought by CMS at a much lower cost

Passive reporting of ADRs must be combined with active reporting to improve reporting

Pile-up of expired commodities awaiting appropriate disposal

Emerging problems includes the counterfeit products, these products are sometimes difficult to control given the porous borders and the capacity of TFDA to monitor all ports of entry

Shortage of Human resources to implement properly various strategies in the pharmaceutical sector

4. Interests and Expectations

Improve Pharmaceutical services in Tanzania (Pharmaceutical Personnel)

Learn best practices from other participating countries

Strengthen Tanzania pharmaceutical regulatory system in line with EAC harmonisation

Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

ZAMBIA

ZAMBIA
Ministry of Health

Principal Pharmacist
Southern Province

MAP OF ZAMBIA

- Zambia harbors a population of about 14,000,000 while the Southern Province a population of 1,778,540.
- Victoria Falls in Zambia

INTRODUCTION

- I work in the Ministry of Health – Southern Province Health Office
- I have been working at PHO for over 12 years now (First at Central hospital)
- The Pharmaceutical Services operate under the department of Clinical Care and Diagnostic Services at the SPHO with other units like -Laboratory services, Nursing standards, dental and medical equipment
- -

Objectives of the pharmaceutical unit

1. **Logistics Management-To** ensure the availability of adequate quality, safe, efficacious and affordable essential medicines and medical supplies to all the 284 health facilities in the Province (Adapted from National objective that takes into consideration procurement and cooperation with Pharmaceutical companies)

2. RMU- Accessibility and promotion of the rational use of these life saving commodities i.e. essential medicines and medical supplies.

3. Management of Stocks- to constantly monitor stock levels of essential & medical supplies at all the 84 levels of supply chain in the province

Regulatory services

Work in collaboration with the office of Zambia Medicines Regulatory Authority (ZAMRA) as an inspector, Drug and Enforcement Office (DEC) and the Customs Office. Also with the Health Professions Council of Zambia an independent department for the three mentioned above.

Services include:

- Inspections of medicines and medical supplies at border entry points (Southern province has 3 border entry points i.e. Zimbabwe, Botswana and Namibia including 1 international airport).

Regulatory services Cont'd

-Checking for conformity with what has been allowed by ZAMR

-Checking to see if there is any expired, near to expire or damaged items

-checking to see if there are any narcotics not allowed by ZAMRA

- Inspections of premises handling pharmaceuticals and medical supplies for conformity with ZAMRA regulations for suitability

Regulatory services Cont'd

- Providing technical support in the disposal of expired drugs and medical supplies in the province
- Inspection of health facilities both private and public concerning suitability of facilities to deal with pharmaceuticals and also other parameters concerned with standards for a health facility like availability of valid licenses of premises and individual valid staff practising licenses

SPECIFIC PROVINCIAL ROLES

1. Coordinate pharmaceutical services and to provide supervision and technical support to lower levels (Hospitals and Districts – 284 facilities)
2. To ensure the availability of essential medicines and medical supplies in the province to be maintained within and above 85%
3. To strengthen existing operational systems through effective and efficient (MTC) functioning
4. To Halt and Reverse the value of medicines and medical supplies expiring

Positions of Pharmacist in Zambia

Pharmacist positions are:

- Chief pharmacist
- Principal pharmacists (National, Regional)
- Hospital Pharmacy in-charges (Senior, Pharmacist)
- Ward pharmacist (clinical and stock mgt)
- District pharmacist (oversees the district)
- Mobile hospital pharmacist (in-charge of mobile Hospital pharmacy….)

Roles of pharmacists

- 1. Coordinates and undertakes effectively, the preparations of action plans in order to facilitate effective delivery of health services
- 2. Orders timely, essential drugs and other pharmaceuticals in order to ensure effective and efficient delivery of services
- 3. Undertakes effectively, the preparations of the budget in order to facilitate the acquisition of financial resources
- 4. Coordinates timely, the undertaking of quality control measures in order to ensure adherence to set standards

Roles of pharmacists

- 5. Monitors and evaluates regularly, activities in the delivery of Pharmaceutical Services in order to implement appropriate interventions
- 6. Undertakes timely delivery and implementation of capacity building interventions in order to impart knowledge and skills
- 7. Undertakes effectively development of individual and unit work plans in order to monitor and evaluate performance

Roles of pharmacists

- 8. Undertakes regularly, research on pharmaceutical services and programmes in order to generate information
- 9. Undertakes regularly, updating of the database in order to ensure storage and retrieval of information (though very little done)

GOOD PRACTICES ACHIEVEMENTS

1. Since 2006, only two times imported drugs were confiscated by me
2. Good cooperation from organisations involved in importation of medicines in the province
3. Support from the Provincial Health office
4. Established improved storage capacities and conditions for health commodities with support from partners in 4 out of 13 districts
5. Increase in medicines availability >85% until recent few months
6. Implemented Vaccine logistics information system LOGISTIMO for the management of vaccines

Failed Countermeasures to deal with

- To have a full time officer at all border posts
- Lack of funds to conduct pharmaceutical business as it should be
- Lack of funds to train all pharmaceutical staff in Good Pharmaceutical Practices (GMP, GPP)
- Transport to conduct pharmaceutical services uninterruptedly like monitoring GPP in facilities, TSS and OJT

➢ Failure to undertake studies and surveys on the rational use of medicines and medical supplies.

Failed Counter measures

- Improving inactive Medicines & Therapeutic Committees at all levels of health care system.
- Inactive Pharmacovigilance activities (low reporting rates)
- Inadequate pharmaceutically trained staff to provide quality pharmaceutical services
- Unscheduled distribution by MSL due to lack of fleets and sometimes availability of medicines (creating stock outs)

Failed Countermeasures

- Failure to undertake studies and surveys on the rational use of medicines and medical supplies.
- Lobbying for a dedicated transport for pharmaceutical services in logistics management, pharmacy mentorship and M&E activities.
- Improving the inactive Pharmacovigilance activities
- Increasing pharmaceutically trained staff to provide quality pharmaceutical services
- Acquiring adequate funds for Pharmaceutical programmes(Rationale medicine use trainings, MTC training workshops, OJT in facilities)

Difficulties/Lessons learnt

1. Lack of dedicated transport
2. Weak medicines/supplies logistics management especially in Health center.
3. Inadequate pharmacy personnel
4. Inadequate storage spaces & conditions
5. Irrational medicine use
6. Weak internal controls
7. Weak drug utilization studies

EMERGING/RE-EMERGING CHALLENGES

1. Weak medicines/supplies logistics management especially in Health center (No Pharmaceutical personnel)
2. Inadequate pharmacy personnel ?
3. Inadequate storage spaces & conditions
4. Irrational medicine use
5. Weak internal controls
6. Weak drug utilization studies
7. Inadequate inclusion in training for pharmacy personnel

18

Expected outcomes from training

1. Acquire knowledge - Capacity building in my roles of regulatory authority participation
2. Adopt some Japanese and other participating countries practices in regulatory roles practices
3. Acquire support financially in conducting regulatory activities improvement back home (e.g. building capacity in other pharmaceutical staff and other healthcare workers, and providing mentorship, provision of DEDICATED transport, and conducting scheduled regulatory active inspections of shops-illegal sale of medicines)
4. Support for improvement of storage facilities to meet GPP

THE END

Arigato gozaimasu

Anne desu

Shigotowa yakuzaishi desu

Kuni wa Zambia desu

REPUBLIC OF ZAMBIA

MINISTRY OF HEALTH

ROLES OF REGULATORY SYSTEMS AND PHARMACISTS ON ENSURING PROPER ACCESS TO QUALITY ASSURED MEDICINES

INCEPTION REPORT

JICA TOKYO INTERNATIONAL CENTRE

28TH JUNE TO 2ND AUGUST 2017

1.0 Introduction

The Government of the Republic of Zambia recognizes health as one of the priority sectors that contribute to the well-being of the nation and, therefore, remains committed to providing quality health services to all its citizens. The Government will remain committed to ensuring continued investment in the health sector, in order to ensure sustainability of the nation's human capital base, required for sustainable economic growth.

The Ministry of Health has been on a drive to improve access to Essential Medicines and Medical Supplies (EMMS) to the population of Zambia. In recent years there have been a number of interventions by Government and cooperating partners to improve and ensure availability, accessibility and accountability of adequate quality, safe and efficacious EMMS which are affordable and rationally used at every level of health care.

Appropriate legislation for medicines regulation was enacted through the establishment of Zambia Medicines Regulatory Authority (ZAMRA) with the basic infrastructure and activities necessary to operate efficiently and effectively.

Medical Stores Limited (MSL) as a government owned institution is mandated to store and distribute pharmaceuticals and medical supplies to public health institutions in the country. Significant investments have been made in upgrading the MSL infrastructure and drugs logistics systems.

The National Supply Chain Strategy 2013-2016 has been developed and presents a significant change in the way the supply chain of EMMS is managed. This places emphasis on having a single lead entity managing and coordinating all elements of the public health supply chain cycle which include quantification, procurement and distribution up to the last mile. The National Supply Chain Strategy was developed within the context of the overall public health sector agenda, and forms an integral part of the National Health Strategic Plan 2013-2016 which is linked to multi-sector strategic frameworks, with relevance to the public health in Zambia.

2.0 Situation Analysis

2.1 National Supply Chain Strategy

Vision	An effective, efficient and sustainable national supply chain which enables a healthy and productive people
Mission	To provide equitable access to affordable quality essential medicines and medical supplies to support the Zambian public health system.
Overall Goal	To improve the health status of people in Zambia in order to contribute to socio-economic development

Principles	• Efficiency, transparency, accountability and cost-effectiveness in the procurement, supply and distribution of drugs and medical supplies • Decentralisation and equity of access of medical supplies across Zambia • Private sector participation • A coordinated approach to resource utilisation and programme implementation • Clarity of roles of supply chain members • People centred • Environmentally aware • Operate within the country's legal frameworks

2.2 National Drug Policy

A number of significant interventions have been attempted to improve the availability of health commodities and enhance the performance of the supply chain within the Ministry of Health. Another example was the development and adoption of the National Drug Policy (NDP) in 1996 to provide, among other things, policy direction to the management of EMMS. The NDP reflects government's commitment to addressing the issues affecting the Pharmaceutical Sector in a comprehensive manner. The NDP is currently under review, to respond to emerging issues and challenges in the Pharmaceutical Sector.

2.3 Zambia Medicines Regulatory Authority

The Zambia Medicines Regulatory Authority (ZAMRA) is the Statutory National Medicines Regulatory Body for Zambia established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia to regulate and control the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances.

2.3.1 Objective

The main objective of the Authority is to ensure that all medicines and allied substances being made available to the Zambian people consistently meet the set standards of quality, safety and efficacy.

2.3.2 Mission Statement

To effectively regulate and control Medicines and Allied Substances made available to the Zambian population to ensure their conformity to set standards thereby safeguarding public health.

2.3.3 Functions

The functions of the Authority are stipulated by the Medicines and Allied substances Act (No. 3) of 2013 to:

1. Grant pharmaceuticals license and marketing authorization.
2. Inspect any premises used for the purpose of manufacturing, distribution, sale, importation or exportation of medicines or allied substances
3. Regulate and control the manufacture, importation or exportation, distribution, sale of medicines and allied substances
4. Regulate and control the advertisement and promotion of medicines and allied substances
5. Register and regulate pharmacies and ago-veterinary shops.
6. In consultation with relevant professional bodies, establish, maintain and develop standards for the operations of pharmacies and agro-veterinary shops.
7. Serve and protect the public interest in all matters relating to the sale of medicines and allied substances.
8. Regulate and monitor the conduct of clinical trials
9. Establish, maintain and enforce standards relating to the manufacture, importation, exportation, distribution and sale of medicines and allied substances
10. Conduct post-market surveillance
11. Establish, maintain and enforce standards for drug quality control laboratories
12. Advise the Minister of Health on policies relating to the regulation and control of medicines and allied substances
13. Collaborate with corresponding medicines regulatory authorities in other countries
14. In consultation with the relevant research institutions, determine national priorities in pharmaceuticals research

2.4 Quality Assurance:

The Government through the Minister of Health laid a foundation stone in June 2017 for the construction of the National Drug Quality Control Laboratory. This infrastructure will also accommodate ZAMRA offices once fully functional. This development will enhance monitoring of quality and safety of products circulating on the Zambian market which poses a serious risk to public health from substandard or counterfeit medicines and related products. In addition, post-marketing surveillance at all levels needs to be strengthened.

Reference

1. Zambia National Health Strategy Plan 2011 - 2015
2. Zambia Medicines Regulatory Authority website
3. Zambia National Supply Chain Strategy for Essential Medicines and Medical Supplies 2013-2016

REPUBLIC OF ZAMBIA

MINISTRY OF HEALTH

LUSAKA PROVINCIAL HEALTH OFFICE

ROLES OF REGULATORY SYSTEMS & PHARMACISTS ON ENSURING PROPER ACCESS TO QUALITY ASSURED MEDICINES

JICA TOKYO INT'L CENTRE
28TH JUNE TO 2ND AUGUST 2017

National Hierarchy-Pharmaceutical Services

Ministry of Health

↓

Director-Clinical Care and Diagnostic Services

↓

Chief Pharmacist

↓

Principal Pharmacist-RUM & Logistics (MOH)

↓

Provincial Principal Pharmacist

↓

District Pharmacist

Provincial Principal Pharmacist

Objective

To ensure availability, accessibility and accountability of EMMS.

Roles & responsibilities

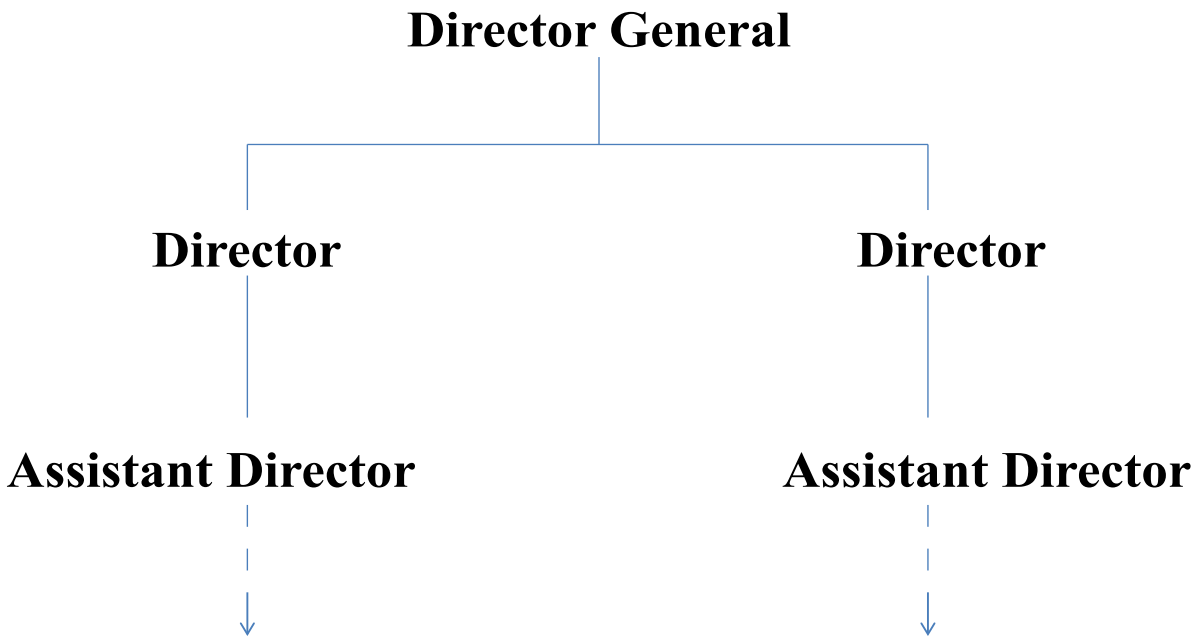
Coordinates pharmaceutical services in order to ensure effective & efficient service delivery in the Province.

(eight districts, one 2nd level & three specialized hospitals)

Zambia Medicines Regulatory Authority

ZAMRA is the Statutory National Medicines Regulatory Body for Zambia established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia to regulate and control the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances

ZAMRA Hierarchy



Objective of ZAMRA

The main objective of the Authority is to ensure that all medicines and allied substances being made available to the Zambian people consistently meet the set standards of quality, safety and efficacy.

Useful links

- Ministry of Health
- MSL
- HPCZ
- Zambia Bureau of Standards
- Patents & Companies Registration Office

Functions of ZAMRA

The functions of the Authority are stipulated by the Medicines and Allied substances Act (No. 3) of 2013 to:

- Grant pharmaceuticals license and marketing authorization.
- Inspect any premises used for the purpose of manufacturing, distribution, sale, importation or exportation of medicines or allied substances
- Regulate and control the manufacture, importation or exportation, distribution, sale of medicines and allied substances
- Regulate and control the advertisement and promotion of medicines and allied substances

Functions of ZAMRA cont'd

- Register and regulate pharmacies and ago-veterinary shops.
- In consultation with relevant professional bodies, establish, maintain and develop standards for the operations of pharmacies and agro-veterinary shops.
- Serve and protect the public interest in all matters relating to the sale of medicines and allied substances.
- Regulate and monitor the conduct of clinical trials
- Establish, maintain and enforce standards relating to the manufacture, importation, exportation, distribution and sale of medicines and allied substances

Functions of ZAMRA cont'd

- Conduct post-market surveillance
- Establish, maintain and enforce standards for drug quality control laboratories
- Advise the Minister of Health on policies relating to the regulation and control of medicines and allied substances
- Collaborate with corresponding medicines regulatory authorities in other countries
- In consultation with the relevant research institutions, determine national priorities in pharmaceuticals research

Successes

- Increased drug availability and reduced expiries due to improved drug management (M&E, Audit trails).
- Improved data visibility to enable timely reporting and impactful supply chain decisions (eLMIS/logistimo).
- Improved storage facilities and conditions (SIBs) resulting in reduction in running costs.
- Secured land to erect the National Drug Quality Control Laboratory
- Established regional offices across the country
- Created awareness in pharmacovigilance across the country

Challenges

SN	Challenges	Best practices
1	Inadequate storage facilities	Provide space by constructing
2	Lack of dedicated transport for logistics management	Lobby for transport/integrate activities
3	Inability to attain zero stock out rate of EMMS	Revise EDL & RHC Kits & redistribution
4	Weak post-marketing surveillance	Strengthen post-marketing surveillance at all levels
5	Lack of a full-fledged National Drug Quality Control Laboratory	Establish a fully functional National Drug Quality Control Laboratory
6	Illegal retail pharmacy outlets	Strengthen & enforce inspections

Expectations from JICA training

- Share good practices & experiences
- Share new updates regarding roles of regulatory systems & pharmacists
- Capacity building

Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

BRAZIL

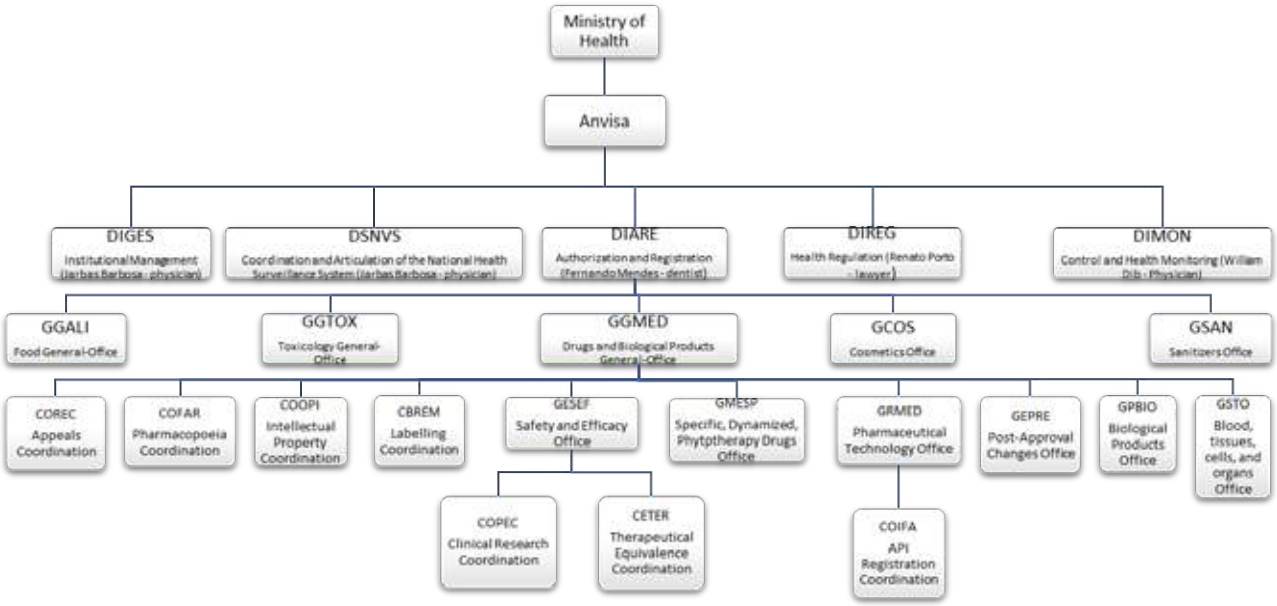
"Roles of Regulatory Systems and Pharmacists on Ensuring Proper Access to Quality Assured Medicines (J17-04206)"

Inception Report

Country: **BRAZIL**
Organization/Department/Division: **BRAZILIAN HEALTH REGULATORY AGENCY (Anvisa)**

① Organizational Chart

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



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

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

The agency's institutional mission is "to protect and promote public health, by exercising health surveillance over products and services, including processes, ingredients and technologies that pose any health risks.". The scope of regulatory authority action includes food, cosmetics, sanitizers, tobacco, pesticides, health services, medicines, medical devices, official laboratories, blood, tissues and organs, pharmacovigilance, advertisement, ports, airports and borders, international affairs and

National Health Surveillance System coordination. (www.portal.anvisa.gov.br)

Anvisa is structured in five board of directors: 1. Institutional Management (DIGES), 2. Health Regulation (DIREG), 3. Coordination and Articulation of the National Health Surveillance System (DSNVS), 4. Authorization and Registration (DIARE), and 5. Control and Health Monitoring (DIMON).

The participants selected by JICA work in the office of safety and efficacy assessment of new synthetic drugs (GESEF) and in the office of pharmaceutical technology assessment of synthetic drugs(GRMED), both subordinated to the Drugs and Biological Products General-Office. We are responsible for the review of clinical and non-clinical reports, and chemical manufacturing and controls documentation sent by the pharmaceutical companies, with the purpose of granting a marketing authorization.

- Please briefly describe each role and responsibility on pharmaceutical administration. (hospital pharmacy only): Not applicable.

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

Brazil has almost 200,000 licensed pharmacists who work mainly in hospitals, industries, pharmacies, drugstores, and public health services.

The duties of a hospital pharmacist include manipulation and dispensation of medicines, participation in multidisciplinary assistance teams, health surveillance activities, and management activities (selection, planning, and acquisition of medicines, medical devices, sanitizers…).

Pharmacists who works in industries are responsible for the enforcement of health surveillance regulations, and for the implementation of quality system, among others.

The role of the pharmacist in Brazilian public medical care system is divided between care and management actions. The management activities are mainly focused on the logistics of medicines. This logistic encompass plan, execute, and supervise local acquisition of medicines, assure adequate storage and efficient distribution. On the other hand, the care activities are focused on the patient, and includes all activities that have the purpose of correct use of medication and effectiveness of treatment. Among those activities are community health education, and orientation regarding the correct use of prescribed medicines.

Recently, the approval of Resolution No. 585/2013, which regulates the clinical pharmacist's attributions, along with Resolution No. 586/2013, which regulates pharmaceutical prescription in Brazil, introduced a change in Brazilian pharmaceutical field. Although not fully applied in practice, those regulations allow the pharmacist to participate in the planning and evaluation of pharmacotherapy, provide pharmaceutical consultation, request laboratory tests, proceed a patients' pharmacotherapeutic follow-up, and to perform prescription of medicines and other products for therapeutic purposes, which dispensing does not require medical prescription, for example. Those measures are part of a fought for social recognition of the pharmacists as a healthcare professional, not only as medicine-based experts.

② Legislation on pharmaceutical administration

- Please briefly bulletined major laws/acts

◆National Level

Law 6360/1976 – provides for the Health Surveillance that the medicines, drugs, and the API, cosmetics & sanitizing and other products are subjected, and gives other provisions.
Decreet 8077/2013 – regulates the activities described in the Law 6360/1976.
Law 5991/ 1973 – provides for the sanitary control for sale of medicines, drugs, API and correlates, and give other provisions.
Law 6437/1977 – define sanitary infractions to the federal law and relative penalties
Law 8080/1990 – define the Unified Health System in Brazil
Law 9782/1999 – establish the role and responsibilities of Anvisa and define the National Health Surveillance System
Resolution RDC 60/2014 – provides the criteria required to grant a new marketing authorization for synthetic and semi synthetic drugs.

◆Local Level

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

◆PIC/S

Yes ＯＲ No If yes, joined when

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

Anvisa participated in the PIC/S between the years 2015-2016 and exchanged experience with England and Austria in Good Clinical Practice.

③ Regulatory Services

- Please describe pharmaceutical regulatory services of your country in response to each issues 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.

◆ Drug Import/Export

・ Systems, Regulations, etc.

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

petitions to import products within it scope. For example, the Office of blood, tissues, cells, and organs (GSTCO), decides over the importation of blood.

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

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

◆ Pharmaceutical Manufacturing

▪ Systems, Regulations, etc

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

Another document issued by Anvisa for drug product's manufacturers is the good manufacturing practices (GMP) certificate (certificado de boas práticas de fabricação - CBPF). The minimum regulatory requirements for manufacture of drug products are described in Resolution RDC nº 17/2010, which also guides the inspections to verify compliance with the principles of GMP. The GMP inspection team is generally composed for two inspectors who evaluate technical items throughout all the company departments, such as warehouse, utility sections (for example, HVAC, and water for pharmaceutical use), manufacturing, and quality control. An inspection can get three results: satisfactory, on-demand, and unsatisfactory. As a result of a satisfactory GMP inspection the company is granted a certificate (CBPF) valid for two years.

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

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

Good Clinical Practice

The major regulation in Good Clinical Practice in Brazil is the resolution RDC nº09/2015, which regulates the conduction of clinical trials with drugs in Brazil. Nowadays, this resolution is the only one among our resolutions that incorporates an ICH guideline, the E6 (Good Clinical Practice). The GCP's inspections made by Anvisa analyses the clinical research centers' systems, the ethical documents, the case report forms. The inspections are done in some centers based on risk factors

(such as population involved and disease studied) and on the number of patients recruited (centers with a greater number of patients recruited are preferred). An inspection may also be conducted after a complaint.

Good Laboratory Practices

The Office of Health Public Laboratories (GELAS) is responsible for coordinating the National Network of Sanitary Surveillance Laboratories (RNLVISA) and the Brazilian Network of Analytical Laboratories for Health (REBLAS). Actions should be coordinated with sanitary authorities of the states and municipalities. Among other responsibilities, GELAS/ Anvisa is responsible for participate in the development of public polices and national directives for RNLVISA, in partnership with the Ministry of Health policies and for the development of technical normatives for the laboratories which analyses products and services under sanitary surveillance.

RNLVISA is composed by 27 Central Public Health Laboratories, one for each state and for the Federal District, the National Institute of Quality Control in Health (INCQS) and five municipal laboratories.

REBLAS is composed of analytical laboratories, public or private, enabled by Anvisa and capable to offer services of sanitary interest with quality, confidence, safety and traceability.

For being part of REBLAS, the laboratories must have a license issued by the sanitary authority and must be have its conformance status certified or recognized by the National Institute of Metrology, Normatization and Industrial Quality (INMETRO). The habilitation is valid for a 2 years period and is specific for a certain scope of activities.

The qualification of laboratories is conducted following ABNT resolutions, the principles of Good Laboratory Practice, complementary documents of the Organization for Cooperation and Economic Development (OCDE) and other applicable legislations and directives.

A list of REBLAS laboratories and of RNLVISA laboratories and its analytical capabilities is available at Anvisa website.

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

◆ Marketing Authorization

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

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

Anvisa establish several categories of medicines, according to medicines' properties and origin, and for each category there is specific legislation and requirements. Currently, medicines are categorized as new synthetic medicines, generic medicines, brand generic medicines, herbal medicines, biologic medicines, radiopharmaceuticals, homeopathic and dynamized medicines and specific medicines. The process described below will focus on actions related to assessment of new synthetic medicines applications for marketing authorization.

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

Several departaments of the General-office of drugs and biological products (GGMED) are involved in application assessment.Before application submission, the marketing authorization holder may

request a pre submission meeting with Anvisa reviewers to discuss technical aspects of the data, especially when there is specific or unusual issues. For new synthetic medicines, application submission is made through an electronic system called Eletronic Register System.

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

The labelling coordination (CBREM) evaluates the regulatory content of package and leaflets, focusing in compliance with standard format and mandatory statements according to specific legislations (RDC 71/2009 for labels and RDC 47/2009 for leaflet).

The office of assessment of pharmaceutical technology (GRMED) reviews the chemical, manufacturing, and controls documentation of the dossier. This includes the drug master file of the active pharmaceutical ingredient (API) used, the drug product production report, the quality control report, analytical method validation, stability studies, and for generic or branded generic, pharmaceutical equivalence studies. The requirements for analytical method validation are provided by resolution RE nº 899/2003; the resolution RE nº 1/2005, approved the Guideline for conducting stability studies of drug products; and the pharmaceutical equivalence studies are regulated by resolution RDC nº 31/2010. GRMED is responsible for suggesting the approval or rejection of the petition, based on its own review of quality documentation and on GESEF's reports about safety and efficacy.

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

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

・ Systems, Regulations, etc

※Example: Good Quality Practice

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

・ Systems, Regulations, etc

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

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

CONITEC (National Comission of Health Technology Assessment for the Unified Health System) is a collegiate permanent commission that is part of MoH structure. CONITEC objective is support the MoH on decisions related to incorporation, exclusion or change of health technologies

adopted by SUS. CONITEC should follow some directives such as adopting rational criteria and efficacy, efficiency and effectiveness parameters adequate for the health necessities and incorporate health technologies relevant for the citizens and the health system, based on a cost effectiveness positive relationship. CONITEC should also review the National Relation of Essential Medicines (RENAME).

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

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

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

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

Anvisa issue Certificates of Good Distribution or Storage Practice for medicines, devices and active pharmaceutical ingredients companies in Brazil.

※Example: Good Distribution Practice

◆ Medicine Safety (post-marketing)

・ Systems, Regulations, etc.

The main national regulations in pharmacovigilance are RDC 04/2009, which regulates how the pharmacovigilance should be done by the marketing authorization holders and RDC nº36/2013, which establishes rules for the patient's safety in health care system.

The post-marketing pharmacovigilance is made mainly by the voluntary reporting of adverse events (AEs) by health practitioners and by patients. A web form is available at ANVISA's website (http://portal.anvisa.gov.br/como-notificar-) for both practitioners (http://www8.anvisa.gov.br/notivisa/frmlogin.asp) and patients (http://www16.anvisa.gov.br/notivisaServicos/cidadao/notificacao/evento-adverso). The adverse events' reports are also collected by the ombudsman service.

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

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

The notifications received through Notivisa may be used for:

- Underpin the National Health Surveillance System (SNVS) to identify adverse reactions or

unpleasant product effects;
- Improve the knowledge about product effects and, as appropriate, change the recommendations of use;
- Promote actions for public health protection through regulation of marketing products in the country

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

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

※Example: Good Pharmacovigilance Practice

◆ Relief System for Adverse Drug Reactions

When important adverse drug reactions are detected, after Anvisa's evaluation, the warnings are published at Anvisa's website and the marketing authorization holders must send a letter to the health practitioners. This letter is sent to medical associations, to hospitals and institutions that are member of a sentinel network and they are also published at Anvisa's web page.
Anvisa is looking for another ways of spreading such important information in order to be closer to the patients such as using social network media.

・ Systems, Regulations, etc.

④ Drug Pricing

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

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

Anvisa holds the position of Executive Secretariat in the CMED, monitor the price of drug products commercialized in Brazil, and oversees the settling of prices for new drug products. The agency publishes a list with the maximum prices allowed for drug products sold directly to the consumer by drugstores and pharmacies (http://portal.anvisa.gov.br/documents/374947/2829072/LISTA+CONFORMIDADE_2017-05-22.pdf/21e1fb07-ea45-4bc6-933e-dc2e1b5af0c1).
CMED also created a mandatory minimum discount (price-cap) applied for pharmaceutical distributers and manufacturers when selling medicines to public administration. Local government generally acquire drug products through electronic trading, and performs annual drug acquisition, among other strategies to promote resource optimization.

⑤ Statistic Data

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

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

1: Number of pharmacists: 195.022 pharmacists in Brazil (Source: http://www.cff.org.br/pagina.php?id=801&menu=801&titulo=Dados+2015+, Federal council of pharmacy, data from 2015).

2: Number of GMP inspector (National & Local): National: 28 (Source: Anvisa, June, 2016). We don't have the number of local inspectors (municipal and state government inspectors).

3: Number of pharmaceutical manufacturers / manufacturing sites: 914 national pharmaceutical manufacturers (Source: Anvisa, May/2016) .

4: Number of traditional medicine manufacturers / manufacturing sites: (YEAR)
We don't have this data, only the total number of pharmaceutical manufacturers.

5: Number of pharmaceutical importers: (YEAR)
11.498 importers, distributors and transporters (Source: Anvisa, May/2016).

6: Number of pharmaceutical wholesalers : (YEAR)
We have only the total number of importers, distributors and transporters.

⑥ Not applicable ※hospital pharmacy only
⑦ Not applicable ※hospital pharmacy only

⑧Side effect report

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

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

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

About 50% of the AE's reporting is from the Sentinel Network, a group of hospitals

coordinated by ANVISA that act strongly in the reporting of AEs. In a lesser quantity, the AEs reports come from the MAH and the health care providers.

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

Brazilian Health Regulatory Agency Overview

GESEF and GRMED/ GGMED/ ANVISA

Tokyo, July 2017

REGULATORY AGENCY

Agência Nacional de Vigilância Sanitária - Anvisa

ANVISA
Agência Nacional de Vigilância Sanitária

- Set up by Law 9.872/1999: 18 years
- Regulatory governmental agency
- Administrative independent and financially autonomic
- Connected to the Ministry of Health
- Management contract: indicators and goals
- Stable board of 5 directors
- Designated by the President for a 3 years mandate, renewable for more 3 years

SCOPE OF REGULATORY ACTIVITY

Agência Nacional de Vigilância Sanitária - Anvisa

FOODS

COSMETICS

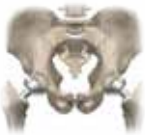
SANITIZERS

TABACCO

PESTICIDES

HEALTH SERVICES

MEDICINES



MEDICAL DEVICES

OFFICIAL LABORATORIES

BLOOD, TISSUES AND ORGANS

PHARMACOVIGILANCE

ADVERTISEMENT

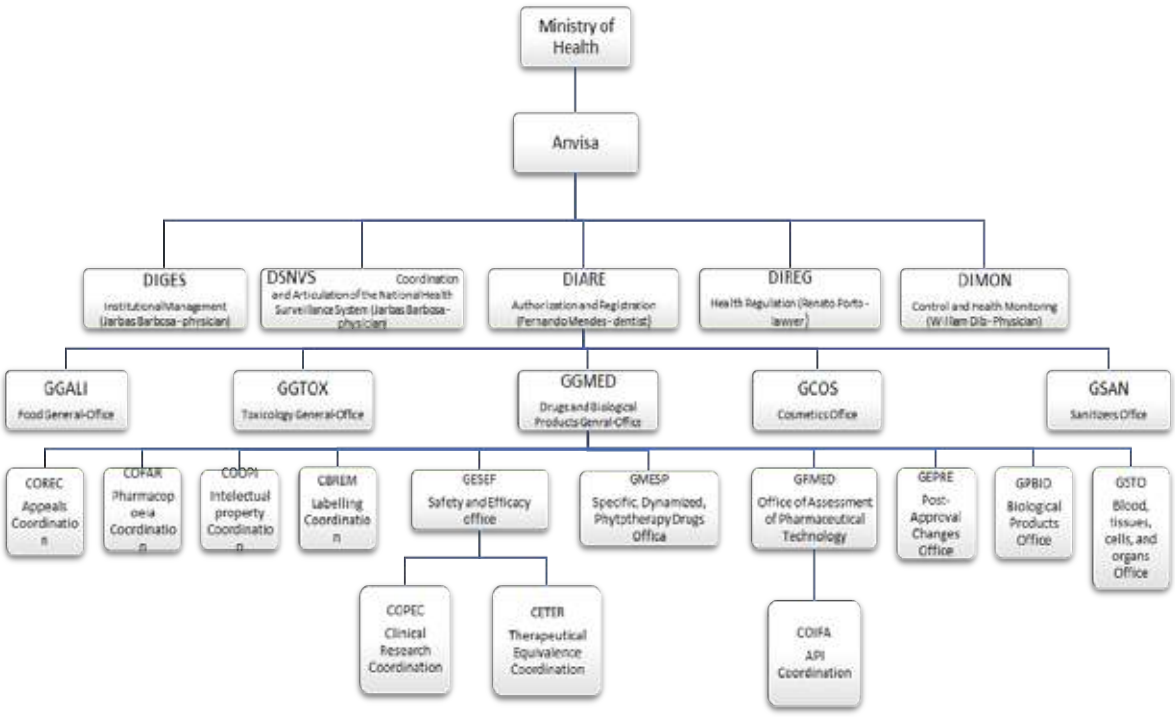
PORTS, AIRPORTS AND BORDERS

INTERNACIONAL AFFAIRS

SNVS COORDINATION

REGULATORY AGENCY

Agência Nacional de Vigilância Sanitária - Anvisa



- Pharmacist – public medical care system

- Management:
Acquisition of medicines
Adequate storage
Efficient distribution

- Care:
Orientation
Community health education
Monitoring of effectiveness of treatment

- News

- Clinical attributions: pharmaceutical consultation, requisition of laboratory tests, development of pharmaceutical care plan.

- Pharmaceutical prescription: non medical prescription medicines.

ROLES AND RESPONSIBILITIES
Agência Nacional de Vigilância Sanitária - Anvisa

- Office of Assessment of Pharmaceutical Technology of Synthetic Drugs (GRMED):

Review chemistry, manufacturing, and controls documentation of generic, branded generic, and new drug applications to market of synthetic medicines → technical opinion on whether the product´s application should be approved, considering other offices reports.

Harmonize technical and operational procedures.

Provide regulatory guidance → citizens and regulated industries (Anvisa's contact channels).

Assist GMP inspections pertaining synthetic drugs.

ROLES AND RESPONSIBILITIES

Agência Nacional de Vigilância Sanitária - Anvisa

- Office of Drugs Safety and Efficacy Evaluation (GESEF):

Analyze and report a detailed conclusive opinion about new register, renewal and post-marketing applications of synthetic medicines.

Harmonize technical and operational procedures.

Express, in thorough manner, the positions of the agency about questions related to drugs safety and efficacy.

Participate in inspections related to efficacy and safety studies of drugs under its jurisdiction.

PERSONAL EXPERIENCES

Agência Nacional de Vigilância Sanitária - Anvisa

- Luiza Novaes Borges – Industrial pharmacy degree and PPCR specialization

Experience with regulatory affairs and clinical trials assessment in multinational pharmaceutical company.

Work as Specialist in Regulation and Health Surveillance at ANVISA in the Office of Drugs Safety and Efficacy Evaluation.

Has been working as spokesperson in national and international meetings about benefit-risk assessment and risk based strategies for prioritization of analysis.

- Letícia Sousa – bachelor in pharmacy and master of pharmaceutical sciences

Experience with local public health services, community health edducation, medicines distribution and dispensation.

Work as Specialist in Regulation and Health Surveillance at ANVISA in the Office of Assessment of Pharmaceutical Technology of Synthetic Drugs.

Part of technical regulatory committees which oversees partnerships between public pharmaceutical industries and private companies for the purpose of transfer technology related to drug products provided by the Brazilian public health system (SUS).

➢ **Office of Assessment of Pharmaceutical Technology of Synthetic Drugs (GRMED):**

- Improve efficiency and reduce review time
- Increase transparency about the minimmun technical requirements for CMC documentation approval
- Establish the directives for abbreviated review of low risk products

➢ **Office of Drugs Safety and Efficacy Evaluation (GESEF):**

- Accelerated register (Phase II): for medicines used for serious life threatening diseases without therapeutical alternatives
- Establish the directives for follow up medicines registered based on phase II trials
- Definition of aceptable clinical endpoints
- Increase transparency about the specific requirements for safety and efficacy studies by therapeutical classes

Have a broad knowledge and practical experience about the structure of health regulation system in Japan.

Assist improvement of medicine's authorization process and harmonization of technical requirements for registration with other regulatory authorities.

Reach a higher standard of regulatory practices adopted in Brazil ensuring access of quality, safety and efficacy assured medicines to Brazilian population.

Benchmarking activity is aligned with first project defined in the Strategic Program Plan of the Agency for the 2016-2019 period:

Betterment of procedures to register products in Brazil in alignment with the best regulatory international practices

THANK YOU!

Contacts

Agência Nacional de Vigilância Sanitária - Anvisa
SIA Trecho 5 - Área especial 57 - Lote 200
CEP: 71205-050
Brasília - DF
Phone: + 55 61 3462 6000

www.anvisa.gov.br
www.twitter.com/anvisa_oficial
Anvisa Atende: 0800-642-9782

ouvidoria@anvisa.gov.br

SUS ANVISA Agência Nacional de Vigilância Sanitária Ministério da Saúde BRASIL

Japan International Corporation of Welfare Services (JICWELS) was established with the sanction of the Minister for Health, Labour and Welfare in July 1983 and implements international technical cooperation programmes with purpose of contributiing to the promotion of health and social welfare activities in the friendly nations.

Japan International Corporation of Welfare Services (JICWELS)
Toranomon YHK Bldg. 4F, 2-3-20, Toranomon
Minato-ku, Tokyo 105-0001 JAPAN
Phone: +81-(0)3-6206-1137
Fax: +81-(0)3-6206-1164
http://www.jicwels.or.jp

公益社団法人国際厚生事業団（JICWELS）は、国際的な保健・福祉分野の国際協力に貢献することを目的として、1983 年（昭和 58 年）7 月 7 日に厚生省（現厚生労働省）から社団法人の認可を受け設立されました。開発途上国の行政官研修や WHO フェローの受入れ、調査企画や研究開発並びに情報の交換及び広報活動など、海外諸国との国際交流活動を推進しています。

公益社団 国際厚生事業団 JICWELS
広報活動委員会

〒105-0001
東京都港区虎ノ門 2-3-20 虎ノ門ＹＨＫビル 4 階
電話 03-6206-1137（事業部）　Fax03-6206-1164
http://www.jicwels.or.jp