Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

Country Reports

Japan International Corporation of Welfare Services (JICWELS)

Contents

INDONESIA

National Agency for Drug and Food Control
Republic of Indonesia

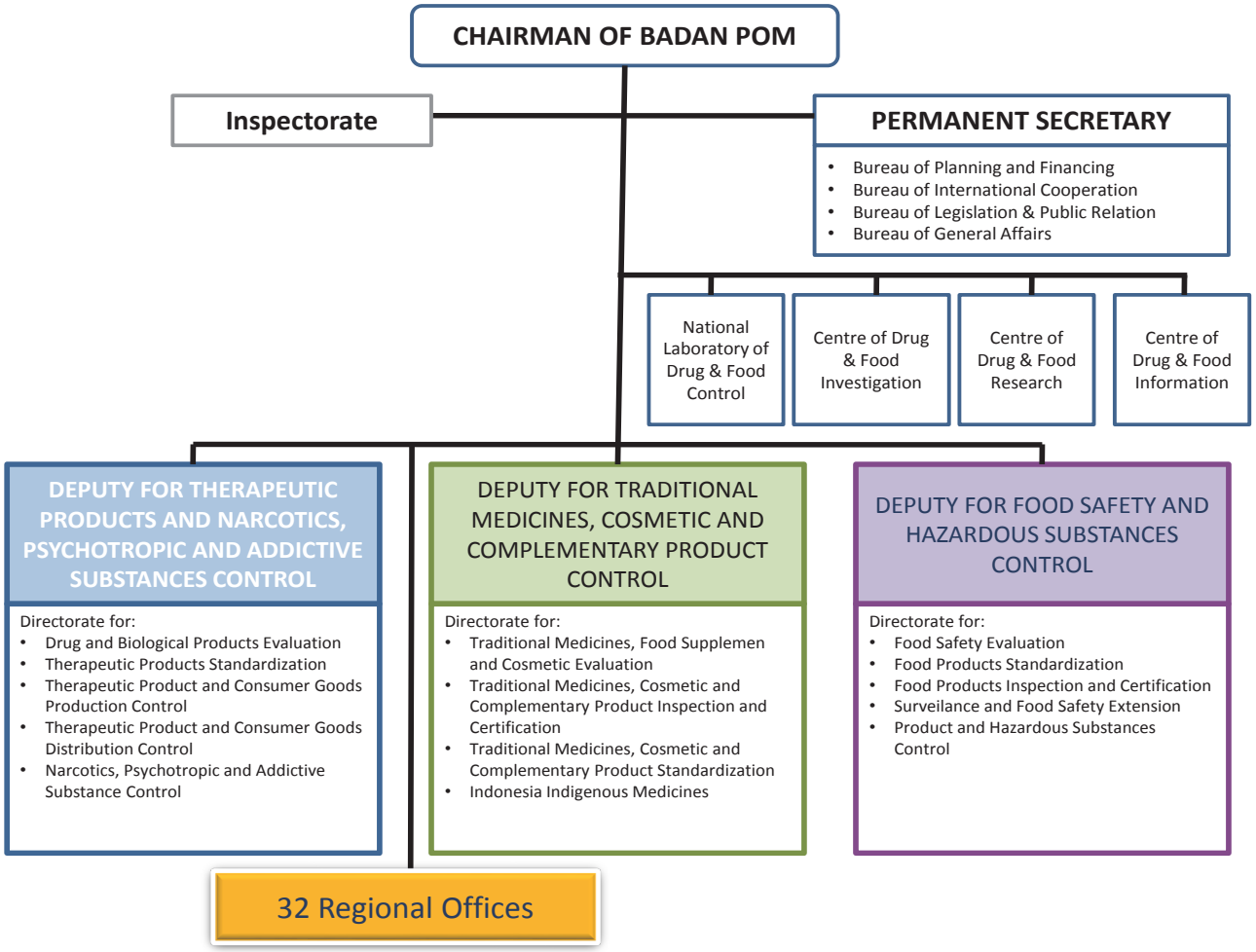
Tokyo, Japan
July 2016

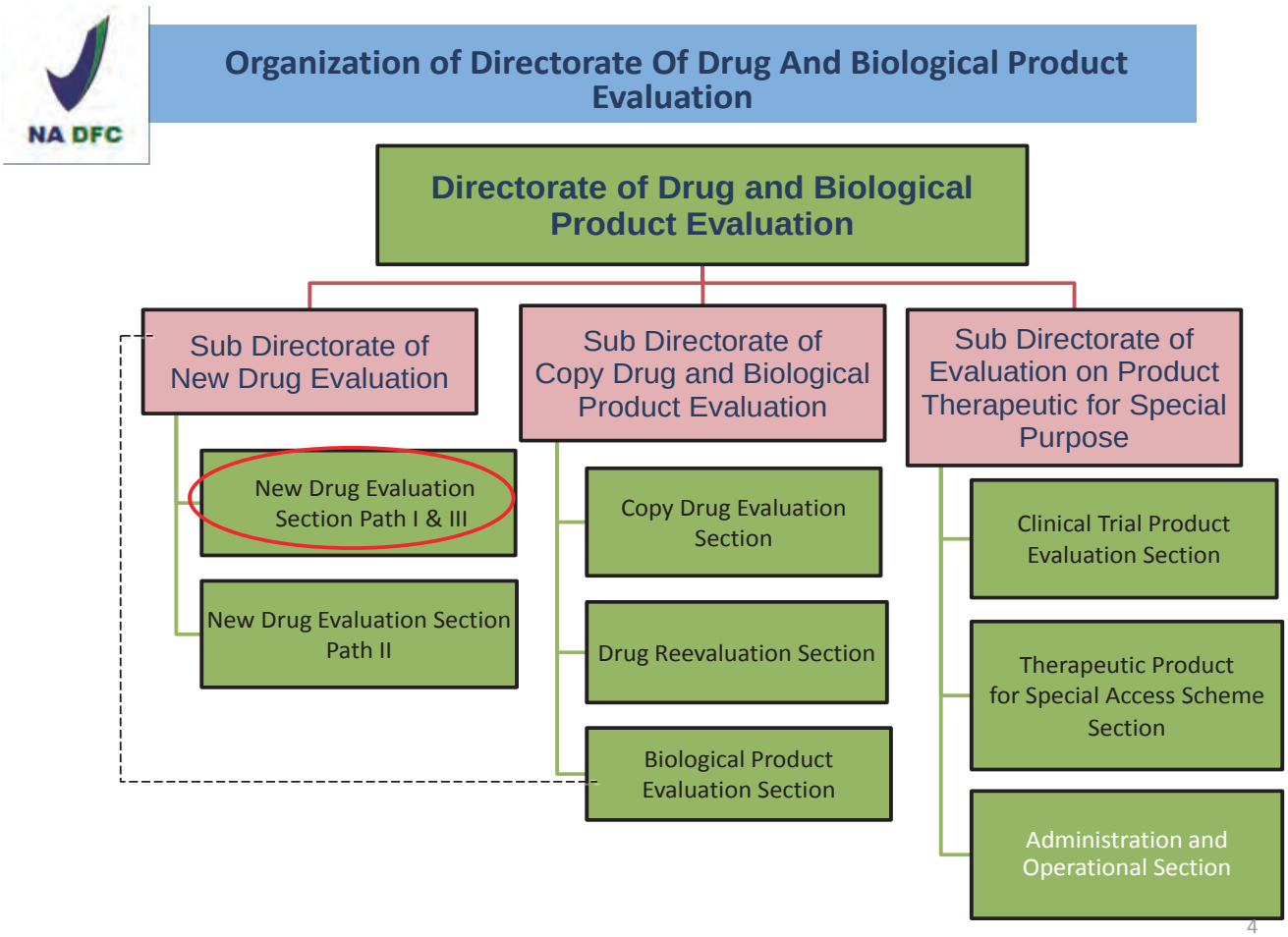
Vision

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

Mission

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


CHAIRMAN OF BADAN POM
Inspectorate
PERMANENT SECRETARY
Bureau of Planning and Financing
Bureau of International Cooperation
Bureau of Legislation & Public Relation
Bureau of General Affairs
National Laboratory of Drug & Food Control
Centre of Drug & Food Investigation
Centre of Drug & Food Research
Centre of Drug & Food Information
DEPUTY FOR THERAPEUTIC PRODUCTS AND NARCOTICS, PSYCHOTROPIC AND ADDICTIVE SUBSTANCES CONTROL
Directorate for:
Drug and Biological Products Evaluation
Therapeutic Products Standardization
Therapeutic Product and Consumer Goods Production Control
Therapeutic Product and Consumer Goods Distribution Control
Narcotics, Psychotropic and Addictive Substance Control
DEPUTY FOR TRADITIONAL MEDICINES, COSMETIC AND COMPLEMENTARY PRODUCT CONTROL
Directorate for:
Traditional Medicines, Food Supplemen and Cosmetic Evaluation
Traditional Medicines, Cosmetic and Complementary Product Inspection and Certification
Traditional Medicines, Cosmetic and Complementary Product Standardization
Indonesia Indigenous Medicines
DEPUTY FOR FOOD SAFETY AND HAZARDOUS SUBSTANCES CONTROL
Directorate for:
Food Safety Evaluation
Food Products Standardization
Food Products Inspection and Certification
Surveilance and Food Safety Extension
Product and Hazardous Substances Control
32 Regional Offices


NA DFC
Organization of Directorate Of Drug And Biological Product Evaluation
Directorate of Drug and Biological Product Evaluation
Sub Directorate of New Drug Evaluation
New Drug Evaluation Section Path I & III
New Drug Evaluation Section Path II
Sub Directorate of Copy Drug and Biological Product Evaluation
Copy Drug Evaluation Section
Drug Reevaluation Section
Biological Product Evaluation Section
Sub Directorate of Evaluation on Product Therapeutic for Special Purpose
Clinical Trial Product Evaluation Section
Therapeutic Product for Special Access Scheme Section
Administration and Operational Section
4

Drug Regulatory System in Indonesia

- Pre Market Control
- Post Market Control

CORE OF REGULATORY FUNCTION

Pre-Market

- Review and approval of medicinal products for clinical trials → *Clinical Trial Authorization (CTA); import permit*
- GMP (Good Manufacturing Practices) inspections of medicinal products manufacturers, including biologicals
- Benefit-risk assessment and approval of medicinal products, including biologicals → *Market Authorization*

Post-Market

- Safety monitoring & risk-benefit assessment of marketed products
- Risk communication & provision of unbiased information to healthcare professionals & consumers
- Quality surveillance of marketed products
- GMP and GDP (Good Distribution Practices) inspections
- Investigation & enforcement of regulation administered by NADFC
- Prosecution of offenders

PRE MARKET CONTROL

DRUG EVALUATION/ REGISTRATION

The Role of NADFC on Drug Registration

- **Regulation of the Minister of Health No.1010/MENKES/PER/XI/2008 on Drug Registration**
- **Decree of Head of NADFC No. HK.03.1.23.10.11.08481, 2011 on Criteria and Procedure of Drug Registration**

Therapeutic product to be marketed in Indonesia shall be registered through registration process in NADFC prior to ***Marketing Authorization***

ASEAN Guideline For Evaluation

- ASEAN Guideline on Submission of Manufacturing Process on Validation Data for Drug Registration
- ASEAN Guidelines for Validation of Analytical Procedures
- ASEAN Guideline on Stability Study of Drug Product
- ASEAN Guidelines for the Conduct of Bioavailability and Bioequivalence Studies
- The ASEAN Common Technical Dossier (ACTD) for the Registration of Pharmaceuticals for Human Use.
- ICH Guidelines
- WHO TRS Reports

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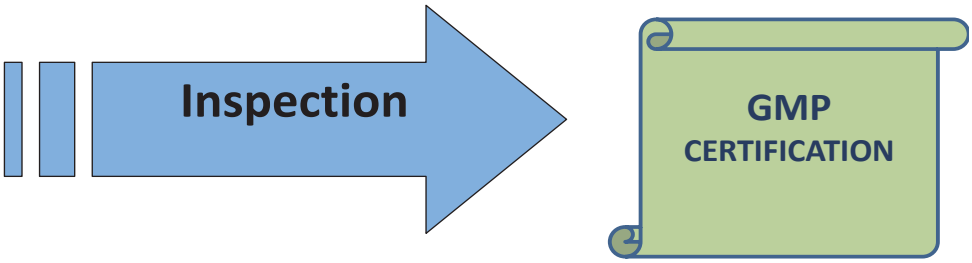
Good Manufacturing Practice



- Manufacturer should confirm with GMP requirements
- GMP Certificate will be given if the requirements is confirmed
- GMP Certificate is issued for each dosage form

NA DFC

WHO SHOULD APPLY?

Pharmaceutical Industries Located in Indonesia ➔MAH

How to apply registration for MA?

Pre-registration

* Determination of the registration category and evaluation path/timeline
* Consultation on completeness of registration dossier/document
* Registration Fee

Registration

* Submit registration dossier according to the registration category ,completed with bank receipt of registration fee

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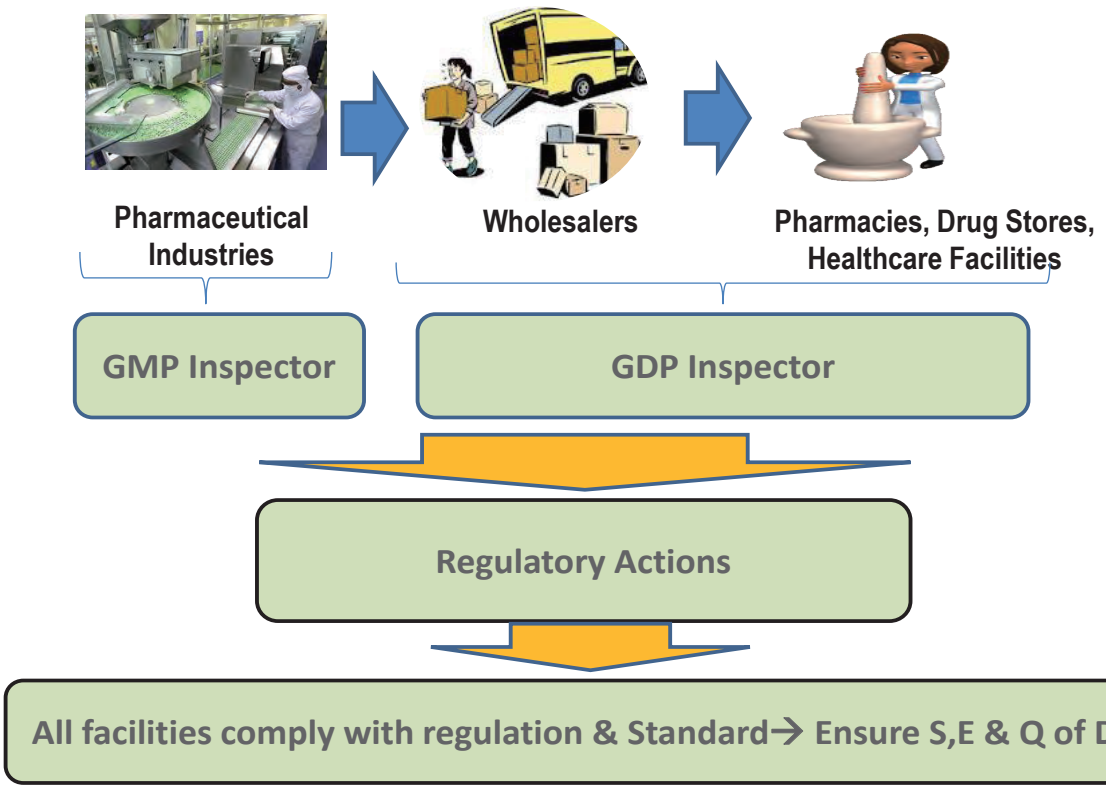
POST MARKET CONTROL

INSPECTION

INSPECTION



INSPECTION

Legislation	• National Law of Health No 36, 2009 • Government Regulation No 72 regarding Safeguarding of Pharmaceutical Product and Medical Devices • Ministry of Health Decree No 1799, 2010 regarding Pharmaceutical Industry • Ministry of Health Decree No 1148, 20101 regarding Wholesaler • Head of NADFC Regulation regarding Implementation of GMP & GDP.
Standards	• Indonesia GMP Code 2012 Edition • Indonesia GDP Code 2012 Edition • Operational Guidance for Industries • GMP Code for API Manufacturing Year 2009

Roles of Regulatory Systems and Pharmacists

Inception Report

Name : Windi Gusviani

Country : Indonesia

Organization/Division: National Agency of Drug and Food Control (NADFC)/ Directorate of Drug and Biological Product Evaluation

National Agency of Drug and Food Control Republic of Indonesia (NADFC) is assigned and Functioned as national regulatory authority on pharmaceutical administration in Indonesia.

Vision of NADFC: 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.

Organizational Chart

The organizational chart of NADFC at national & provincial offices (Attachment 1).
Organization of Directorate Of Drug And Biological Product Evaluation (Attachment 2).

Legislation on Pharmaceutical administration

In national level, legislation on pharmaceutical administration is conducted by Indonesia NADFC, under The Deputy of Therapetic Product and Narcotics, Psychotropic and Additive Substance Control. The technical implementation of drug control locally is conducted by NADFC regional offices in 32 provinces

Indonesia has become a PIC/S member No.41, effective since 1st July 2012.

Regulatory services

Regulatory services for pharmaceutical product are conducted by NADFC, under the Deputy of Therapeutic Products and Narcotics, Psychotropic and Addictive Substances Control, which responsible for the administration of:

<u>Drug distribution, drug import/export system</u>

Administered by : Directorate of Therapeutic Product Distribution Control Control (Sub-Directorate of Inspection and Certification of Distribution Facilities)

Standard : Indonesia GDP Code 2012 Edition

Pharmaceutical manufacturing
Administered by : Directorate of Therapeutic Product Production Control
Standard : Indonesia GMP Code 2012 Edition

Merketing authorization
Administered by : Directorate of Drug and Biological Product Evaluation
Standard : Regulation of the Minister of Health on Drug Registration, Decree of Head of NADFC on Criteria and Procedure of Drug Registration

Medicine safety (post-marketing)
Administered by : Directorate of Therapeutic Product Distribution Control (Sub-Directorate of Surveillance and Risk Analysis of Therapeutic Products, Sub-Directorate of Promotion and Labelling Control)
Standard : Decree of Head of NADFC on the Application of Pharmacovigilance for Pharmaceutical Industry

Pharmaceutical standardization
Administered by : Directorate of Therapeutic Product Standardization
Standard : Indonesia Pharmacopoeia 1995 Edition

Drug registration in Indonesia

The role and law of NADFC on Drug Registration
- Regulation of the Minister of Health No.1010/MENKES/PER/XI/2008 on Drug Registration.
- Decree of Head of NADFC No. HK.03.1.23.10.11.08481, 2011 on Criteria and Procedure of Drug Registration

  By these laws, Therapeutic product to be marketed in Indonesia shall be registered through registration process in NADFC prior to *Marketing Authorization.*

  In our country, Drug registration can only be registered by Pharmaceutical Industries located in Indonesia and they are as Marketing Athorization holder.

There are 2 stages of new registration which are pre-registration and registration.

a. **Pre-registration**

Pra registration should be done before registration. The purposes of this step are to determine the registration category, timeline, and registration fee. At this step, the applicant can also consult to the officers about the requirement that should be provided in registration dossier or document. After the pre registration step is finished, the applicant can proceed to the registration stage.

b. **Registration**

Submit registration dossier according to the registration category, completed with bank receipt of registration fee.

There are 3 (three) types of registration:

a. New registration, including new registraton for originator product, generic and other.
b. Variation registration, which is to register the product that has had approval but there are some changes in their product, such as labelling, production, source of material, etc.
c. Renewal, is the registration for product which the registration number has expired.

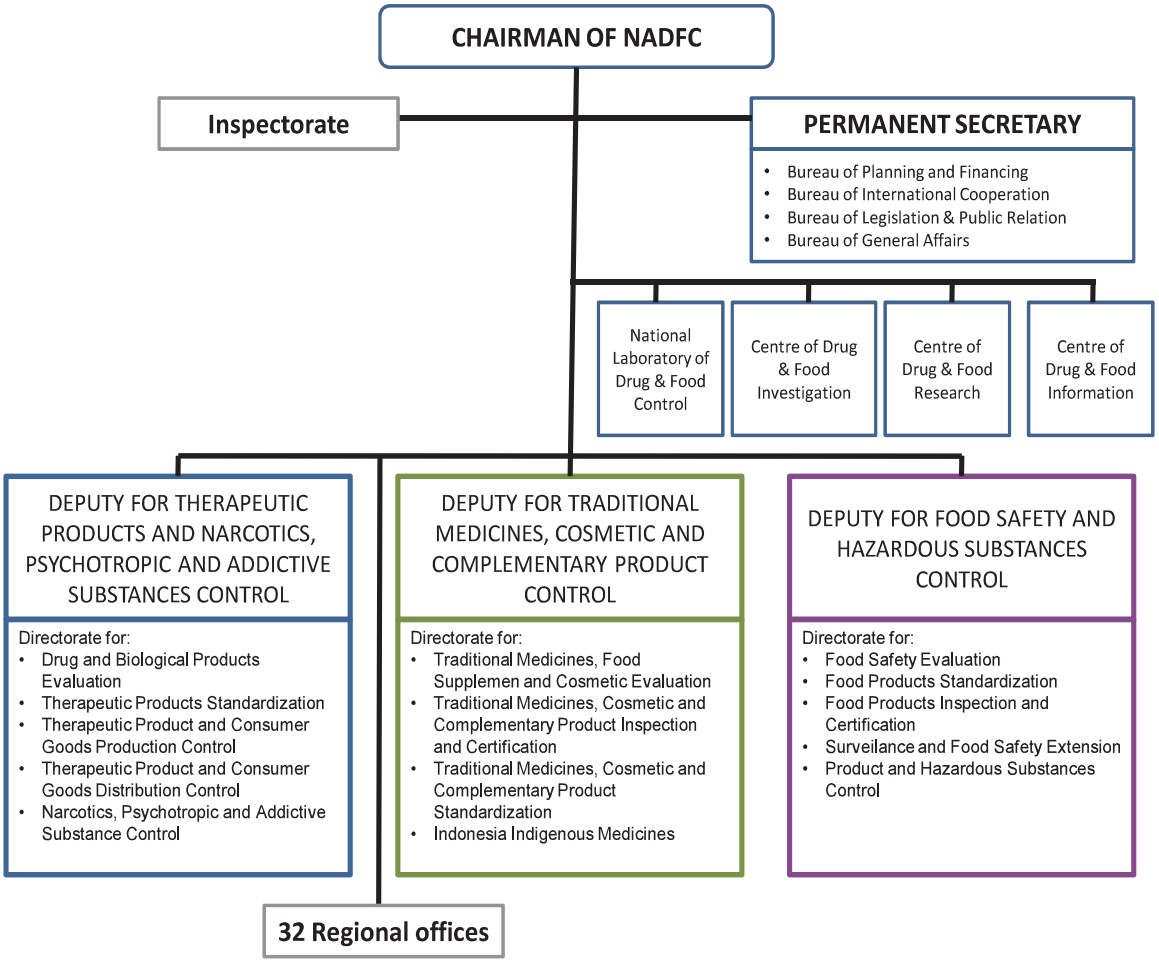
When the applicant register their product, they have to submit the dossier in ACTD format. ACTD dossier is harmonized registration dossier in ASEAN countries.

The approved product has a validity of marketing authorization not more than 5 years. It means, the validity can be less than 5 years, for example licensed or imported product, the validity of marketing authorization is depend on the aggrement between the applicant and the product owner. After that, the applicant or MAH has to renew their product if the product is still be marketed.

There are some guidelines that we use when we evaluate the dossier:

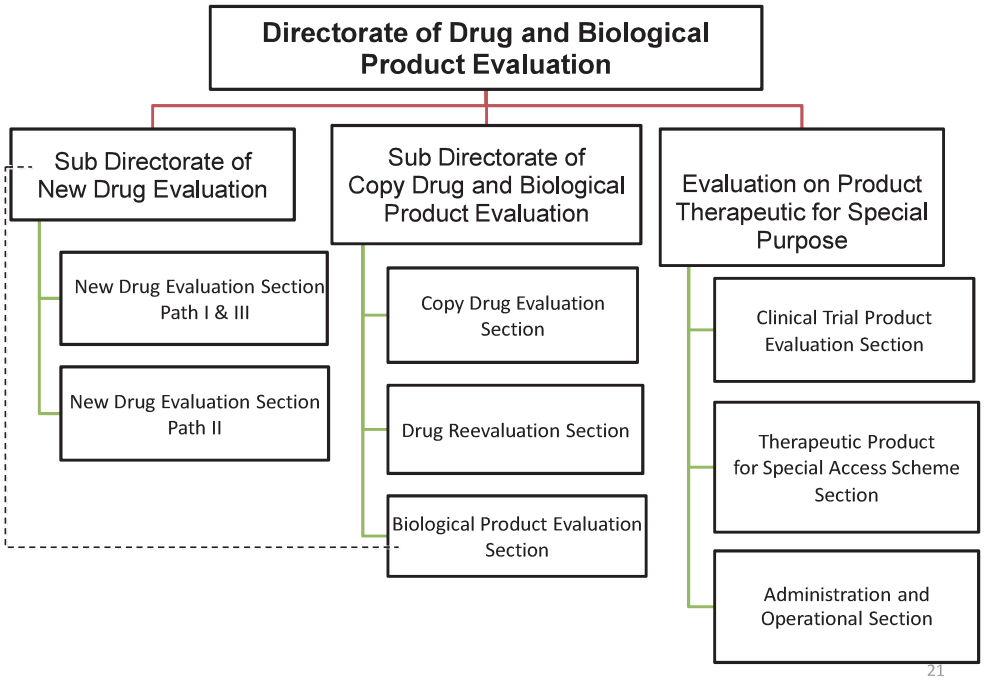
- ASEAN Guideline on Submission of Manufacturing Process on Validation Data for Drug Registration
- ASEAN Guidelines for Validation of Analytical Procedures
- ASEAN Guideline on Stability Study of Drug Product
- ASEAN Guidelines for the Conduct of Bioavailability and Bioequivalence Studies
- The ASEAN Common Technical Dossier (ACTD) for the Registration of Pharmaceuticals for Human Use.
- ICH Guidelines
- WHO TRS Reports

The organizational chart of NADFC at national & provincial offices



Attachment 2

Organization of Directorate Of Drug And Biological Product Evaluation



CHINA

Roles of Regulatory Systems and Pharmacists
on Ensuring Proper Access to Quality Assured Medicines（JFY 2016）

Inception Report

Name: Xuetao Wang	
Coui China	
Organization/Departm ent/Division:	National Health and Family Planning Commission/Department of Drug Policy and Essential

As indicated in the General Information, all participants are requested to prepare an inception report (Part Ⅰ and Part Ⅱ) and send it to JICA TOKYO and JICWELS (E-mail: ticthd@jica.go.jp, jigyo@jicwels.or.jp) by 27 June, 2016. Please include 'the course title' and 'course number (J1604254)' in the e-mail title.

【Notes】
・The report should be typed in English.

This report consists of two parts: Part I and Part I. The main purpose of this report is to collect information in regard to pharmaceutical regulatory services of your country and more to help each participant to understand and compare other countries' situations.
Your report given here will be shared with every participants to prepare for active discussions throughout the program.
In each part, "why, what, when and how"to be used is explained. Please follow the directions in each part.

Part I: INFORMATION SHARING

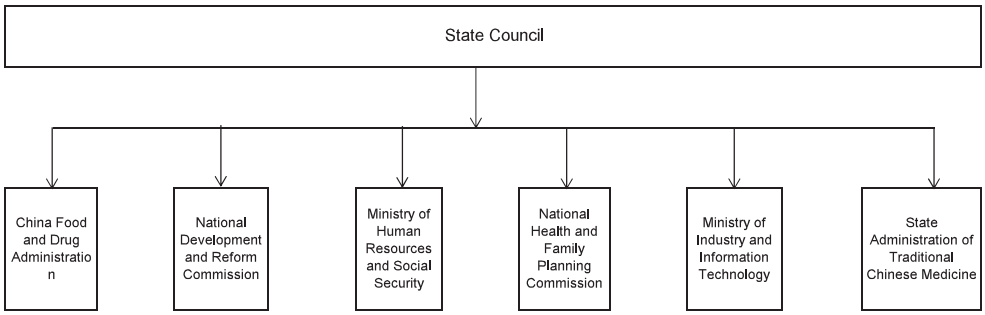
Why? → To clarify and share the basic information on each country and yourself among all participants.

What: → Information that overviews pharmaceutical administration framework/pharmaceutical management, services, relating laws and regulations in your country.

When → Prepare your own reports before coming to Japan, and share them with other participants at the arrival in Japan.

How? → Collect necessary information in your country and prepare reports, and presentation materials. Deepen understanding by comparison with other countries through presentation and discussions.

① **Organizational Chart**
–Please attach the organizational chart 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 to focus on the position of the pharmacist in medical institutions.



1 National Health and Family Planning Commission: Centralized procurement of medicines, rational clinical use of medicines, planning of pharmaceutical policy and update of essential medicine list, and gurantee of supply of medicines in shortage 2 China Food and Drug Administration: Approval for medicines, quality control (GSP and GMP), collection and release of adverse reaction reports, and exam for licensed pharmacists 3 National Development and Reform Commission: post-market price supervision 4 Ministry of Human Resources and Social Security: Update of basic medical insurance list, and formulation of reimbursed price 5 State Administration of Traditional Chinese Medicine: Planning of policy of traditional Chinese medicine 5 Ministry of Industry and Information Technology: Planning of pharmaceutical industry policy

② **Legislation on pharmaceutical administration**
–Please briefly bulletined major laws/acts
◆National Level
・Drug Administration Law administered by National People's Congress
administered by
administered by
◆Local Level
・ administered by
・ administered by

◆PIC/S
No

③ **Regulatory Services**
–Please describe pharmaceutical regulatory services of your country in response to each issues described below.
–It is recommended to add supplemental informations such as systems, regulations, responsible administrators, since you are expected to explain them to other participa

◆ Drug Import/Export
・ Systems, Regulations, etc
Management Procedures for Imported Drugs administered by China Food and Drug Administration, General Administration of Custor

	administered by	

◆ Pharmaceutical Manufacturing

・Systems, Regulations, etc

Good Manufacturing Practice	administered by	China Food and Drug Administration
Good Clinical Practice	administered by	China Food and Drug Administration
Good Laboratory Practice	administered by	China Food and Drug Administration
Regulations on the Protection of Types of Traditional Chinese Medic	administered by	China Food and Drug Administration

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

◆ Marketing Authorization

・Systems, Regulations, etc

Drug Registration Regulation	administered by	China Food and Drug Administration
Provision on Classification for Prescription and Non-Prescription Mec	administered by	China Food and Drug Administration

※Example: Good Quality Practice

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

・Systems, Regulations, etc

National Essential Medicine List New Rural Cooperative Medicial Scheme Reimbursement	administered by	National Health and Family Planning Commission
Regulations on Centralized Pharmaceutical Procurement by Public Medical Institutions	administered by	National Health and Family Planning Commission
Regulation on Internet Information Service for Medicines	administered by	China Food and Drug Administration
Measures for the Examination of Drug Advertisements	administered by	China Food and Drug Administration, State Administration for Industry & Commerce
Provisions for Supervision of Drug Distribution	administered by	China Food and Drug Administration
Good Supply Practice	administered by	China Food and Drug Administration
Basic Medical Insurance List and Reimbursement	administered by	Ministry of Human Resources and Social Security

※Example: Good Distribution Practice

◆ Medicine Safety (post-marketing)

・ Systems, Regulations, etc

Practice on Management of Prescriptions	administered by	National Health and Family Planning Commission
Good Preparation Practice for Medical Institutes	administered by	China Food and Drug Administration
Administrative Measures for Drug Recalls	administered by	China Food and Drug Administration
Regulations of Pharmacy Affairs for Medical Institutions	administered by	National Health and Family Planning Commission

※Example: Good Pharmacovigilance Practice

◆ Relief System for Adverse Drug Reactions

・ Systems, Regulations, etc

Measures for the Reporting and Monitoring of Adverse Drug Reactio	administered by	China Food and Drug Administration

④ **Drug Pricing**

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

Before 2015, there are three ways for drug pricing: (1) National Development and Reform Commission(NDRC) regulated price of drugs in basic medical insurance list (2) There was free pricing for non-reimbursed drug (3) There was price control over special medicines by NDRC . After 2015, the retail price cap of a majority of medicines was canceled, except medicines for public health and special medicines .

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	540,000	2014		
2: Number of GMP inspector (National & Local)		(YEAR)		
3: Number of pharmaceutical manufacturers / manufacturing sites			5000	2014
4: Number of traditional medicine manufacturers / manufacturing sites			1620	2016
5: Number of pharmaceutical importers		(YEAR)		
6: Number of pharmaceutical wholesalers	13200	2014		

⑥ **Information on your hospital pharmacy** ※hospital pharmacy only

(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?

_____ m^2

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

If "Yes", please describe it in detail

Yes / No

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:

⑦ Education and License of Pharmacists in your country ※hospital pharmacy only

(1) Number of years in primary, secondary and high school education
Primary _____ years
Secondary _____ years
High school _____ years

(2) Number of years / weeks in the following categories during university or college.
University / college: _____ years
Professional education: _____ years
Practical training: _____ years
Duration of training by each facility:
Hospital pharmacy: _____ weeks
Community pharmacy: _____ weeks
Pharmaceutical company: _____ weeks
Others: _____ weeks
Age at graduation: _____ years old

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

Academic Exams _____ days(only Academic exams)
_____

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.

The subjects are related to pharmacy or traditional medicines.

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

(5) Number of pharmaceutical university or college graduates:
_____ people / per year
The alumni's placement rate (%)
a. Hospital: _____ %
b. Community Pharmacy: _____ %
c. Government Organization: _____ %
d. Enterprise: _____ %
f. Others: _____ %

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.

Part II: INCEPTION REPORT PRESENTATION

Why? → *To make a presentations and discussions in order to understand each other and compare among the participants*

What? → *Report of the current situation about your work, your experiences to be shared and expectations to this program.*

When? → *Report presentation is held on the beginning of the program in Japan.(It is expected on July 15)*

How? → *Refer to the outline described below. It is strongly recommended to prepare with Power Point (PPT).*

【Notes】・Please prepare presentation within 10 slides.

・Each presentation is allocated about 15 min. including Q/A.

◆Presentation OUTLINE

Category A	Introduction of your work —Organization & department that you belong to —Job tenure Role and position of pharmacists in your country, etc —Please describe your regulatory services that you are engaged in.
Category B	Good Practice —Please describe your experiences about Good Practices *(Examples)* ・Achievements ・Solutions for past problems ・On-going projects to deal with current problems ・Successful countermeasures against problems
Category C	Difficulties/Lessons Learned from Past Experience —Please describe your experiences you have faced difficulties, or struggled; *(Examples)* ・Problems that cannot be improved or solved ・Failed countermeasures to deal with the problems ・Emerging or Re-emerging Problems, if any
Category D	Your interests —Please describe issues you are expecting to this program.(at maximum 3(three)

监管体系和药师作用培训班开班汇报

Course of Roles of Regulatory System and Pharmacists on Ensuring Proper Access to Quality Assured Medicines Inception Report Presentation

王雪涛 中国
China Xue tao Wang
2016. 07 Tokyo

汇报提纲

Outline of the presentation

01 情况介绍
Introduction of the work

02 良好实践
Good Practice

03 经验总结
Difficulties/Lessons learned from past experience

04 关注事项
Interests

情况介绍
Introduction

王 雪 涛
Wang xuetao
副巡视员
Deputy Inspector
药物政策与基本药物制度司
Department of Drug Policy & Essential Medicine
国家卫生和计划生育委员会
National Health and Family Planning Commission of P.R.C

职责： Roles and responsibilities

- 负责基层药学人员基本药物合理使用培训
  responsible for basic medicine personnel essential medicine rational use， making training plan
- 参与药物采购供应政策制定
  Participant in drug procurement supply policy-making

良好实践
Good Practice

培训项目例子 Training project example

- 设立基层医务人员培训项目，组织编写基本药物临床用药指南和处方集
  In 2011, Set up grassroots medical staff training project, Organizes compiling formulary and clinical practice guideline of essential medicine
- 解决基层医务人员没有规范培训教材和培训项目
  To solve no grassroots medical staff training project and standardized training materials
- 通过以上两个措施，提高处方质量，促进合理用药，确保用药安全
  Through the above two measures, improve prescription quality, promote rational drug use， ensure drug safety
- 继续加强基本药物临床用药指南和处方集培训工作
  At present, Continue to do formulary and clinical practice guideline of essential medicine training work

Formulary and Clinical Practice Guidelines (Chemical Drugs and Traditional Chinese Medicine)

2009

2012

经 验 总 结

Difficulties & Lessons

当前和重复出现问题

Current and Re-emerging problems

- 人员培训经费和制作教学光盘经费不足

  Insufficient funds for personnel training funds and teaching CD manufacturing。

- 培训模式单一，课堂教学为主。许多偏远地区没通网络,路远，经费不足，无法参加课堂和网上学习

  Training method is single，classroom teaching should be the priority. Many remote areas，no internet，no fund ,road is far，neither take part in the classroom learning ，nor can online learning

- 缺乏培训评估标准，难以了解掌握培训真实效果

  Lacking of training evaluation criteria ，it is difficult to grasp training actual effect

关注事项
Interests

- 日本在药师培训方面的经验、模式、方法和经费来源

  Experience, mode, method and funding source in training pharmacists in Japan

- 日本《药师法》的主要内容和立法经验

  Main content and legislation experience of Pharmacist's Law in Japan

- 日本药品采购方法、报销方式

  Drug procurement supply approach and drug reimbursement in Japan

MYANMAR

Ministry of Health and Sports Myanmar

Department of Food and Drug Administration, Myanmar

Roles of Regulatory Services and Pharmacists on Ensuring Proper Access to Quality Assured Medicine

(J 16-04254)

Inception Report

Part 1

Country Profile

Location

The Republic of Union of Myanmar is the westernmost country in South East Asia. It located on the Bay of Bengal and Andaman Sea. It is bordered by the Lao, Thailand, Republic of China, Republic of India, and Republic of Bangladesh.

Geography

The country is divided administratively into

- Naypyidaw Union Territory
- 7 Regions
- 7 States

It consists of (70) Districts, (330) Townships, and (84) Sub-townships.

Demography

The current population of **Myanmar (formerly Burma)** is **54,346,162** as of Saturday, June 18, 2016, based on the latest United Nations estimates. About 70.4% of the population resides in the rural whereas the remaining are urban dwellers.

Religions

The Republic of the Union of Myanmar is made up of (135) national races speaking over 100 languages and dialects.

Organization

Ministry of Health

The Ministry of Health (MOH) is the major organization responsible for upgrading the health status of the people and accomplishes this through provision of comprehensive health services: promotive, preventive, curative and rehabilitative measures.

The Ministry of Health is headed by the Union Minister. The ministry has six functioning departments, each under a Director General. They are

- Department of Public Health
- Department of Medical Services
- Department of Medical Research
- Department of Health Professional Resource Development and Management
- Department of Traditional Medicine
- Department of Food and Drug Administration

The Ministry of Health laid down the following objectives

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:

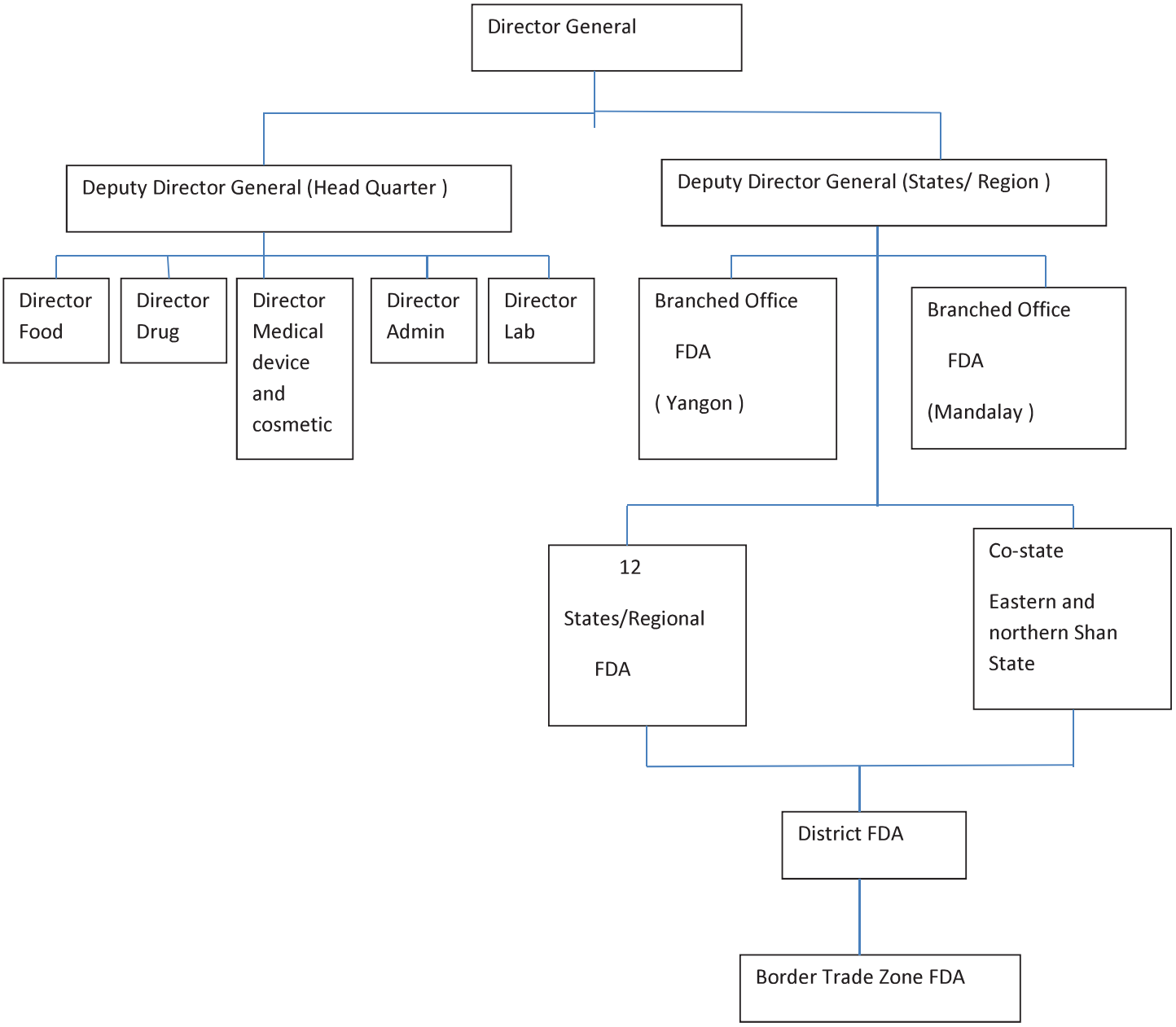
1. Widespread disseminations of health information and education to reach the rural areas.
2. Enhancing disease prevention activities
3. Providing effective treatment of prevailing

Department of Food and Drug Administration

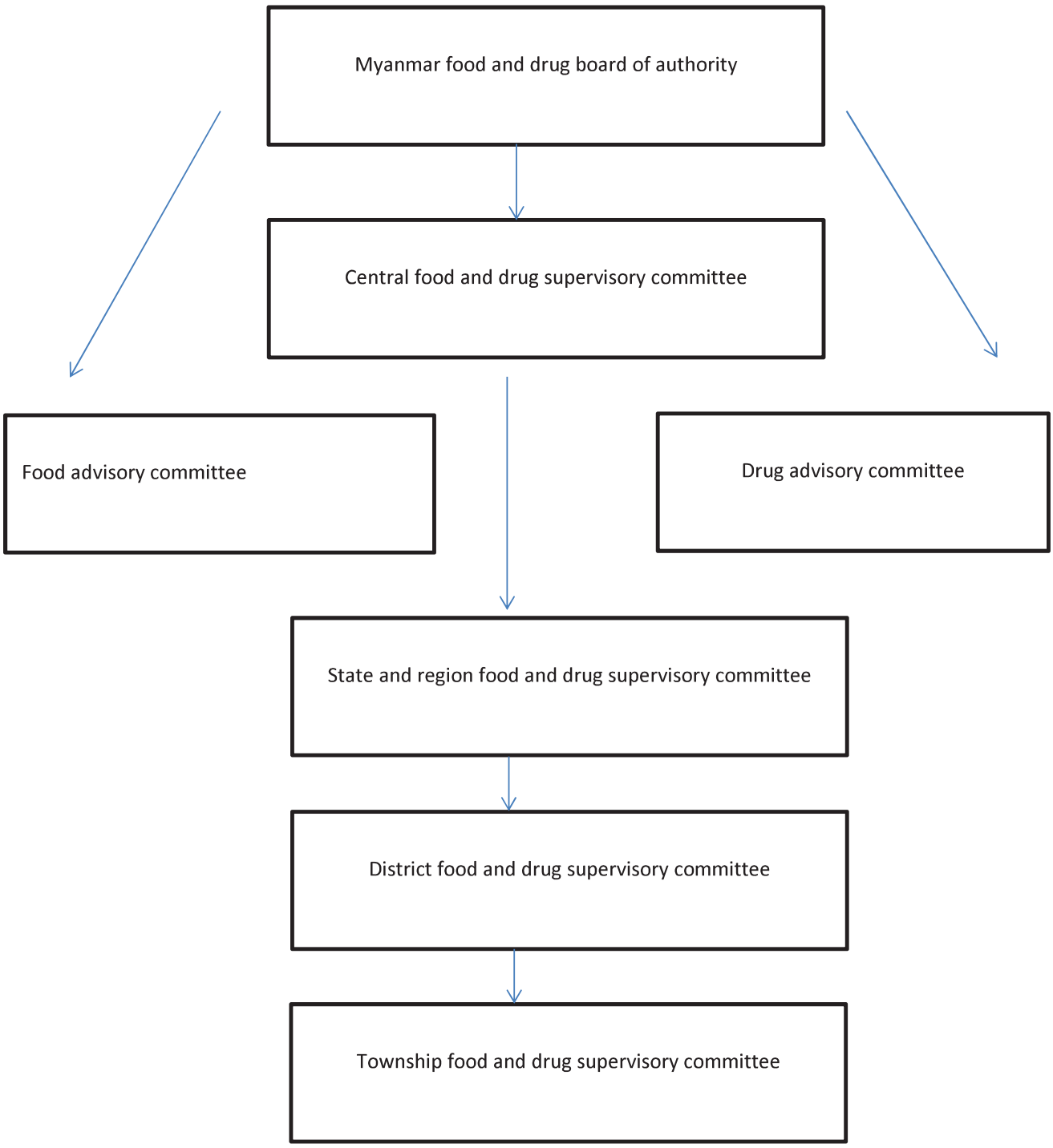
The Food and Drug Administration (FDA) was established in 1995 as one of the divisions under the Department of Health. The FDA division was upgraded to a separate department in April, 2013. The aim of the department is to ensure the safety and quality of Food, Drugs, Medical Devices and Cosmetics in the country. FDA Headquarter is located in Nay Pyi Taw, the capital city of Myanmar, with five major divisions:

Administrative division, Drug Control division, Food Control division, Cosmetic and Medical Device Control division and Laboratory division while preexisting Yangon and Mandalay branches acting are still as major branches, control activities have greatly expanded with the establishment of new FDA branches in other Regions and State. In addition, FDA has also established branches in important border trade zones such as Muse, Kalthaung, Myawaddy, Tamu, and Tachileik.

Department of Food and Drug Administration – Organization Chart



Food and drug supervisory committee



Legislation

Pharmaceutical administration is based on

No.	Law	Year
1.	Public Health Law	1972
2	National Drug Law	1992 (April 2014)
3	Narcotic Drugs and Psychotropic Substances Law	1993
4	Traditional Drug Law	1996
5	National Food Law	1997

Part 2

Regulatory Services

Food Control Section

FDA is responsible for issuing Health Recommendation for local food manufacturing business, import and export recommendation, and import and export Health Certificate.

Drug Control Section

Drug control sesction has both pre and post market control activities. They are -

(1) Marketing authorization for new products, Renewal Registration and variation of existing authorization

(2) Good manufacturing practice inspection and licensing of manufacturers.

(3) Good Storage & Good distribution Practice Inspection of Importer.

(4) Post market Surveillance

(5) Adverse drug reaction monitoring

(6) Training of inspectors and reviewers and Health Education to public

Currently there are about 208 drug importers and 19,400 drugs are registered at Myanmar FDA. Food and Drug Administration takes the enforcement and legal action to illegal drug Importers as well as Drug Sellers/ Pharmacies. FDA also notified to public and health care professional for counterfeit and unregistered medicine as alert notice.

Medical Devices / Cosmetics Control Section

Medical Device/Cosmetics control division has issued the notification and import recommendation for medical devices, acknowledgement of cosmetic notification and import recommendation for oral hygiene products. Moreover, FDA has been conducting the Good Manufacturing Practices inspection and issues Manufacturer License for disposable syringes & Certificate of Cosmetic manufacturer. During 2014, FDA has issued 788 import recommendations for disposable medical devices, 163notification of import recommendation for rapid diagnostic test kits, 19 notification of importer commendation for medical devices, one manufacturing license for disposable syringes, (844) acknowledgement of cosmetic notification, 135 import recommendation for oral hygiene products and 6 certificate of cosmetic manufacturer. The post market cosmetic samples 90 have been tested not only in cosmetic quality control laboratory but also by test kits as spot test during 2014.

Laboratory Section

FDA has three main laboratories, one each in Yangon, Nay Pyi Taw and Mandalay. Food laboratory in Yangon is mainly responsible for quality and safety of local, import and export products. Drug laboratory in Nay Pyi Taw carries out quality assessment and efficacy of all imported drugs including post marketing samples according to United State Pharmacopoeia and British Pharmacopoeia. Water and alcohol beverages for import licensing and samples submitted for licensing of manufacturers are tested in food laboratory, Nay Pyi Taw. Post marketing samples of food and drugs are investigated in food and drug laboratories of Mandalay. Medical devices and Cosmetics are tested in Nay Pyi Taw laboratory. There is a plan for drug laboratory to upgrade into WHO prequalification standard. It is also planned for food laboratory to obtain accreditation laboratory (ISO 17025).

Laboratories are responsible for screening and identification of harmful substances and microorganisms in water and food according to standard guidelines (eg. CODEX and AOAC). Quality assurance of drugs, medical devices and cosmetics are performed according to United State Pharmacopoeia, British Pharmacopoeia and ASEAN Cosmetic Methods.

Mini-laboratory services were established at Muse 105 miles Border trade Zone (near the China border), Myawaddy Border trade Zone (near the Thailand border), Tachilake Border trade Zone(near the Thailand border) and Tamu Border trade Zone(near the India border) in 2013.

Kawthaung, Myeik and Chin Shwe Haw border trade zone branches have been established in 2014. Mini-laboratories have also been set up at FDA offices in 12 States/Regions of the country. Mini-laboratories were established following international standards as per guidance of United State Pharmacopoeia and they can detect counterfeit and substandard drug in 42 items of drugs including anti-malaria, anti-tuberculosis, anti-microbial and some analgesics.

FDA closely collaborates and cooperates with other Ministries including Ministry of Commerce, Ministry of Home Affairs, Ministry of Information, Department of Custom and also with City Development Committees for control of imported food, drugs, medical devices and cosmetics

Statistic Data

1	No. of Pharmacist	M Pharm – about 80 B Pharm – about 3000
2	No. of GMP Inspectors	10-20
3	No. of Pharmaceutical Manufacturers Manufacturing Sites	(8) Yangon, Pyin Oo Lwin,Kyaut Sae, Sagaing
4	No. of Traditional Medicine Manufacturers Manufacturing Sites	About 100
5	No. of Pharmaceutical Importer	208
6	No. of Pharmaceutical Wholesalers	>700

Current issues in Myanmar

- Man power shortage to implement all the required activities
- Infrastructures are not enough for all sections (lab, devices, and machines)
- Weak in stake holders' collaborations
- Constraint in awareness of public for food and drug safety in remote areas.
- Illegal drug and unregistered drug trade is still existing in Myanmar

My Interest

- Quality assurance system of the Pharmaceuticals
- Good Pharmacy Practice

Inception Report

Myanmar

By

Dr. Su Thiri Hnin

Republic of Union of Myanmar

Location

- The westernmost country in South East Asia
- It located on the Bay of Bengal and Andaman Sea.
- It is bordered by the Lao, Thailand, Republic of China, Republic of India, and Republic of Bangladesh.

Geography

Divided into

- Naypyidaw Union Territory
- 7 Regions
- 7 States

Consists of

- (70) Districts
- (330) Townships
- (84) Sub-townships

Demography

- Population - over 54 millions
- About 70.4% of the population resides in the rural whereas the remaining are urban dwellers.

Religions

The Republic of the Union of Myanmar is made up of (135) national races speaking over 100 languages and dialects.

Ministry of Health & Sports

- Department of Public Health
- Department of Medical Services
- Department of Medical Research
- Department of Health Professional Resource Development and Management
- Department of Traditional Medicine
- Department of Food and Drug Administration

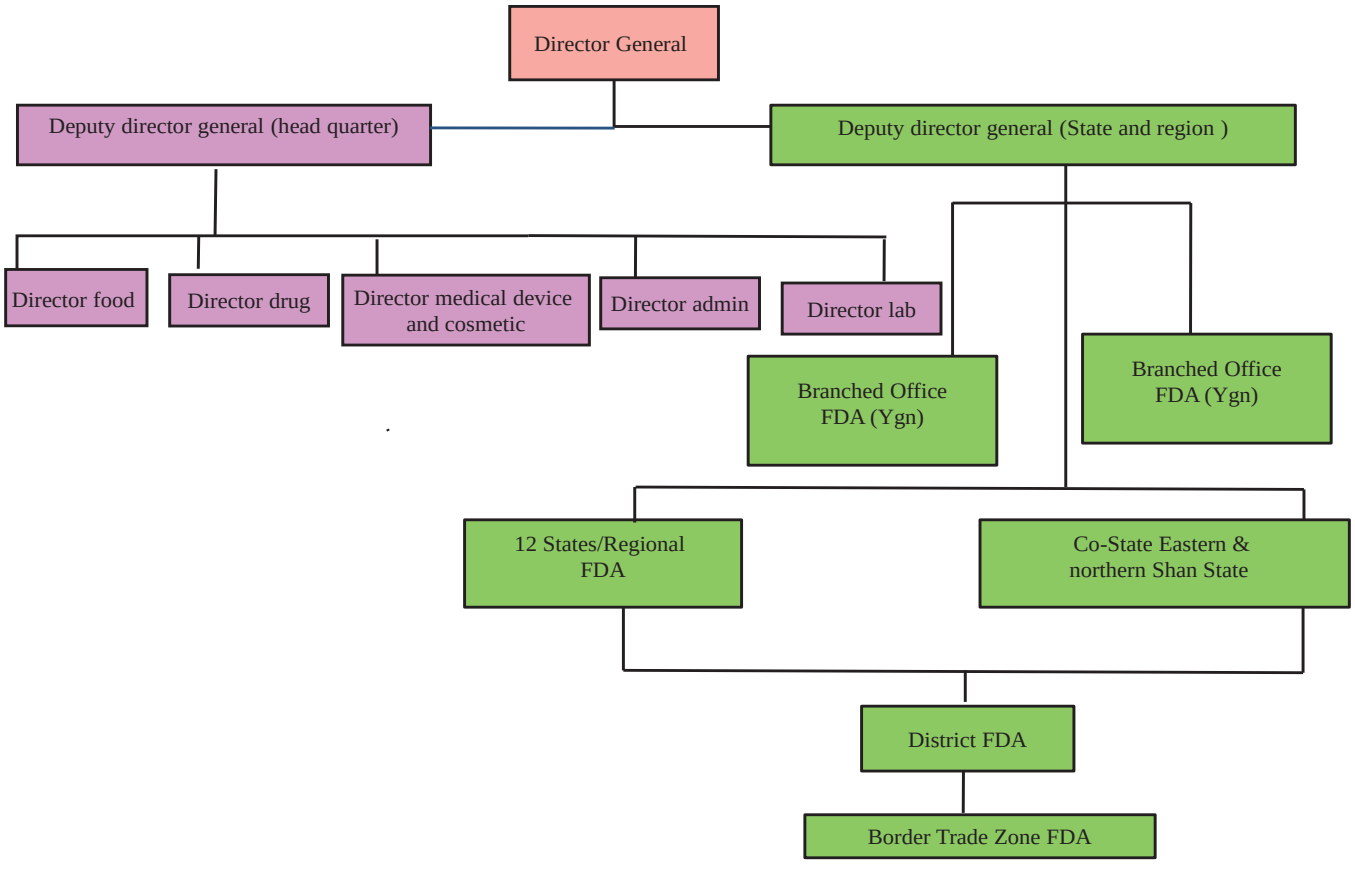
Department of Food and Drug Administration

- Established in 1995 as one of the divisions under the Department of Health
- Upgraded to a separate department in April, 2013
- Aim: to ensure the safety and quality of Food, Drugs, Medical Devices and Cosmetics in the country

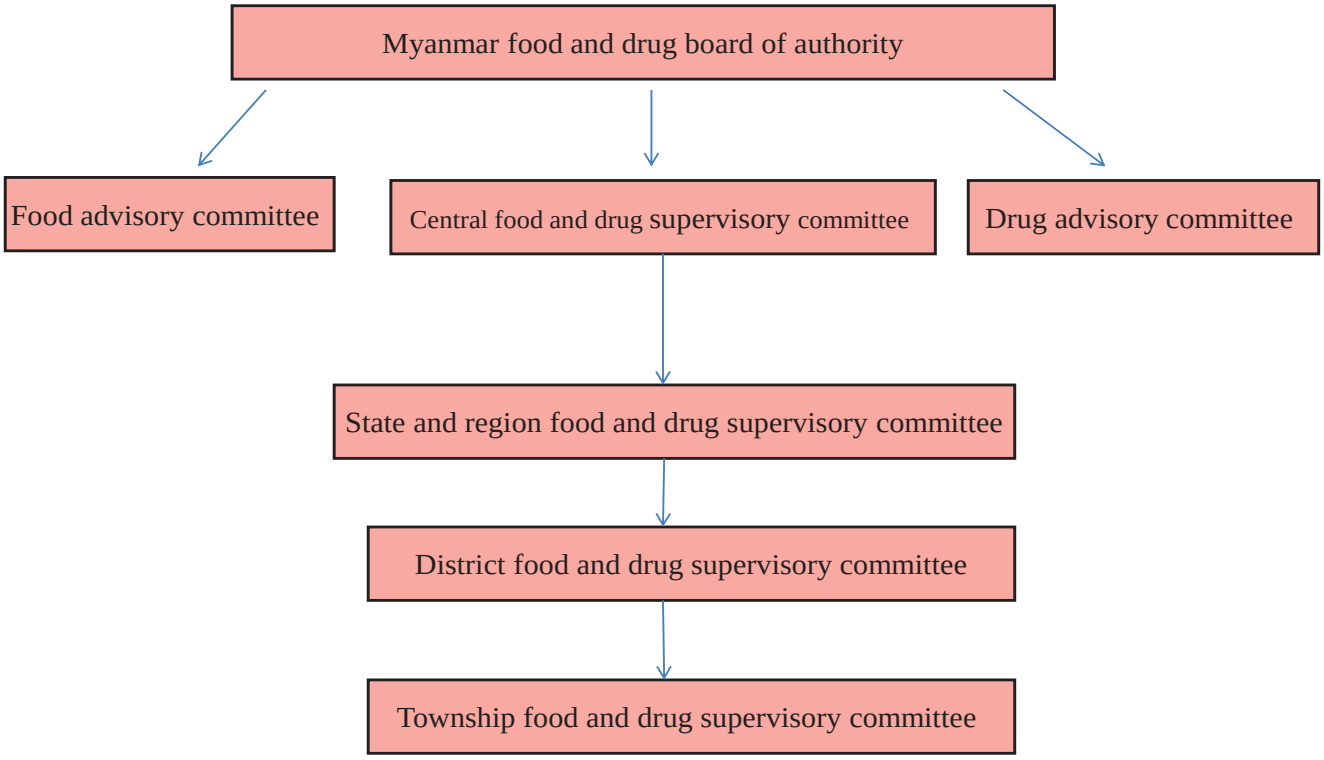
Department of Food and Drug Administration

- Headquarter: Nay Pyi Taw with five major divisions:
- Yangon and Mandalay branches
- New FDA branches in other Regions and States
- Important border trade zones: Muse, Kalthaung, Myawaddy, Tamu, and Tachileik.

Department of food and drug administration – organization chart



Food and drug supervisory committee



Legislation

No.	Law	Year
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Regulatory Services

Food Control Division

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Drug Control Division : pre and post market control activities

(1) Marketing authorization for new products, Renewal Registration and variation of existing authorization

(2) Good manufacturing practice inspection and licensing of manufacturers.

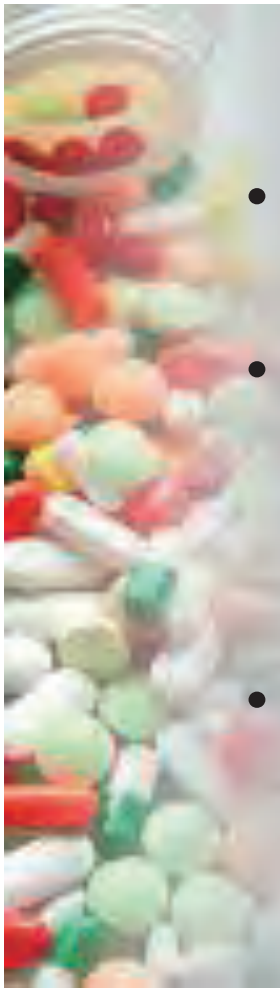
(3) Good Storage & Good distribution Practice Inspection of Importer.

(4) Post market Surveillance

(5) Adverse drug reaction monitoring

(6) Training of inspectors and reviewers and Health Education to public

(7)Mini-laboratory services in State & Region



Regulatory Services

- Registered drugs: 208 drug importers and 19,400 drugs
- Food and Drug Administration takes the enforcement and legal action to illegal drug Importers as well as Drug Sellers/ Pharmacies.
- FDA also notified to public and health care professional for counterfeit and unregistered medicine as alert notice.

Regulatory Services

Medical Devices / Cosmetics Control Section

- issued the notification and import recommendation for medical devices, acknowledgement of cosmetic notification and import recommendation for oral hygiene products
- conducting the Good Manufacturing Practices inspection and issues Manufacturer License for disposable syringes &Certificate of Cosmetic manufacturer.

Regulatory Services

Laboratory Section

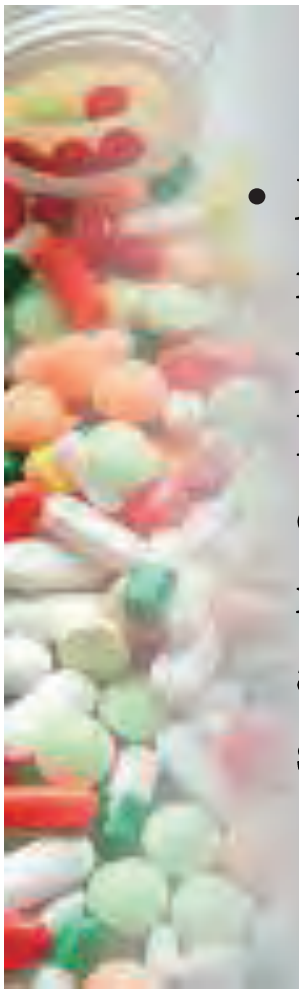
- FDA has three main laboratories, one each in Yangon, Nay Pyi Taw and Mandalay.
- Food laboratory in Yangon is mainly responsible for quality and safety of local, import and export products

Regulatory Services

- Drug laboratory in Nay Pyi Taw carries out quality assessment and efficacy of all imported drugs including post marketing samples according to United State Pharmacopoeia and British Pharmacopoeia
- Quality assurance of drugs, medical devices and cosmetics are performed according to United State Pharmacopoeia, British Pharmacopoeia and ASEAN Cosmetic Methods

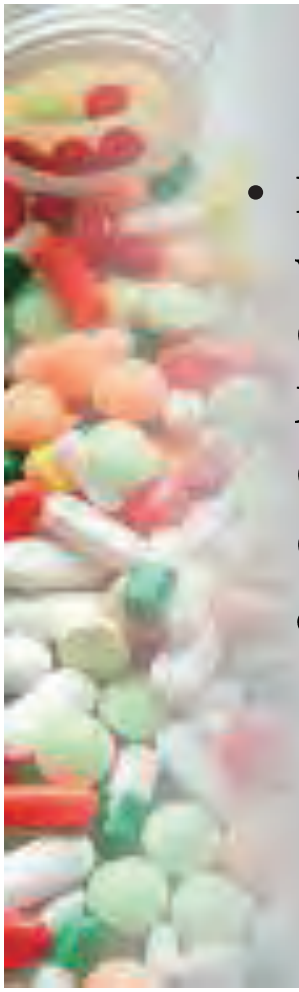
Regulatory Services

- Mini-laboratory services were established at Muse , Myawaddy , Tachilake and Tamu Border trade Zone in 2013
- Kawthaung, Myeik and Chin Shwe Haw border trade zone branches have been established in2014 Mini-laboratories have also been set up at FDA offices in 12 States/Regions of the country



Regulatory Services

- Mini-laboratories were established following international standards as per guidance of United State Pharmacopoeia and they can detect counterfeit and substandard drug in 42 items of drugs including anti-malaria, anti-tuberculosis, anti-microbial and some analgesics

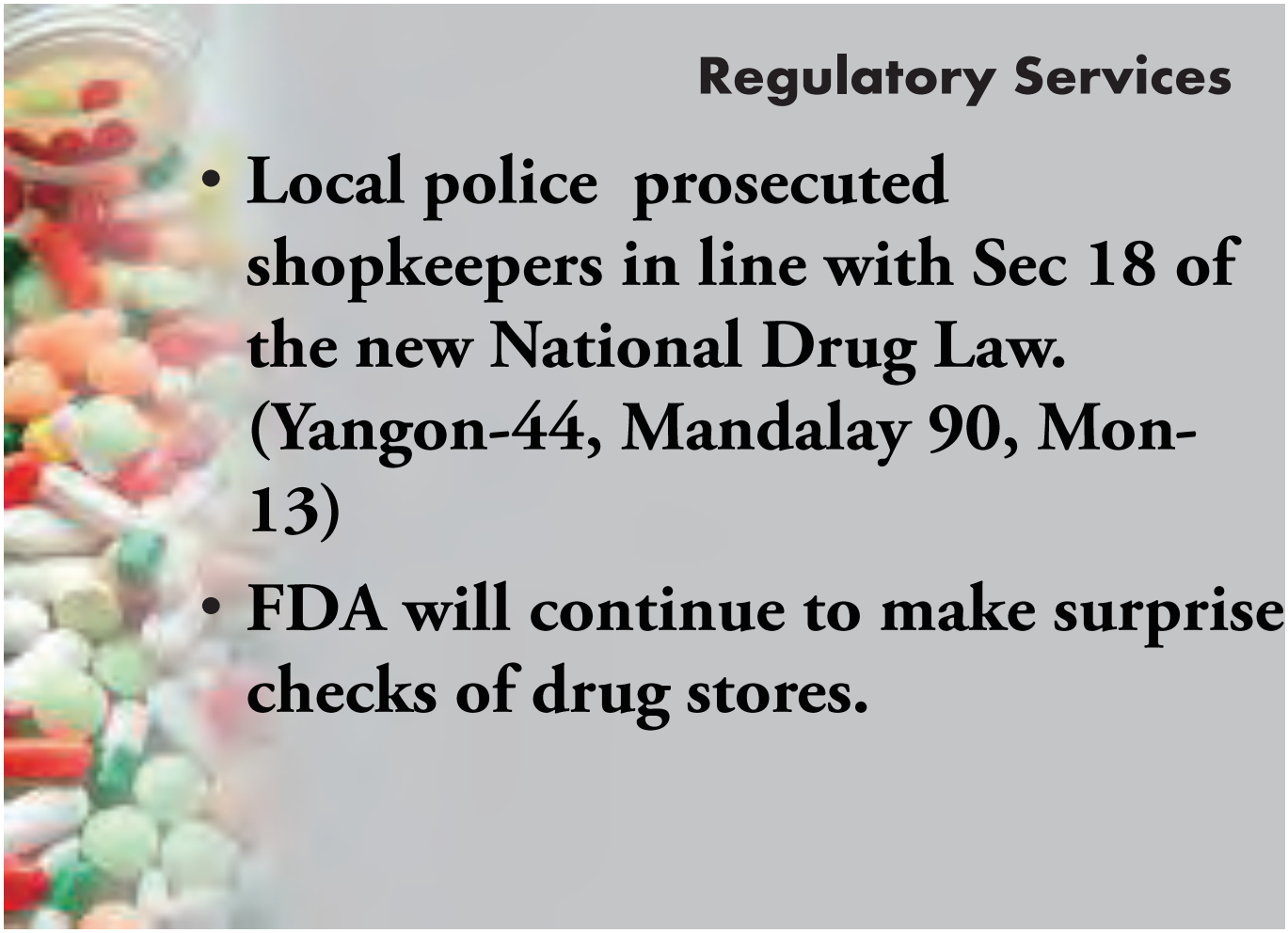


Regulatory Services

- FDA closely collaborates and cooperates with other Ministries including Ministry of Commerce, Ministry of Home Affairs, Ministry of Information, Department of Custom and also with City Development Committees for control of imported food, drugs, medical devices and cosmetic

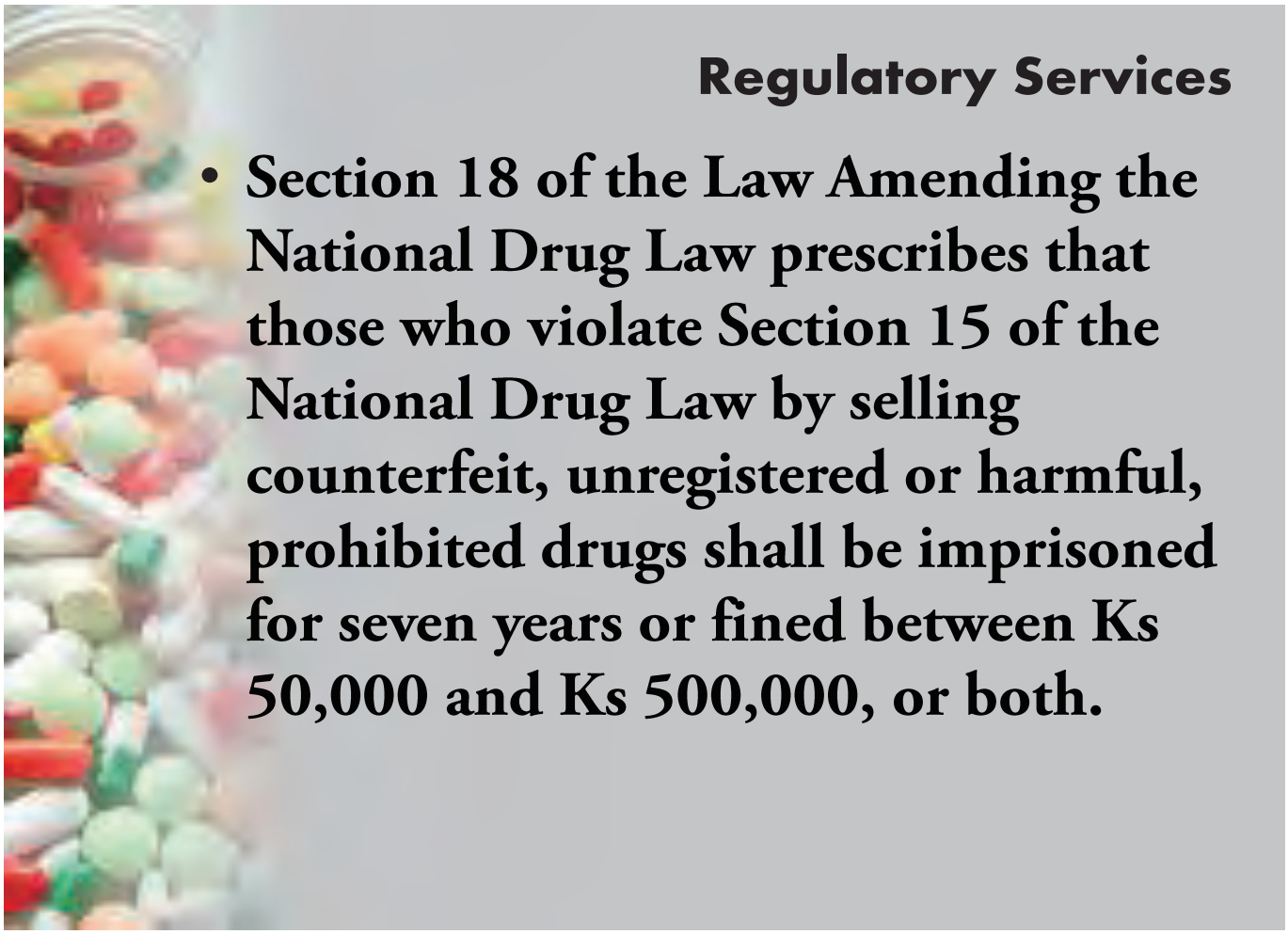
Regulatory Services

- Online Operation Pangea IX
- Nationwide project in cooperation with Interpol and Myanmar Police Force, City Development Committee, an Anti- Narcotic Drug Squad and the Customs and the General Administrative together with the FDA
- To combat counterfeit and illegal drugs that are not registered in Myanmar
- To prevent selling of unlicensed and expired drugs



Regulatory Services

- Local police prosecuted shopkeepers in line with Sec 18 of the new National Drug Law. (Yangon-44, Mandalay 90, Mon-13)
- FDA will continue to make surprise checks of drug stores.



Regulatory Services

- Section 18 of the Law Amending the National Drug Law prescribes that those who violate Section 15 of the National Drug Law by selling counterfeit, unregistered or harmful, prohibited drugs shall be imprisoned for seven years or fined between Ks 50,000 and Ks 500,000, or both.

Good practices
counters measure against the fake drugs

Good practices
Market Survey (GSP, GPP Inspection)

Good practices
Notify the public


www.fdamyanmar.gov.mm/index.ph

Ministry of Health, Union of Myanmar

Food and Drug Administration, Myanmar
Quality, Safety and Protection

FDA Myanmar Website is officially launched at 10:26 AM September 18, 2015.

HOME ORGANIZATION NEWS & EVENT FOOD DRUG COSMETIC MEDICAL DEVICES LAB REGULATION
GUIDELINE PUBLIC COMMUNICATION

Details
Created on Monday, 13 June 2016 14:52
Published on Monday, 13 June 2016 14:52
Hits: 158

၁၄	Compound Ketoconazole Cream	
၂၈	Chlorpheniramine Tablets (Chlorpheniramine maleate 4mg)	K.B P'cal Co. Ltd, Bangkok
၂၈	Cleatrin Powder (Neomycin sulphate BP 3300units/g, Bacitracin Zinc BP 250 units/g)	GlaxoSmithKline Pakistan Ltd. Karachi
၃၀	Chloramphenicol Capsules (Chloramphenicol BP 250mg)	Jiangxi LB P'cal Co. Ltd. P.R.China
၅၀	Chloramphenicol Palmitate Oral Suspension BP [Chloramphenicol 125mg (as Chloramphenicol palmitate BP)]/5ml	Torque P'cals (P) Ltd
၆၀	Buscopan Tablets (Hyoscine Butylbromide BP 10mg)	Merck(PVT) Ltd, Pakistan
၇၀	Analjin-500 Tablet (Metamizole sodium 500mg)	Shanxi Hengruida P'cal Co., Ltd.
၈၀	Nifedipine Tablet 10mg	Lin Fen Bao Zhu P'cal Co. Ltd.
၉၀	Cycovit 25 Tablets [(Vitamin B_{12} (Cyanocobalamin25mcg)]	Chalermchai Ltd, Partnership
၁၀၀	Piyenchin Solution 10ml (Naphazoline HCl solution 1:1000)	Jiangxi Xier Kangtai P'cal Co. Ltd.

Details
Created on Wednesday, 11 May 2016 17:45
Published on Wednesday, 11 May 2016 17:45
Hits: 341

Good practices
Mini-laboratory services

Good practices
Management of expired products

Good practices
Management of expired products

Good practices
Trainings

Good practices
Public awareness

Good practices
Public awareness

Challenges

- Man power shortage
- Infrastructures are not enough for all Sections (lab, devices, and machines)
- Constraint in awareness of public for food and drug safety in remote areas.
- Illegal drug and unregister drug trade are still existing in Myanmar.
- Weak in stake holders' collaborations

SRI LANKA

Annex 1

Roles of regulatory systems and pharmacists on ensuring proper access to quality assured medicines (JFY 2016)

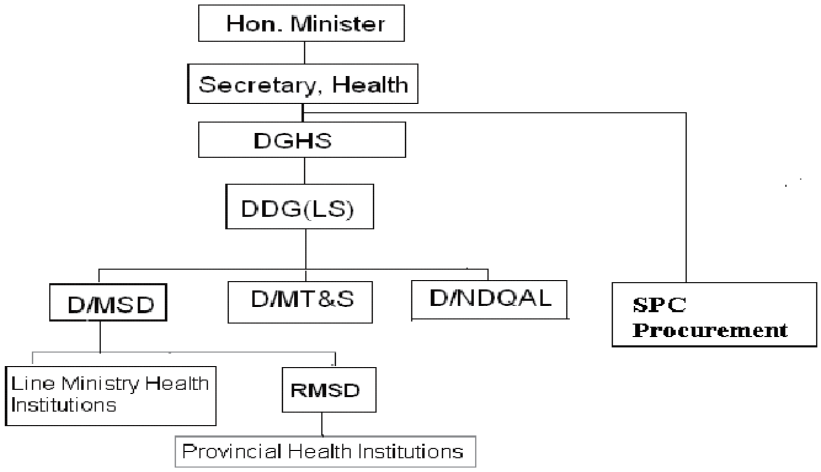
Inception Report

Name: R. M. R. M. Ranasingha
Country: Sri Lanka
Organization: State Pharmaceutical Manufacturing Corporation of Sri Lanka

1. Overview of country and organization

Sri Lanka is an Island in South Asia surrounded by the Indian Ocean with a Population about 21 million and 65610 sq. Km land. Politically it is a country governs by parliament Democracy and headed by the Executive President selected by adult citizens of the country.
Sri Lanka is practicing a Government provided free Healthcare System which is providing Healthcare facilities (including the Hospital care) to people irrespective of their wealth , income or social status. Apart from the Government Healthcare system, there are private Healthcare institutions also operating all over the country where patients have to access only on payments. Majority of the pharmaceuticals (Western Medicines) are coming as imports to the country and comparatively few items are manufactured by local manufacturers.

1.1 Organizational chart at National/State and Local level on pharmaceutical administration



- **Minister of Health**- Policy making such as introducing necessary amendments to the act and making regulations.
- **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.
- **DDG (LS)**- Deputy Director General of Laboratory Services

- **Medical Supplies Division**-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 Medical Technology and Supply (D/MT&S)** -Issuing of certificates of registration of the drugs and licenses to import, distribute, sell and manufacture drugs under the regulations of the Act, are implemented by the Director/MT&S
- **Director National Medicines Quality Assurance Laboratory (D/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 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 consumables 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.
- **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.

2. Legislation Govern the Pharmaceutical Administration in Sri Lanka.

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

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

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

ii. 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.

iii. 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.

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

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

vi. Recommend appropriate amendments to relevant laws pertaining to medicines, medical devices and borderline products.

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

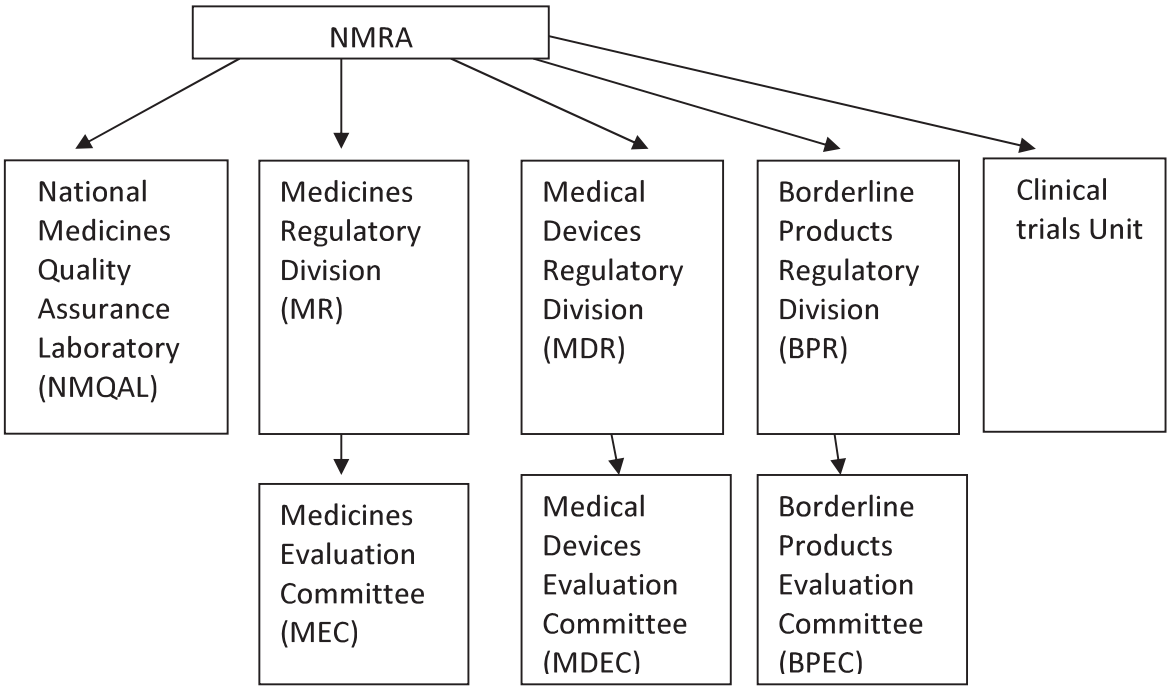
viii. Regulate the promotion and marketing of medicines, medical devices and borderline products.

ix. Regulate the availability of the medicines, medical devices and borderline products.

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

xi. Regulate all matters pertaining to the conduct of clinical trials in Sri Lanka.

2.1 Institutions established under NMRA act



3. Regulatory Service

Issues on pharmaceutical regulatory services – in view of State Pharmaceuticals Corporation and State pharmaceuticals Manufacturing Corporation of Sri Lanka.

- Inflow of substandard pharmaceuticals to the country has an impact on national health care system, proper therapeutic administration and fair play in the market.
- Lack of sufficient number of trained personnel for regulatory affairs of the industry and issues arising out of lack of adequate actions on regulating the industry.
- Lack of facilities for scientific testing /researches on acceptability of products for registration, quality related issues, post market surveillance.

I. Drug import / export

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 State Pharmaceuticals Corporation. 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 drugs imports to Sri Lanka should be registered under Medicines Regulatory Division (MR Division) established under NMRA.

II. Pharmaceutical Manufacturing

Both public and private sectors are involved in pharmaceutical manufacturing in Sri Lanka. Any manufacturer must obtain an approval of formulation to carryout trials to obtain a stable formula and followed by a license for manufacturing 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 Medicines Regulatory Division (MR Division).

III. Marketing Authorization

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

IV. Drug Distribution

For public sector, drug distribution is mainly controlled and monitored by 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 is government owned pharmacies known as “Osusalas” managed by State Pharmaceuticals Corporation (SPC). SPC is responsible in supplying medicines and other additional pharmaceutical products for all the pharmacies (“Osusala”) located island wide.

V. Medicine Safety (Post - Marketing Surveillance)

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 (NMQUAL). They monitor the safety and efficacy of the drugs, prevails within the island.

VI. 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 subjected 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 private sector there is no such regulation in prices, where the same drug is available in different prices in the market.

5. Statistical Data

Category	Data	Year
a) Number of government pharmacists	1386	2014
b) Number of GMP inspectors (Pharmacists do inspections)	26	2016
c) Number of pharmaceutical Manufacturers (Medicines)	38 (Small sacle-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

Roles of regulatory systems and pharmacists
on ensuring proper access to quality assured medicines (JFY 2016)

Inception Report

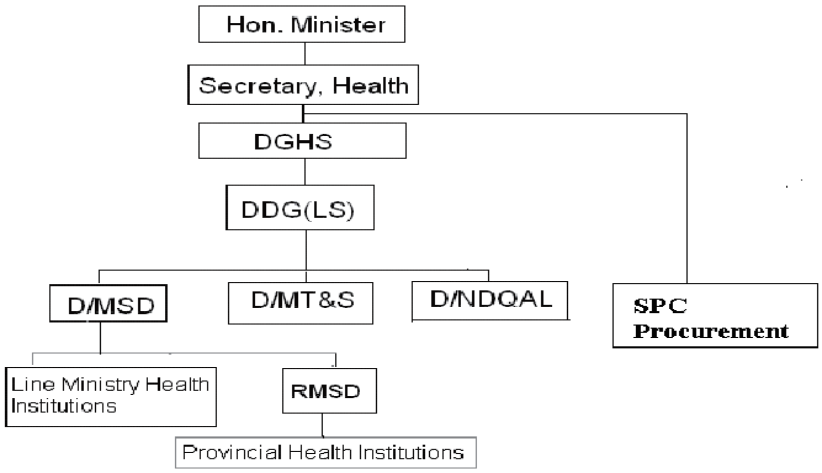
Name: Hewa Kankanamlage Prabha Priyadarshani Dayawansa
Country: Sri Lanka
Organization: National Medicines Regulatory Authority (NMRA)

Overview of country

Sri Lanka is an island located in the Indian ocean which has significant characteristics. Naturally it has several climatic zones since it is a small island. Politically Sri Lanka is governed by Parliament Democracy and headed by the Executive President. Free education system, free medical services and religious freedom are the most significant futures benefited by the citizens.

Health policy in Sri Lanka is responsible for ensuring an adequate supply of safe and effective drugs of acceptable quality. Provision of essential medicines is one of the elements in the primary health care package.

1.1 Organizational chart at National/State and Local level on pharmaceutical administration



The organizational chart at national/ state and local level on pharmaceutical administration has changed slightly after establishing the National Medicines Regulatory Authority (NMRA) on 1st of July, 2015. Former Medical Technology & Supplies (MT & S) and National Drugs Quality Assurance Laboratory (NDQAL) both come under NMRA.

1. Role and responsibility of each pharmaceutical administration unit

1.1 National Medicines Regulatory Authority (NMRA)- NMRA functions as central regulator for all matters connected with the regulation , licensing, cancelation of registration or licensing, pricing, manufacture, importation, storage, transport, distribution, sale, advertising and disposal of medicines, medical devices and borderline products.

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

1.3 Director General of Health Services (DGHS) - DGHS is the head of the National/State and Local level on pharmaceutical administration except the National Medicines Regulatory authority.

1.4 DDG (LS)- Deputy Director General of Laboratory Services

1.5 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. The MSD consolidates the estimates sent by all the government institutions and forecasts the annual requirements and then places the orders with the State Pharmaceutical Corporation (SPC). Drugs procured are sent to the MSD by the SPC for storage and distribution to all government medical institutions.

1.6 National Medicines Quality Assurance Laboratory (NMQAL) (former National Medicines Quality Assurance Laboratory -NMQAL)-

Functions:

(a) Primary function is testing of the quality of medicines, medical devices or borderline products submitted by the Authority.

(b) To function, as an additional approved Analyst, when the circumstances so require

1.7 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 to distribute to the government healthcare institutions.

1.8 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.

Role of Pharmacist in medical care system in Sri Lanka

Pharmacist is responsible for dispensing, supplying and procurement of Medicines, Medical Devices & Borderline Products. Pharmacy Degree has been established in Sri Lanka very recently. Therefore the role of a Clinical Pharmacist has not been introduced to the health sector in Sri Lanka yet.

2. Legislation on Pharmaceutical Administration in Sri Lanka.

National level and local level pharmaceutical administration is done by the National Medicines Regulatory Authority (NMRA).

2.1 The establishment of National Medicines Regulatory Authority (NMRA)

National Medicines Regulatory Authority Act, No. 5 of 2015 certified on 19th March, 2015 provide for the establishment of a Regulatory Authority to be known as the National Medicines Regulatory Authority which shall be responsible for the regulation and control of, registration, licensing, manufacture, importation and all other aspects pertaining to Medicines, Medical Devices, Borderline Products and for the conducting Clinical trials in manner compatible with the National Medicines Policy; to repeal the Cosmetics, Devices and Drugs Act, no.27 of 1980.

2.2 Authority consists of the following members:

(a) Three-Ex-officio members-DGHS, the Secretary to the treasury or his nominee, the Chief Executive Officer (CEO) of the Authority function as the Secretary to the Authority

(b) Four Specialist Clinicians- Nominated by their respective professional bodies

(c) A Professor of Pharmacology of any university

(d) A Professor or Senior Lecture in Pharmacy of any university

(e) Four professionals, who have gained eminence in fields of management, law, accounting or health respectively

The Minister shall, in consultation with the Authority appoint one of the appointed members to be the Chairman of the Authority.

The Authority shall in consultation with the Minister, appoint to the Authority Chief Executive Officer (CEO) from among persons who hold a post graduate degree from a recognized university in Medicines, Pharmacology, Pharmacy or any other related discipline.

2.3 Objects of the National Medicines Regulatory Authority (NMRA):

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

ii. 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.

iii. 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.

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

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

vi. Recommend appropriate amendments to relevant laws pertaining to medicines, medical devices and borderline products.

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

viii. Regulate the promotion and marketing of medicines, medical devices and borderline products.

ix. Regulate the availability of the medicines, medical devices and borderline products.

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

xi. Regulate all matters pertaining to the conduct of clinical trials in Sri Lanka.

2. 4 Divisions of the NMRA

i. Medicines Regulatory Division
ii. Medical Devices Regulatory Division
iii. Borderline Products Regulatory Division
iv. Clinical Trials Regulatory Division
v. National Medicines Quality Assurance Laboratory (NMQAL)

3. Regulatory Services (NMRA as per the NMRA act.)

3.1 Drug Import / Export:

All the drugs imports to Sri Lanka should be registered in NMRA. 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 State Pharmaceuticals Corporation (SPC). They procure all the essential drugs and medical devices for the Medical Supplies Division (MSD), which lies as the main unit responsible in distributing drugs and medical devices to government sector hospitals. Private sector importation is done by the local agents to distribute drugs and medical devices to the private medical institutions and pharmacies.

Regulations:
No person shall import, distribute, exhibit or sell any medicine that is manufactured, prepared, packaged or stored under insanitary conditions.

No person shall import or distribute any medicine without adhering to Good Distribution Practices (GDP) and any other prescribed guidelines and conditions.

No person shall, without prior written approval of the Authority, import, sell or distribute any medicine to the general public as a treatment, prevention or cure for any of the prescribed diseases, disorders or abnormal physical states.

3.2 **Pharmaceutical Manufacturing:,**

Both public and private sector are involved in pharmaceutical manufacturing in Sri Lanka. Any manufacturer should obtain the formulation approval from the NMRA prior to the manufacturing starts. The items to be manufactured commercially should have to obtain separate manufacturing license for each dosage form and strength. After GMP inspection completed, manufacture is able to submit the dossier with two samples for requesting registration certificates. This license can be provisional (PR) which is valid for one year, and can be upgraded to a full registration (FR) with necessary additional acceptable documentation.

State Pharmaceutical Manufacturing Corporation (SPMC) is the leading government manufacture and there are other leading private sector manufactures present in Sri Lanka.

Regulations:
No person shall, manufacture**,** prepare, store, preserve, package or re-pack any medicine without adhering to Good Manufacturing Practices (GMP) and any other prescribed guidelines or conditions.
No person shall sell, exhibit or distribute any medicines as may be prescribed unless the premises in which the medicine was manufactured and the process and conditions of manufacture of that medicine have been approved in the prescribed form and manner as being suitable to ensure that the medicine will be safe for use.

3.3 **Marketing Authorization**:

Marketing authorization is taken from the NMRA either by the manufacturer or importers to market their products as per the NMRA act no 5 in 2015.

Regulations:
No person shall manufacture or import any medicine without registering such medicine with the Authority and obtaining a license from the Authority therefor**.**

3.4 **Drug distribution (including drug selection, procurement, and sale)**

For public sector, drugs and medical devices distribution is mainly controlled and monitored by Medical Supplies Division (MSD). This is a centrally located government organization under Ministry Of Health, and there are Regional Medical Supplies Divisions (RMSD) for provisional supply of medicines and medical devices. MSD is responsible for drug selection, storing and distribution of drugs and medical devices. Procurement for government sector is done by the State Pharmaceutical Corporation (SPC). For procuring of 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 is government owned pharmacies known as "Osusalas" managed by State Pharmaceuticals Corporation (SPC). SPC is responsible in supplying medicines and other additional pharmaceutical products for all the pharmacies ("Osusala") located island wide.

Regulations:
No person shall, without prior written approval of the Authority, import, sell or distribute any medicine to the general public as a treatment, prevention or cure for any of the prescribed diseases, disorders or abnormal physical states.

3.5 **Medicines safety (post marketing surveillance):**

NMRA considers the safety, efficacy and quality of medicines and medical devices when registering. Presently there is no established proper mechanism for post marketing surveillance, but samples have been collected and analyzed by National Medicines Quality Assurance Laboratory (NMQAL) whenever there is a complaint from government hospitals, private medical institutions, etc.

Regulations:
No person shall import, distribute, exhibit or sell any medicine that is manufactured, prepared, packaged or stored under insanitary conditions.

No person shall label, package, re-pack, treat, process, sell, distribute, exhibit or advertise any medicine in a manner that is false, misleading, deceptive or likely to create an erroneous impression regarding efficacy, quality, composition or safety.

3.6 **Relief System for adverse Drug Reactions**:

There is a established pharmacovigilance unit located at the Department of Pharmacology, Faculty of Medicine University of Colombo and there is a committee known as Safety and Risk Evaluation Subcommittee (SAFRESE) meets regularly under NMRA act. Details of serious adverse drug reactions are collected from government medical institutions, private medical institutions and from the patients.

As per the decisions taken by the committee the drugs are subjected to withhold, withdraw or NMQAL quality testing.

Regulations:
Where the Authority refuses the registration of the medicine, such refusal shall be communicated to the applicant with reasons therefor within the stipulated time period and shall inform the public of such refusal by order published in the Gazette.

4. Drug Pricing

Drug Pricing Control is one of the major aspects of NMRA act and presently it has come under the preview of the NMRA. New regulations are being formed by the Pricing Committee by the NMRA.

Near future the pricing control can be obviously established in Sri Lanka for accessing safe, quality and efficacious medicines in affordable price for the public.

5. Statistical Data

Category	Data	Year
a) Number of government pharmacists	1386	2014
b) Number of GMP inspectors (All the pharmacist in NMRA work as GMP inspectors)	26	Up to date
c) Number of pharmaceutical manufacturers (Medicines)	38 (Small sacle-28 and large scale 10)	Up to date
Number of medical devices manufacturers	57	Up to date
a) Number of traditional medicine manufacturers	Statistical data not available	
b) Number of pharmaceutical importers	1500	Up to date
c) Number of pharmaceutical whole sellers	299	Up to date

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FIJI

Roles of Regulatory Systems and Pharmacists
on Ensuring Proper Access to Quality Assured Medicines (JFY 2016)

INCEPTION REPORT

Name: Emi Lewatoro & Anjani Singh

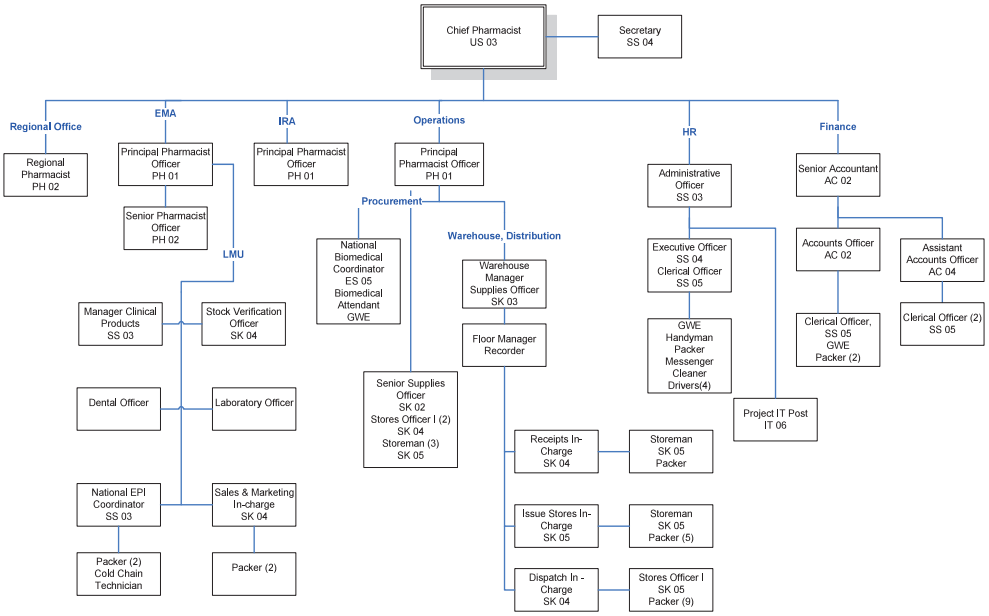
Country: Fiji

Organisation/Department/Division:

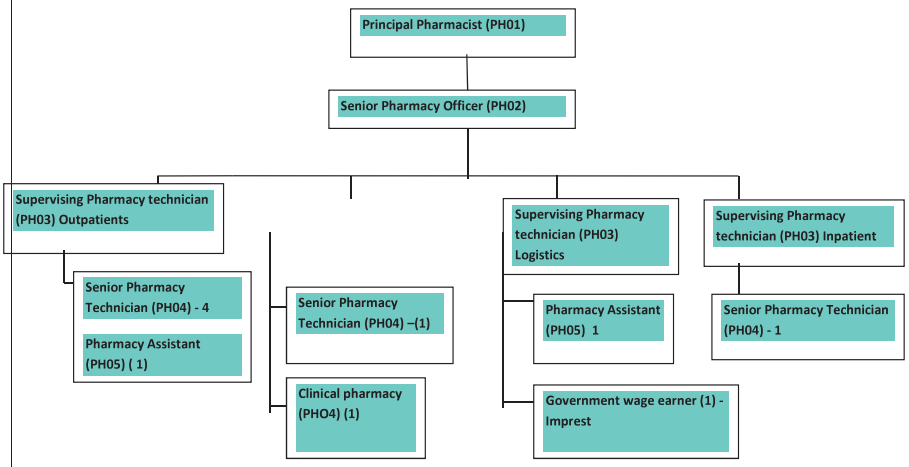
Medicines Regulatory Authority/Lautoka Divisional Hospital,

Ministry of Health and Medical Services.

(1) FIJI PHARMACEUTICAL & BIOMEDICAL SERVICES – ORGANISATION CHART



Hospital - Organization Structure



Lautoka hospital is located on the western side of Viti Levu, the largest island of Fiji. It is the main hospital of the western division and has various departments situated in it. Pharmacy is also a part of the Lautoka Hospital and it caters for all pharmacy services of the division

The Lautoka Hospital pharmacy has 16 staffs in total that comprise of the principal pharmacy officer, Senior Pharmacy Officer, Supervising Pharmacy Technicians, Senior Pharmacy Technicians, Pharmacy Assistants and Imprest staff.

The principal pharmacy officer at the Lautoka Hospital (Head of Department) is responsible for the overall pharmacy services in the whole of the western division including pharmacy services in the sub-divisions. He is assisted by the senior pharmacy officer in the day to day running of pharmacy activities. The supervising pharmacy technicians manage different sections namely outpatients, inpatients, Logistics, Oncology and Clinical Pharmacy and supervise the senior Pharmacy Technicians. The senior pharmacy technicians receive, type, process and dispense prescriptions. They are also required to process inpatients drug charts and make necessary interventions and carry out duties delegated to them by the senior cadres. The Senior Pharmacy technicians also take calls at night and weekends as stipulated in their job descriptions. The Pharmacy assistants help senior pharmacy technicians in all ways possible especially in ordering drugs from stores for outpatients and inpatients, repacking drugs and keeping and maintaining records. The pharmacy attendant (GWE) looks after the imprest system and replenishes the imprest stock in all the wards.

(2) LEGISLATION ON PHARMACEUTICAL ADMINISTRATION

National Level: (i) Fiji Pharmacy Profession Decree 2011 – Fiji Pharmacy Profession Board
(ii) Fiji Medicinal Products Decree 2011 – Fiji Medicinal Products Board
(iii) Illicit Drugs Control Act 2004 – Ministry of Health/Ministry of Justice

(3) REGULATORY SERVICES

(i) Drug Import and Export
(a) Registration of Importers & Exporters – Administered by the Medicines Regulatory Authority
(b) Issuance of Import & Export Permits – Administered by the Medicines Regulatory Authority
(c) Licensing of Medicines Wholesalers – Administered by the Medicines Regulatory Authority, under approval of the Medicinal Products Board

(ii) Pharmaceutical Manufacturing
(a) Issuance of annual manufacturing license (currently Fiji has only one manufacturing plant, which only supplies overseas markets) – Administered by MRA
Legislative provision has been made to regulate the manufacture of medicinal products. Manufacturing plants and processes will be designed to conform to acceptable international requirements such as WHO Good Manufacturing Practices

(iii) Marketing Authorization
(a) Pre-qualification of manufacturers of imported medicines – administered by the MRA
(b) Medicines Registration – administered by the MRA/Medicines Registration Unit

(iv) Drug Distribution (including drug selection, procurement, sale)
(a) *Selection* – administered by the National Medicines and Therapeutics Committee

(b) *Essential Medicines List* – administered by the National Medicines and Therapeutics Committee

(c) *Procurement* (of medicines for the public sector), by open or restricted tender – administered by the Fiji Pharmaceutical and Biomedical Services Centre.

(d) *Sale* – all imported medicines must first be registered by the MRA before they can be permitted for sale in the country. Schedules (classes) of medicinal products are determined in order to control the sale and supply of prescribed or OTC medicines.

(v) Medicines Safety (post marketing)

(a) *Pharmacovigilance activities* – Administered by the MRA/Pharmacovigilance Unit

(b) *Product Quality Reports* – compiled by health facilities and sent to MRA for further action (by HSA, TGA)

(vi) Relief System for Adverse Drug Reaction

(a) *ADR reporting* – compiled by health facility personel/patients/consumers and sent to MRA office

(b) *Product Complaints* – compiled by health facilities/patients/consumers and sent to MRA

(4) DRUG PRICING:

(a) *Public Sector* – medicines are free of charge

(b) *Private Sector* – legal and regulatory provisions affect pricing of medicines. These provisions are aimed at the level of wholesalers and retailers.

(c) *Free Medicines Program* – a government initiative to provide free price controlled medicines (including also in the private sector) to all adult citizens whose annual income is below $20,000 and those below 18 years whose parents combined salary is less than $20,000.

(5) STATISTICAL DATA

(a) *Number of pharmacists* – 178 (registered)

(b) *Number of GMP inspectors* – NIL (currently 2 MRA officers responsible only for inspecting GMP certificates of manufacturers of imported medicines before actual procurement)

(c) *Number of Pharmaceutical Manufacturers* – 1 (for overseas market only)

(d) *Traditional Medicines Manufacturers/Manufacturing sites* – NIL (Fijians mostly rely on traditional medicines/herbs as an alternative to conventional medicine, as a cultural norm)

(e) *Pharmaceutical Importers* – 61 (2016)

(f) *Pharmaceutical Wholesalers* – 23, including 12 retail pharmacists(2016)

(6) INFORMATION ON HOSPITAL PHARMACY

(i) (Organization Structure as above)

(a) Number of Section Chiefs: 1 Principal Pharmacy Officer

(b) Number of Deputy Chiefs: 1 Senior Pharmacy Officer

(c) Number of Managers: 4 Senior Pharmacists managing different sections

(ii) Number of Staff

(a) Number of Pharmacists:3

(b) Number of Clinical Pharmacists:1

(c) Number of Technicians: 4 supervising pharmacy technicians, 7 senior pharmacy technicians

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

(a) Oral medicines: 136 including tablets, capsules, elixirs

(b) Injections:91

(c) Medicines for external use: 6

(iv) Number of Prescriptions dealt in your pharmacy per day

(a) For Inpatients:150

(b) For outpatients: 450

(v) Equipment of the pharmacy in your hospital

(a) *Does the hospital have a dispensary room?* Yes, *How Large?* Actual dispensing area: 2m x 1.5m, Pharmacy area: 3m x 5m

(b) *Does the pharmacy have a clean room or laminar flow hood?* No

(c) *Does the pharmacy have computers?* Yes; *What is the purpose of using them?* For processing prescriptions , accessing patients laboratory and radiology results on PATIS (Patient Information System)

(d) *Do you implement therapeutic Drug Monitoring in your Hospital?* No, but TDM is done at the main Fiji hospital (CWMH)

(e) *Do you prepare TPN?* Yes, mixed for inpatients or those who require it

(f) *Can you use internet at the pharmacy?* Yes, for drug information, emailing, research, and for accessing PATIS which is now web based.

(7) EDUCATION AND LISENCE OF PHARMACISTS IN YOUR COUNTRY

※hospital pharmacy only

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

Primary	8	years
Secondary	5	years
High school		* Secondary and High school classified as one in Fiji

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

University / college:	4	years
Professional education:	4	years
Practical training:	1 year internship	

Duration of training by each facility:

Hospital pharmacy:	2	weeks
Community pharmacy:	1	week

	Pharmaceutical company:	nil	weeks	#NAME?
	Others:	1	#NAME?	
Age at graduation:		23	years old	

(iii) *Are there any national examinations for pharmacists in your country?* ☑

Yes

Academic Exams	2	days	oral and written
Clinical Exams	1	days	

No

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

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

Internship is mandatory and pre requisite for registration exam

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

(v) *Number of pharmaceutical university or college graduates*:

30 approx people / per year

The alumni's placement rate (%)

a. Hospital:	60	* the placement however is not distributed as 40% and 60% always since it depends on their preference
b. Community Pharmacy:	40	%
c. Government Organization:		%
d. Enterprise:		%
f. Others:		%

(8) SIDE EFFECTS REPORT (flow chart)

Severe Side Effect/ADR (reported by patient/carer/consumer)

↓

Pharmacist at nearest HF (or other medical staff if no pharmacist available)

↓

Medicines Information Pharmacist (at the Divisional Hospital)

↓

MRA (Pharmacovigilence Centre)

↓

Annex1

Roles of Regulatory Systems and Pharmacists
on Ensuring Proper Access to Quality Assured Medicines（JFY 2016）

Inception Report

Name:
Country:
Organization/Department/Division:

As indicated in the General Information, all participants are requested to prepare an inception report (Part Ⅰ and Part Ⅱ) and send it to JICA TOKYO and JICWELS (E-mail: ticthd@jica.go.jp, jigyo@jicwels.or.jp) by 27 June, 2016. Please include 'the course title' and 'course number (J1604254)' in the e-mail title.

【Notes】

This report consists of two parts: Part I and Part I. The main purpose of this report is to collect information in regard to pharmaceutical regulatory services of your country and more to help each participant to understand and compare other countries' situations.
Your report given here will be shared with every participants to prepare for active discussions throughout the program.
In each part, "why, what, when and how"to be used is explained. Please follow the directions in each part.

Part I: INFORMATION SHARING

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

What? → Information that overviews pharmaceutical administration framework/pharmaceutical management, services, relating laws and regulations in your country

When? → Prepare your own reports before coming to Japan, and share them with other participants at the arrival in Japan.

How? → Collect necessary information in your country and prepare reports, and presentation materials. Deepen understanding by comparison with other countrie through presentation and discussions.

① **Organizational Chart**
–Please attach the organizational chart 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 to focus on the position of the pharmacist in medical institutions.

② **Legislation on pharmaceutical administration**
–Please briefly bulletined major laws/acts

◆National Level
- administered by
- administered by

◆Local Level
- administered by
- 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 issues described below.
–It is recommended to add supplemental informations such as systems, regulations, responsible administrators, since you are expected to explain them to other particip

◆ Drug Import/Export
- Systems, Regulations, etc

administered by
administered by

◆ Pharmaceutical Manufacturing
- Systems, Regulations, etc

administered by
administered by

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

◆ Marketing Authorization
- Systems, Regulations, etc

administered by
administered by

※Example: Good Quality Practice

◆ Drug Distribution (including drug selection, procurement, sale)
- Systems, Regulations, etc

administered by
administered by

※Example: Good Distribution Practice

◆ Medicine Safety (post-marketing)

・ Systems, Regulations, etc

_____ administered by _____

_____ administered by _____

※Example: Good Pharmacovigilance Practice

◆ Relief System for Adverse Drug Reactions

・ Systems, Regulations, etc

_____ administered by _____

④ **Drug Pricing**

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

⑤ **Statistic Data**

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

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

1: Number of pharmacists _____ (YEAR)

2: Number of GMP inspector (National & Local) _____ (YEAR)

3: Number of pharmaceutical manufacturers / manufacturing sites _____ (YEAR)

4: Number of traditional medicine manufacturers / manufacturing sites _____ (YEAR)

5: Number of pharmaceutical importers _____ (YEAR)

6: Number of pharmaceutical wholesalers _____ (YEAR)

⑥ **Information on your hospital pharmacy** ※hospital pharmacy only

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

a. Number of section chiefs: **1- principal pharmacy officer**

b. Number of deputy chiefs: **1- senior pharmacy officer**

c. Number of managers: **4- supervising pharmacy technicians who manage different sections**

(2) Number of staff

a. Number of pharmacists: **3- registered under the pharmacy and poisons board**

b. Number of clinical pharmacists: **1**

c. Number of technicians: **7- senior pharmacy techncians and 4- supervising pharmacy technicians**

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

a. Oral medicine **136 oral preparations that include tablets, capsules, elixirs etc**

b. Injections **91**

c. Medicines for external use **6**

(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 **Currently there is no special dispensary room.**

_____ ㎡

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

If "Yes", please describe it in detail

Yes / No **NO**

Detail:

_____

_____

c. Does the pharmacy have computers?
Yes / No **YES**
If "Yes", what is the purpose of using them
Purpose:
r processing prescriptions using the PATIS syste
d capturing patients other iresults e.g. lab and radiolo

d. Do you implement Therapeutic Drug Monitoring (TDM:Therapeutic Drug Monitoring) in your hospital?
Yes / No **not done in our lab , but is done in the major hosital of Fiji i.e.** CWM

e. Do you prepare TPN (Total Parental Nutrition)
Yes / No **YES- it is mixed for patients who are admitted and require it**

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

⑦ **Education and License of Pharmacists in your country** ※hospital pharmacy only

(1) Number of years in primary, secondary and high school education
Primary 8 years
Secondary 5 years
High school _____ * Secondary and High school classified as one in Fiji

(2) Number of years / weeks in the following categories during university or college.
University / college: 4 years
Professional education: 4 years
Practical training: 1 #NAME?
Duration of training by each facility:
Hospital pharmacy: 2 weeks
Community pharmacy: 1 weeks
Pharmaceutical company: nil weeks #NAME?
Others: 1 #NAME?
Age at graduation: 23 years old

(3) Are there any national examinations for pharmacists in your country?
Yes ☑
Academic Exams 2 days oral and written
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.
Internship is mandatory and pre requisite for reg
* 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:
30 approx people / per year
The alumni's placement rate (%)
a. Hospital: 60 * the placement however is not distributed as 40% and 60% always since it depends on their preference
b. Community Pharmacy: 40 %
c. Government Organization: _____ %
d. Enterprise: _____ %
f. Others: _____ %

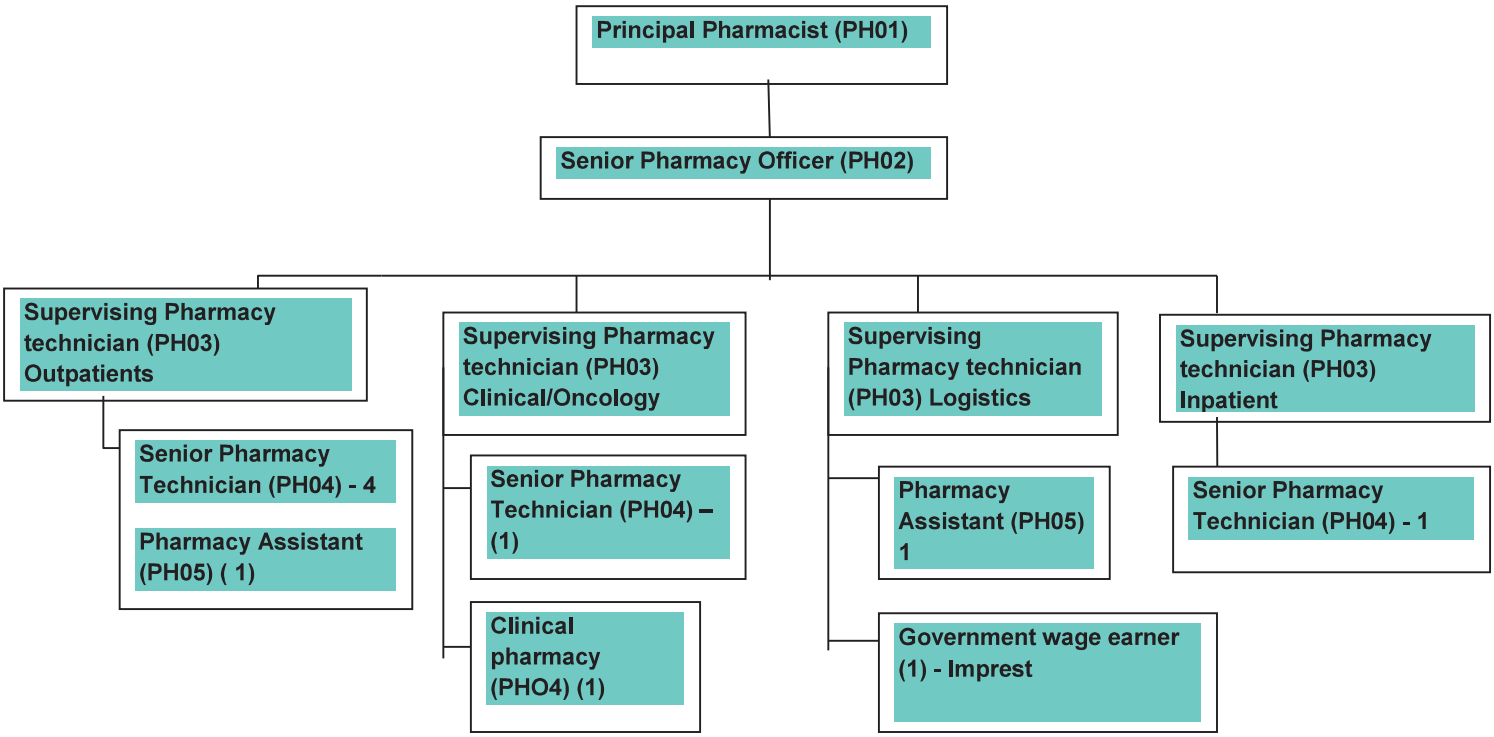
⑧Side effect report
Please describe the flow of reporting (from a medical institution to an administrative agency), when a severe side effect case is occurred in a medical institution. Describe specifically the rule and responsibility of each organization (an administrative agency/a medical institution), and its collaborations.

HOSPITAL PHARMACY
LAUTOKA HOSPITAL
FIJI ISLANDS

Lautoka hospital is located on the western side of Viti Levu, the largest island of Fiji. It is the main hospital of the western division and has various departments situated in it. Pharmacy is also a part of the Lautoka Hospital and it caters for all pharmacy services of the division

The Lautoka Hospital pharmacy has 16 staffs in total that comprise of the principal pharmacy officer, Senior Pharmacy Officer, Supervising Pharmacy Technicians, Senior Pharmacy Technicians, Pharmacy Assistants and Imprest staff.

Organization Structure



The principal pharmacy officer at the Lautoka Hospital (Head of Department) is responsible for the overall pharmacy services in the whole of the western division including pharmacy services in the sub-divisions. He is assisted by the senior pharmacy officer in the day to day running of pharmacy activities. The supervising pharmacy technicians manage different sections namely outpatients, inpatients, Logistics, Oncology and Clinical Pharmacy and supervise the senior Pharmacy Technicians. The senior pharmacy technicians receive, type, process and dispense prescriptions. They are also required to process inpatients drug charts and make necessary interventions and carry out duties delegated to them by the senior cadres. The Senior Pharmacy technicians also take calls at night and weekends as stipulated in their job descriptions. The Pharmacy assistants help senior pharmacy technicians in all ways

possible especially in ordering drugs from stores for outpatients and inpatients, repacking drugs and keeping and maintaining records. The pharmacy attendant (GWE) looks after the imprest system and replenishes the imprest stock in all the wards.

Pharmacy sub-sections

The Lautoka Hospital Pharmacy department has five sub-sections and they are Outpatients Department, inpatients department, Clinical section, Oncology section and Logistics Department. Outpatients department deals with prescriptions received from the General Outpatients clinics, Special Outpatients clinics, Accidents and Emergency, Dental and Ward reviewed patients. It also serves prescriptions from other health facilities around Fiji. Approximately 8000 prescriptions are served by the outpatients department every month.

In the inpatients department , drug charts are processed for non- imprest medications, discharge medications prepared for patients going home, dilutions and other external preparations made and imprest drugs replaced for various wards especially in the weekends. Inpatients department serves around 2000 prescriptions per month which includes discharge charts and inpatient drug charts only.

Except for Logistics, the other sections are situated in one room that is not so big. Hence, the problem of congestion is faced at all times. The room is divided into sub-sections (but there is no partition between them). The front section being allocated to outpatients (there is no special dispensary room), far right to inpatients and the rear section is shared by clinical and oncology. There is a separate locked room for the Principal Pharmacists' office. This is where the narcotics (Dangerous Drugs) are kept under lock and key. The stores (logistics) department is situated in the same building but at the basement. Due to its location, problems of carting drugs to the pharmacy and to other hospital wards are faced at most times.

At the moment, there is no specific room for oncology department. The drugs are kept in the special oncology refrigerator in the same room and processed from there. There are no special equipments and laminar flow cupboard to prepare the injectables. They are prepared in the oncology unit by the doctors.

The pharmacy department is equipped with 7 computers (desk tops); Two for outpatients, one for inpatients, and one for oncology/ clinical, two for logistics and one for the principal pharmacist and senior pharmacy officer to perform administrative duties. All computers have internet access and internet is only used for purpose of receiving and sending emails obtaining drug Information, doing research and preparing Continuing pharmacy education programmes.

The software program used by almost all the government hospitals around Fiji is "PATIS PLUS". It is a web based program and captures all patients' medical records. Patients are issued a National Health Number which serves as an identification for patients visiting hospitals in Fiji. Since, almost all records are linked, tracking patients' records is effortless.

Logistics department uses software named "EPICOR" that links the main Government medical Supplier (Fiji Pharmaceutical and Biomedical Services- FPBS) to all the three divisional hospitals in Fiji. Through

this software the main hospitals are able to be updated of the stock status (availability and quantity). Orders can also be placed via this EPICOR system or via emails to the respective persons. The sub-divisional hospitals, health centers and nursing stations however, order from FPBS on the hardcopy of the standard order forms which are then posted to FPBS.

Essential Medicines List

The essentials Medicines list (EML) is a list of basic/ important medications used by the public sector (government hospitals around Fiji). In Fiji, it is provided free of cost to the general public. The Fiji EML list is based on the World Health Organization's concept of essential medicines, which aim to ensure all medicines listed satisfy the priority health care needs of the Fijian people. By using this concept, the aim is to ensure medicines are rationally prescribed adhering to the relevant Standard Treatment Guideline s; thereby resulting in accurately predicting medicine usage which will ensure medicines availability at all times in adequate amounts, with assured quality, safety and efficacy and affordable price.

There are currently 444 medicines on the EML and some examples of preparations listed in it are 128 oral preparations, 91 injectables, 20 eye preparations (includes eye drops and eye ointments), 13 topical preparations etc.

Selection of medicines for the EML is undertaken by a written process by specialist committees recognized by the National Medicines and Therapeutics Committee (NMTC), Ministry of Health.

Standard Treatment Guidelines (STGs) are regularly updated. They are being advocated and distributed to promote rational use of medicines. All medicines on STGs are available and supplied free of charge by the Ministry of Health. STGs are being developed with technical and financial assistance from Therapeutic Guidelines Limited, Australia and WHO.

Education and License of Pharmacist

A Fijian student spends eight (8) years in primary school (Class 1 to class 8) and five (5) years in secondary school. The pharmacy programme is of four years duration and one year of compulsory extensive internship programme. During their internship, students are required to work under close supervision of a registered pharmacist. The Pharmacy internship Programme, run by the Fiji pharmacy and poisons board through the Fiji Pharmaceutical Services, is an achievement based programme on a set of competence standards that describe the knowledge, skills and attitudes required of a newly registered pharmacist.

The pharmacy internship programme runs concurrently with a 52 week practical training period and is the training and assessment that occurs around that work experience. During this period, interns are expected to work minimum of 37 hours per week. The competency standards that each intern is assessed on are: practice pharmacy in a professional manner, facilitate the rational use of medicines, provide primary health care, apply management and organisation skills, research and provide information, dispense medicines, and prepare pharmaceutical products.

Interns are also urged to actively participate in continuous pharmacy education programs, quality improvement programs, take part in clinical pharmacy activities, increase knowledge in over the counter medicines by being attached in retail pharmacies on a weekly basis, where possible do interventions on prescriptions to increase communication with prescribers and gain confidence.

After the completions of internship successfully, if the preceptor assesses the intern to be competent in all seven competency standards, the intern is permitted to sit the pharmacist registration exam under the Pharmacy and Poisons Board (registering body).Once registered, the pharmacist receives a legal license to own and operate as a pharmacist if he/she wishes to. To practice as a pharmacist in the hospital, it is not compulsory to be registered under the board but to practice in the retail sector one needs to be registered. Hence, it is an individual's personal choice.

There is no specific placement rate for the graduates in pharmaceutical sector. It is totally an individual's choice as to where they would want to do their internship (hospital setting or retail pharmacies) and where they get a placement i.e. the preceptor should agree to accept them as their intern. Based on this, the rate of placement so far has been 60% in hospital sector and 40% in the retail sector (community pharmacy).

Side effect report

Adverse drug Reaction form is available in wards and units for reporting of any suspicious ADR. ADR form can be filled by health professionals.

The form requires demographic details (patient national health card number, age, sex, weight, height and race), all medications in use (name of medication, indication, route, dose, date of starting the medication and date stopped), description of the ADR (date of onset, signs, and symptoms of ADR), treatment of ADR and its outcome and any other comment from the person reporting and finally the details of the person reporting (name, designation and signature).

The ADR report is then handed to the pharmacy department which is then forwarded to the national Drug and Therapeutics committee, Essential medicines Program where the report is evaluated, ADR is entered into the World health Organisation ADR database (manual records are also maintained.)

Prepared by
Ms Anjani Singh
Pharmacist
Lautoka Hospital

PAPUA NEW GUINEA

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

COUNTRY PRESENTATION: PAPUA NEW GUINEA
KILEPA WILLY FEBI
MEDICAL SUPPLIES DISTRIBUTION UNIT

NATIONAL DEPARTMENT OF HEALTH

Introduction

- Pop: 7.5 million
- Language: 700 plus,
- Official Language English and Pidgin

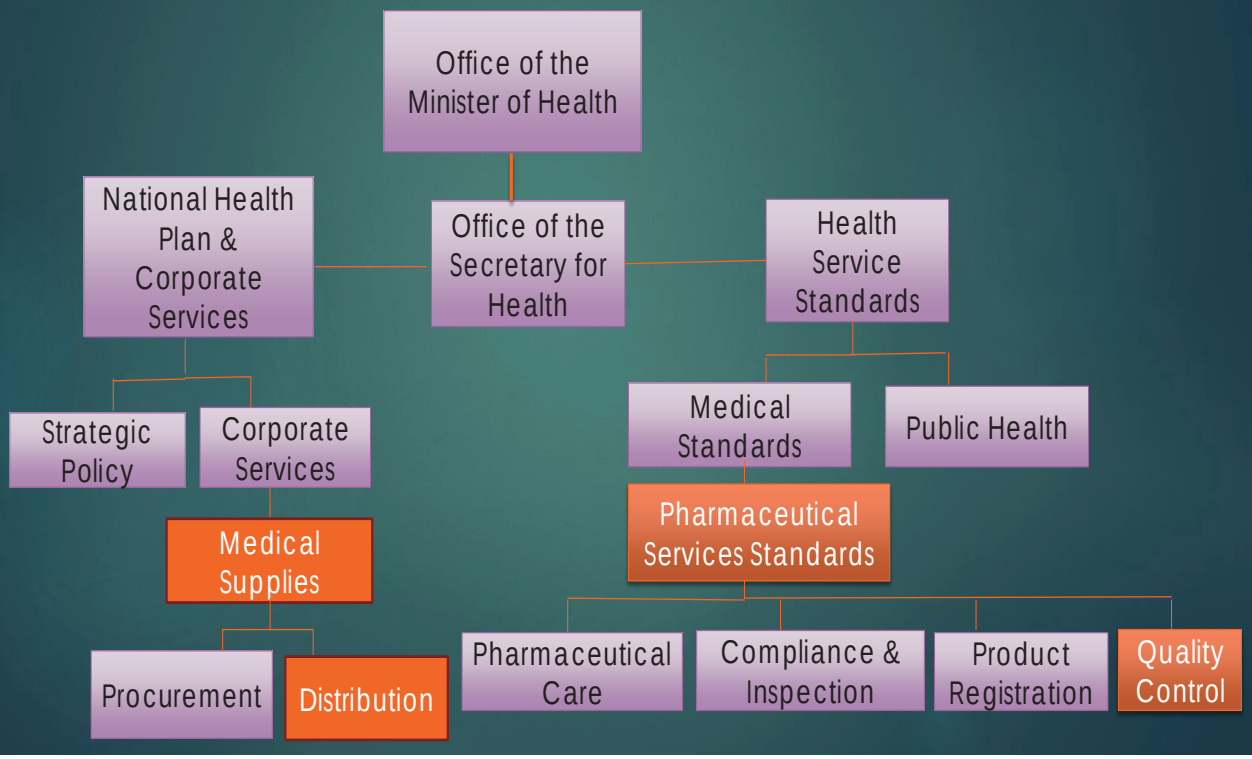
Organization

- National Department of Health
- National Health Policy & Corporate Services
- Corporative Services Division
- Medical Supplies Procurement & Distribution Branch (MSPDB)

-was created recently in 2011 after recommendation by AusAID in 2008
We are working to develop, improve and align drug regulatory systems

- Job tenure – Pharmacist by Profession - Technical Advisor –Medical Supplies Distribution & Area Medical Stores - Almost 4 years of service now, joined in late 2013.
- Regulatory Services engaged in –Quality Control of pharmaceuticals during storage and
  distribution, but support across other Regulatory Areas where required as we buil d our systems.

Organizational Structure – Ministry of Health



Good Practise

Experiences/Examples

- All Area Medical stores are poorly manage due to no Good Storage Practise in placed
- No Good Distribution Practices for the distribution of medical supplies
- Biggest challenges in sourcing medicines from WHO prequalified manufactures

Achievements

- Creation and Designation of Medical Supplies Procurement & Distribution Branch and Pharmaceutical Regulatory Branch in 2010
- Development of National Procurement Plan and Distribution Plan(5 years plan-2014-2019)
- Revision of the Medicines Policy and passed by Gov;t2014

Solutions for past problems

- Good Storage Practices (GSP), Good Distribution Practices (GDP) and Good Pharmacy Practic e (GPP) - WHO Standard
- Sourcing of medicines and vaccines from WHO prequalified manufacturers
- Quality Testing in WHO accredited labs
- Development of Standard Operation Procedures for the Branch,2016

Good Practise cont..

Ongoing projects to deal with current problems

- Improve drug registration process and guidelines for commenceme nt of registration
- Creation of position for Quality Assurance officers at the Area Medical Stores
- Revision of Act and Regulations in partnership with PSSB
- No GMP clearance for overseas manufacturers
- No Regulation of price for medicines .
- Very little post market surveillance

Difficulties/Lessons learn from the past

Maintaining the quality of drugs along the supply chain,

- especially from the storage at AMSs and
- Distribution to the facilities

What we have done

- Adopt good practise guidelines (WHO)
- Ran Training for staff
- Invite NGOs to help

Still have issue with storage and Distribution

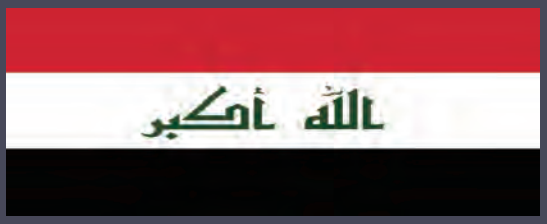
Way forward

- Learn and adopt good practices from other countries
- Ensure strict adhere of Good Practice Guidelines at all levels
- Provide more training on supply chain which more emphasis can be given to quality assurance.

Area of Interest

- Market Approval (generics)
- GMP
- Countermeasure against counterfeits medicines.

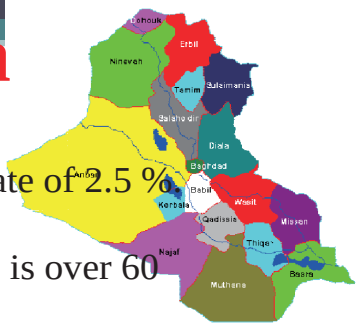
IRAQ



Role of Regulatory System and Pharmacist on Ensuring Proper Access to Quality Medicines

Duration course 6th July to 1oth August 2016
Pharmacist: Hayder Abdul Ameer Kadhim
Ministry of Health/Technical affairs directorate/Pharmacy department

IRAQ Demographic Data



- Total population: 36,933,714 million in 2015 with growth rate of 2.5 %.
- 40,2% of the population is under 15 years of age and 5,01% is over 60 years.
- Urban population is about 69.9% of the total population.
- Life expectancy at birth estimated at 72.56 (71.2 for males and 73.98 for females) .
- Infant mortality rate among under 5 years has fallen gradually to be 25.2/per 1,000 live births.
- Children dying before the age of 1 year dropped to be 19.7 for every 1,000 live births.

•* This information from annual statistical report 2015 /Republic of Iraq/ Ministry of Health

IRAQ

IRAQ

Mesopotamia, from the Ancient Greek: Μεσοποταμία "[land] between rivers"; Arabic: بلاد الرافدين "land of rivers") is a name for the area of the Tigris–Euphrates river system, roughly corresponding to modern-day Iraq,

*Is a country in Western Asia . The country borders Turkey to the north, Iran to the east, Kuwait to the southeast, Saudi Arabia to the south, Jordan to the southwest, and Syria to the west. The southern part of Iraq is within the Arabian Peninsula. The capital, Baghdad, is in the centre of the country and its largest city. The largest ethnic groups in Iraq are Arabs and Kurds. Other ethnic groups include Assyrians, Turkmen, Yazidis, Armenians

Economy of Iraq

*Oil

Iraq's economy is dominated by the oil sector, which has provided about 95% of foreign exchange earnings in modern times

*Agriculture

Given the richest land of Iraq with water in the past, the agriculture sector is an important part of the Iraqi economy to soon. The most important products are seeds, grains, dates, vegetables and fruit. Agricultural areas concentrated around the Tigris and Euphrates rivers and their branches. But the drought that hit central and southern Iraq because of climate change led to agriculture has fallen sharply in Iraq at the moment.

*industry

Diverse industries in Iraq and the Iraqi industry characterized by quality despite old factories, machinery and circumstances experienced by Iraq. Among these industries, construction materials, petrochemicals, tobacco and leather industry.

Top ten diseases causes of death in Iraq

	Diseases
1	Cerebravascular disease
2	Neoplasm's
3	Ischemic heart disease
4	Heart failure
5	Renal failure
6	Hypertensive diseases
7	Respiratory Distress Syndrome
8	operations of war
9	unknown causes of mortality
10	Diabetes mellitus

Health Services

Number of human resources works in Ministry of health and rate per 10000 of population

Human resources	
Physicians	26975
Pharmacists	8001
Nursing staffs	58687
Health assistants	653

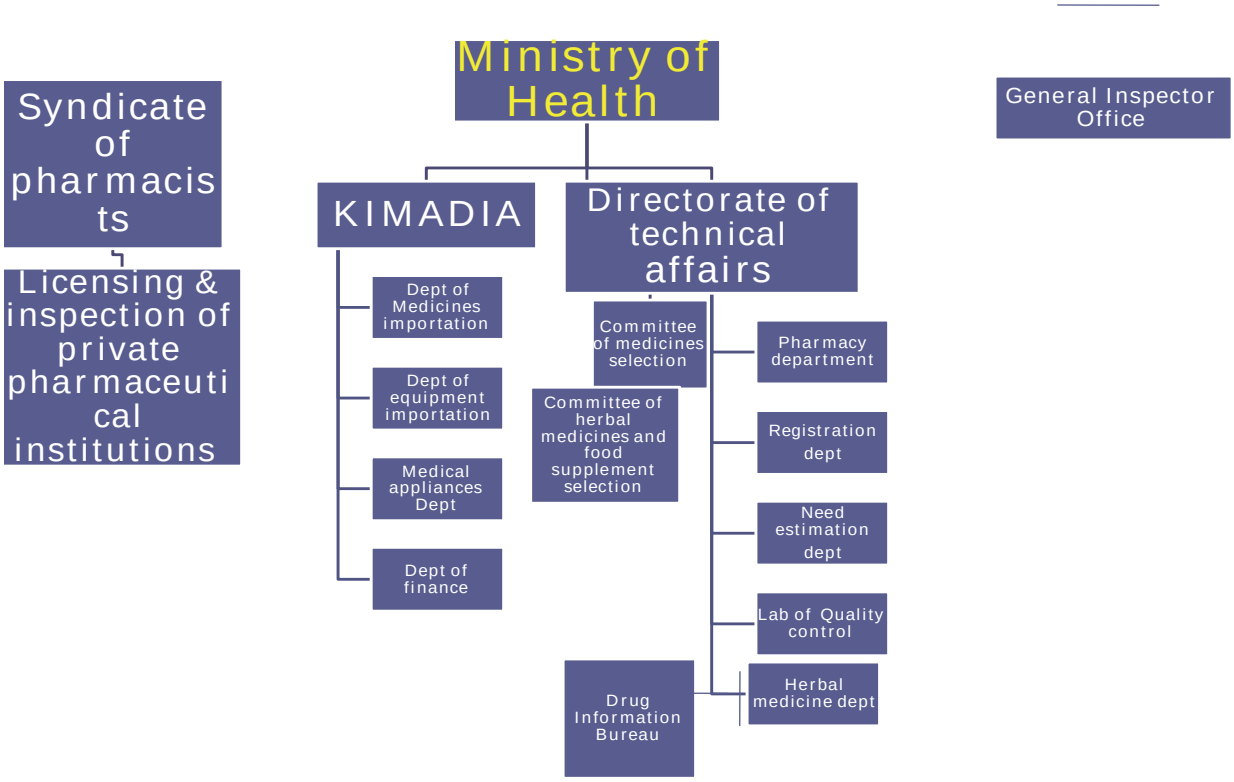
Health Center and Hospital statistics

Infrastructure	
Hospitals	253
Total number of governmental hospitals' beds	44554
Total number of Primary health care center.	2680
Licensed pharmacies	13000

Medicines Regulation

There is no law or act that provides power and responsibilities to medicines regulatory authority(MRA) there are ministerial orders, law here and there, The Directorate of Technical Affairs in ministry of health in addition to the state owned public pharmaceutical procurement and distribution company(KIMADIA) and the Syndicate of pharmacy play the role of a MRA ,the MRA is apart of MOH and have number of functions and has its own website, for which the URL www.techmoh.net

Structure of the Pharmaceutical Sector



KIMADIA= State Company for Procurement and Distribution of Medicines and Medical Appliances

Functions of the national medicines regulatory authority

Function
Marketing authorization / registration
Inspection
Import control
Licensing
Market control
Quality control
Medicines adverting and promotion
Clinical trials control
Pharmacovigilance

1.Marketing authorization / registration

- In Iraq, legal provisions requires marketing authorization (registration) for all pharmaceutical products on the market, there are over 7000 pharmaceutical products registered in Iraq. There are legal provisions requiring the MRA to make the list of registered pharmaceutical products publically available and update it regularly. This updated list can be accessed through www.techmoh.net

2.Regulatory Inspection

- In Iraq ,legal provisions exist allowing for appointment of government pharmaceutical inspectors(law of practicing pharmacy 1970).Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed, such inspections are required by law and are a pre-requisite for the licensing of public and private facilities. Inspection are carried out on a number of entities for good manufacturing practice such as(local manufacture, private distributers wholesalers, retail stores, pharmacies ,public pharmacies and dispensing points if health facilities).

3.Import Control

- Legal provisions exist requiring authorization to import medicines. Law exist that allow the sampling of imported products for testing . Legal provisions exist requiring importation of medicines through authorized ports of entry. Regulations or law exist to allow for inspection of imported pharmaceutical products at authorized ports of entry such as(Official Regulation no.60,MOH(1998),law of public health(1981),official regulation no.2 (2001),ministerial instructions(2008).

4. Licensing

In Iraq ,legal provisions exist requiring manufactures to be licensed(MOH,2007).Legal provisions exist requiring manufactures(both domestic and international)to comply with good manufacture practices(GMP).Legal provisions exist requiring importers/ wholesalers and distributors to be licensed, pharmacist to be registered, private and public pharmacies to be licensed (law of practicing pharmacy 1970) .National Good Pharmacy Practice Guidelines are published by government(Ministerial instructions and Booklet Practice(2010)) for Good Pharmacy

5.Market Control and Quality Control

In Iraq ,legal provisions exist for controlling the pharmaceutical market (law of practicing pharmacy 1970 , continuous ministerial instruction(2011) . A laboratory exist in Iraq for quality control testing.

Medicines testing reasons
For quality monitoring in the public sector *
For quality monitoring in the private sector **
When there are complaints or problem reports
For product registration
For public program products prior to acceptance and/or distribution

* Routine sampling in pharmacy stores and health facilities

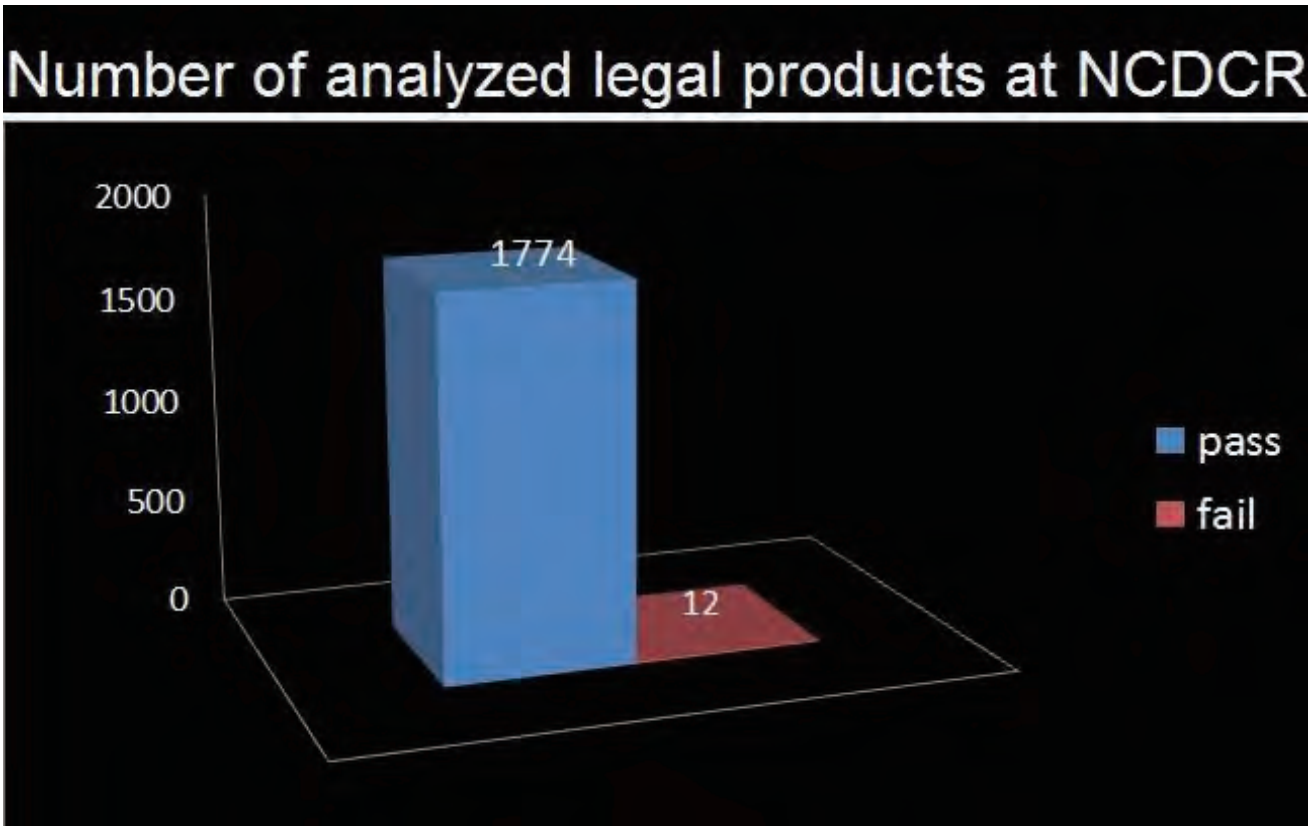
** Routine sampling in retail outlets

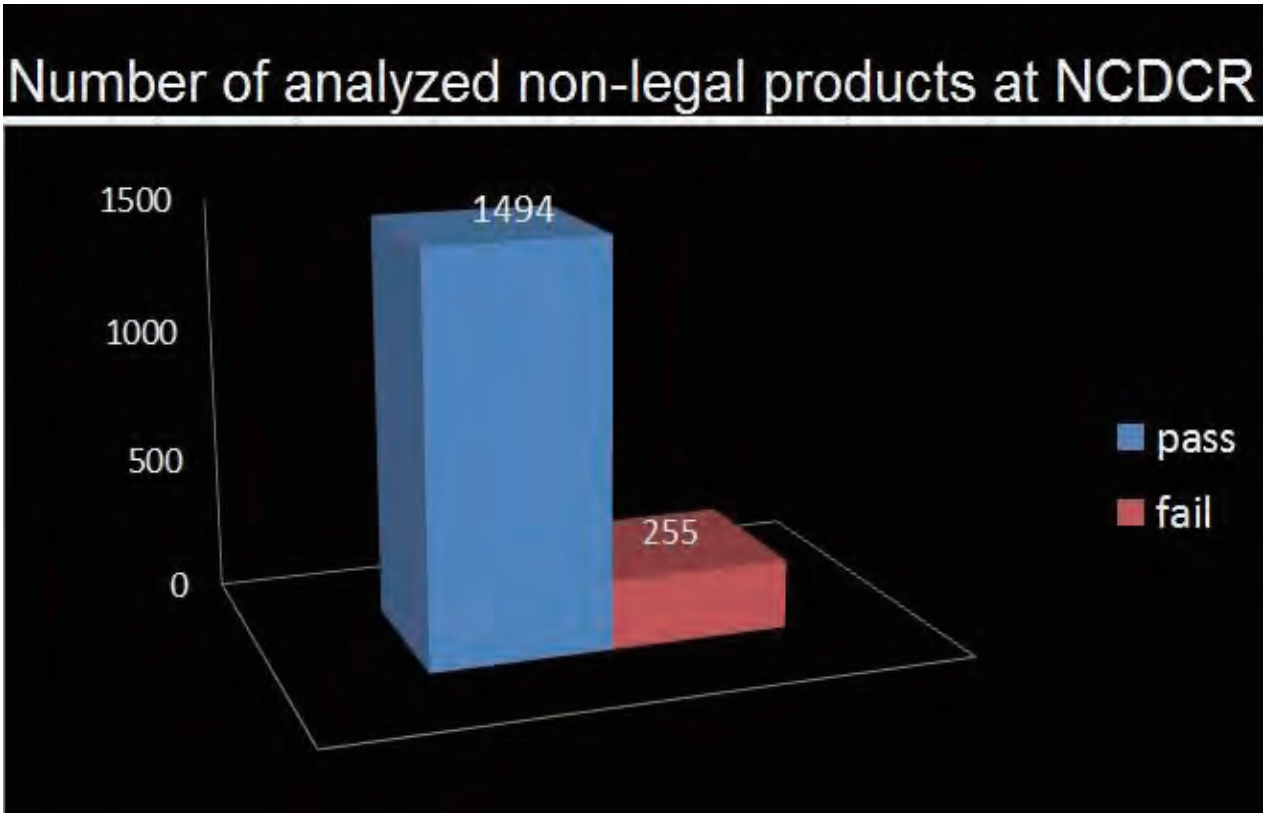
- The National Center for Drug Control and Research (NCDCR)); a quality control entity belonging to the Technical Affairs Directorate - Ministry of Health. The Center conforms to and implements high quality pharmacopoeias standards such as The International Pharmacopeia, BP and USP . The NCDCR's growth and expansion in last years has meant carrying out record numbers of tests efficiently (more than 1,500 tests performed per month i.e. doubling capacity from 2007).

Towards the end of 2014, the NCDCR orchestrated a large scale drug control campaign which resulted in testing large quantities of contraband pharmaceuticals available on Iraqi market shelves.

Approximately 17% of which did not meet the required efficacy and safety standards. The importers were fined and the items were seized & destroyed before reaching and harming Iraqi patients.

However, it is important to note that the majority of legally imported medicines adhere to and pass the NCDCR's stringent quality control procedures.


Number of analyzed legal products at NCDCR
2000
1500
1000
500
0
1774
12
pass
fail


Number of analyzed non-legal products at NCDCR
1500
1000
500
0
1494
255
pass
fail

6.Medicines Advertising and Promotion

- In Iraq ,legal provisions exist to control the promotion and/or advertising of prescription medicines. The ministry of health is responsible for regulating promotion and/or advertising of medicines. Legal provisions prohibit direct advertising of prescription medicines to the public.

7.Clinical Trials

- In Iraq ,legal provisions exist requiring authorization for conducting clinical trials by MRA. There are no additional laws requiring the agreement by an ethics committee or institutional review board of the clinical trials to be performed.

8.Controlled Medicines

- Iraq is a signatory to number of international conventions. Laws exist for the control of narcotic and psychotropic substances, and precursors(Law no.68 ,1965).

International Conventions to which Iraq is a signatory
Single Convention on Narcotic Drug, 1961
1972 Protocol amending the Single Convention on Narcotic Drug, 1961
Convention on psychotropic substances 1971
United Nations Convention against the illicit traffic in Narcotic drug and psychotropic substances,1988

9.Pharmacovigilance

- A national Pharmacovigilance center linked to the pharmacy department exists. An official standardized form for reporting adverse drug reactions(ADR) in Iraq. Information pertaining to ADRs is stored in a national ADR database. These reports are send to the WHO collaborating center in Uppsala. There is national ADR or pharrmacovigilance committee able to provide technical assistance or causality assessment ,risk assessment, risk management and case investigation . The Pharmacovigilance center has its own websites:(iqphvc@yahoo.com , iraqiphcv@moh.gov.iq)

SOUTH AFRICA

Annex1

Roles of Regulatory Systems and Pharmacists
on Ensuring Proper Access to Quality Assured Medicines（JFY 2016）

Inception Report

Name: Silverani Padayachee
Country: South Africa
Organization/Department/Division: National Department of Health

As indicated in the General Information, all participants are requested to prepare an inception report (Part Ⅰ and Part Ⅱ) and send it to JICA TOKYO and JICWELS (E-mail: ticthd@jica.go.jp, jigyo@jicwels.or.jp) by 27 June, 2016. Please include 'the course title' and 'course number (J1604254)' in the e-mail title.

【Notes】

This report consists of two parts: Part Ⅰ and Part Ⅱ. The main purpose of this report is to collect information in regard to pharmaceutical regulatory services of your country and more to help each participant to understand and compare other countries' situations.
Your report given here will be shared with every participants to prepare for active discussions throughout the program.
In each part, "why, what, when and how"to be used is explained. Please follow the directions in each part.

Part Ⅰ: INFORMATION SHARING

Why? → *To clarify and share the basic information on each country and yourself among all participants.*
What? → *Information that overviews pharmaceutical administration framework/pharmaceutical management, services, relating laws and regulations in your country.*
When? → *Prepare your own reports before coming to Japan, and share them with other participants at the arrival in Japan.*
How? → *Collect necessary information in your country and prepare reports, and presentation materials. Deepen understanding by comparison with other countries through presentation and discussions.*

① **Organizational Chart**
—Please attach the organizational chart 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 to focus on the position of the pharmacist in medical institutions.

② **Legislation on pharmaceutical administration**
—Please briefly bulletined major laws/acts
◆National Level
- administered by
- administered by

◆Local Level
- administered by
- administered by

◆PIC/S
Yes X OR No If yes, joined when 01 July 2007

③ **Regulatory Services**
—Please describe pharmaceutical regulatory services of your country in response to each issues described below.
—It is recommended to add supplemental informations such as systems, regulations, responsible administrators, since you are expected to explain them to other participants.

◆ Drug Import/Export
- Systems, Regulations, etc

See Attached presentation administered by
administered by

◆ Pharmaceutical Manufacturing
- Systems, Regulations, etc

See Attached presentation administered by
administered by

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

◆ Marketing Authorization
- Systems, Regulations, etc

See Attached presentation administered by
administered by

※Example: Good Quality Practice

◆ Drug Distribution (including drug selection, procurement, sale)
- Systems, Regulations, etc

See Attached presentation administered by
administered by

※Example: Good Distribution Practice

◆ Medicine Safety (post-marketing)

- Systems, Regulations, etc

See Attached presentation administered by

administered by

※Example: Good Pharmacovigilance Practice

◆ Relief System for Adverse Drug Reactions

- Systems, Regulations, etc

See Attached presentation administered by

④ **Drug Pricing**

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

Included in attached presentation- Drug pricing is managed by NDoH and not from medicines regulatory agency

⑤ **Statistic Data**

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

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

1: Number of pharmacists (YEAR-2016)
2: Number of GMP inspector (National & Local) 12 (YEAR -2016)
3: Number of pharmaceutical manufacturers / manuf: 77(including gas,complementary and packers) (YEAR- 2016)
4: Number of traditional medicine manufacturers / manufacturing sites None- notAR-2016)
5: Number of pharmaceutical importers 171 (YEAR- 2016)
6: Number of pharmaceutical wholesalers 187 (YEAR-2016)

⑥ **Information on your hospital pharmacy** ※hospital pharmacy only

(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?
   _____ m^2

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

⑦ Education and License of Pharmacists in your country ※hospital pharmacy only

(1) Number of years in primary, secondary and high school education
Primary _____ years
Secondary _____ years
High school _____ years

(2) Number of years / weeks in the following categories during university or college.
University / college: _____ years
Professional education: _____ years
Practical training: _____ years
Duration of training by each facility:
Hospital pharmacy: _____ weeks
Community pharmacy: _____ weeks
Pharmaceutical company: _____ weeks
Others: _____ weeks
Age at graduation: _____ years old

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

Academic Exams _____ days
Clinical Exams _____ days
No

(4) Which of the followings must you fulfill to obtain a pharmacist's license?
* If practical training is mandatory, give the subjects and training period.

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

(5) Number of pharmaceutical university or college graduates:
_____ people / per year
The alumni's placement rate (%)
a. Hospital: _____ %
b. Community Pharmacy: _____ %
c. Government Organization: _____ %
d. Enterprise: _____ %
f. Others: _____ %

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.

Info in attached powerpoint presentation- from regulators perspective

Part II: INCEPTION REPORT PRESENTATION

Why? → *To make a presentations and discussions in order to understand each other and compare among the participants*

What? → *Report of the current situation about your work, your experiences to be shared and expectations to this program.*

When? → *Report presentation is held on the beginning of the program in Japan.(It is expected on July 15)*

How? → *Refer to the outline described below. It is strongly recommended to prepare with Power Point (PPT).*

【Notes】・Please prepare presentation within 10 slides.

・Each presentation is allocated about 15 min. including Q/A.

◆Presentation OUTLINE

Category A	Introduction of your work —Organization & department that you belong to —Job tenure Role and position of pharmacists in your country, etc —Please describe your regulatory services that you are engaged in.
Category B	Good Practice —Please describe your experiences about Good Practices *(Examples)* ・Achievements ・Solutions for past problems ・On-going projects to deal with current problems ・Successful countermeasures against problems
Category C	Difficulties/Lessons Learned from Past Experience —Please describe your experiences you have faced difficulties, or struggled; *(Examples)* ・Problems that cannot be improved or solved ・Failed countermeasures to deal with the problems ・Emerging or Re-emerging Problems, if any
Category D	Your interests —Please describe issues you are expecting to this program.(at maximum 3(three)

JICA inception report

Roles of Regulatory Systems and Pharmacists on ensuring
proper access to quality assured medicines

Silverani Padayachee
National Department of Health
South Africa

27 June 2016

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

mcc
MEDICINES CONTROL COUNCIL

Discussion points

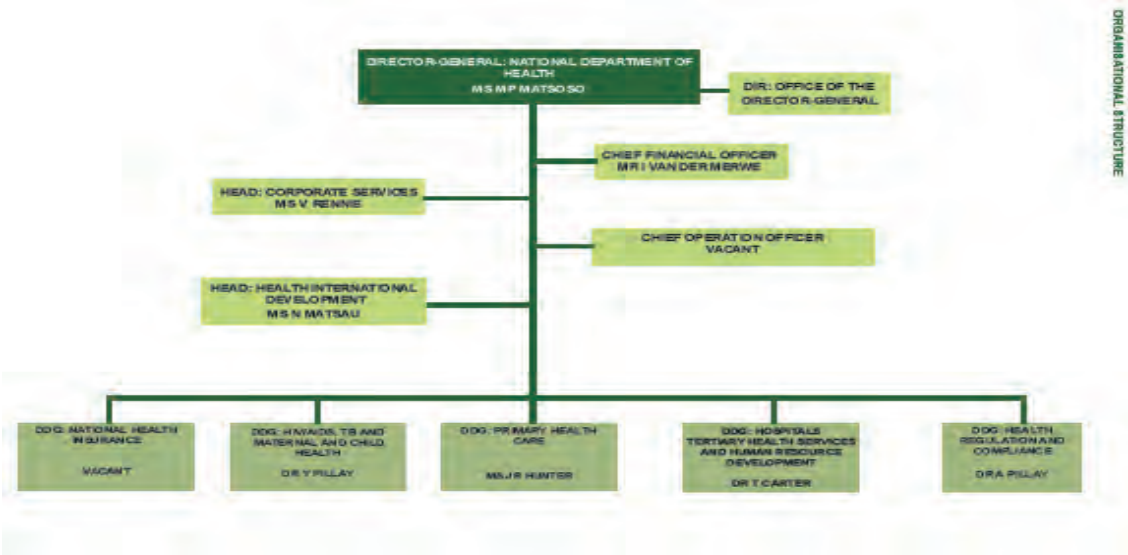
1. Organisational Chart
2. Legislation on Pharmaceutical administration
3. Regulatory Services
4. Drug Pricing
5. Statistical Data
6. Education and License of pharmacists in your country
7. Side Effect report

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

mcc
MEDICINES CONTROL COUNCIL

Organogram from National Level

From Director General to Programme Level



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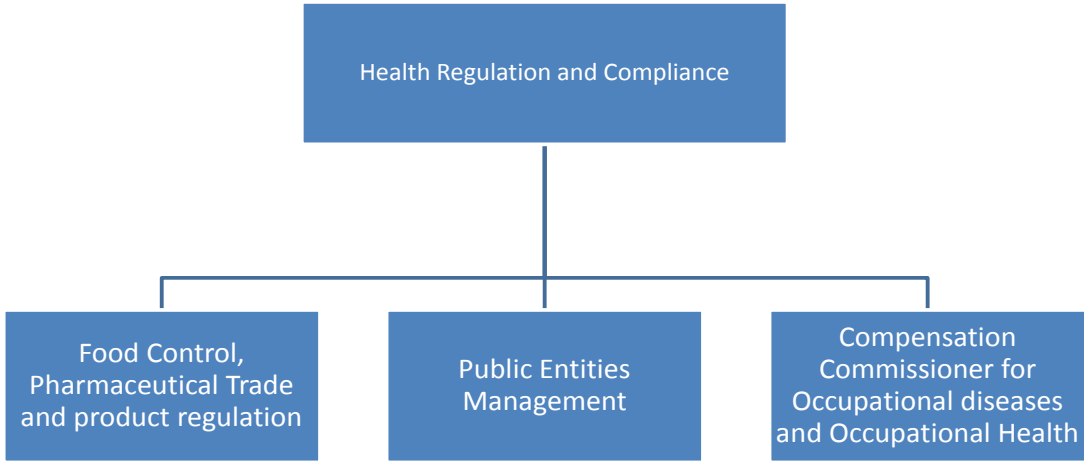
Department:
Health
REPUBLIC OF SOUTH AFRICA

mcc
MEDICINES CONTROL COUNCIL

Organogram from Programme to Subprogramme level

Programme 6: Health Regulation and Compliance Management



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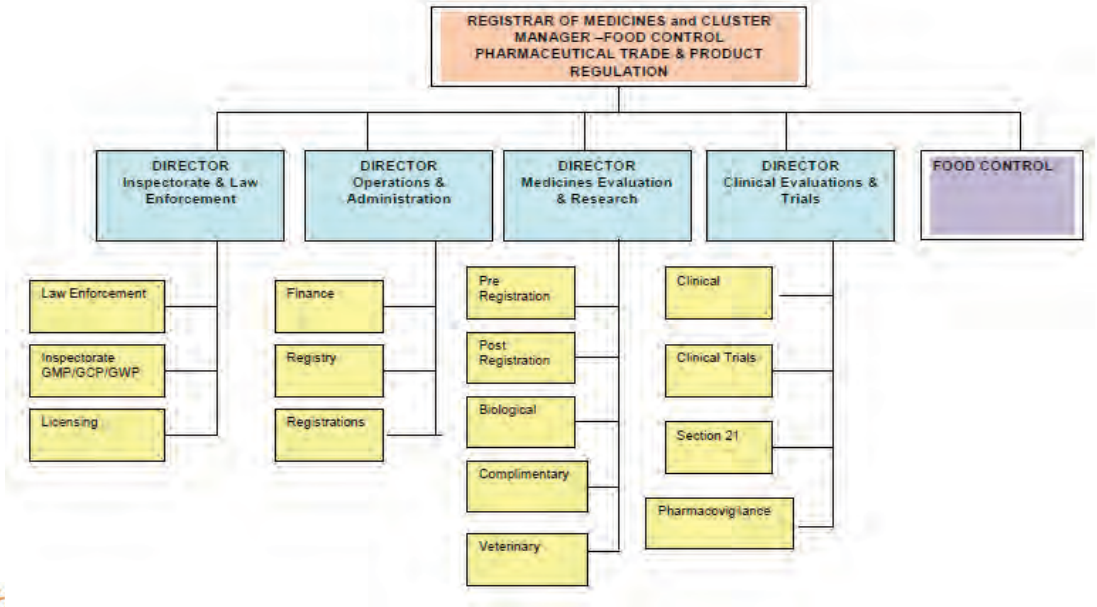
Department:
Health
REPUBLIC OF SOUTH AFRICA

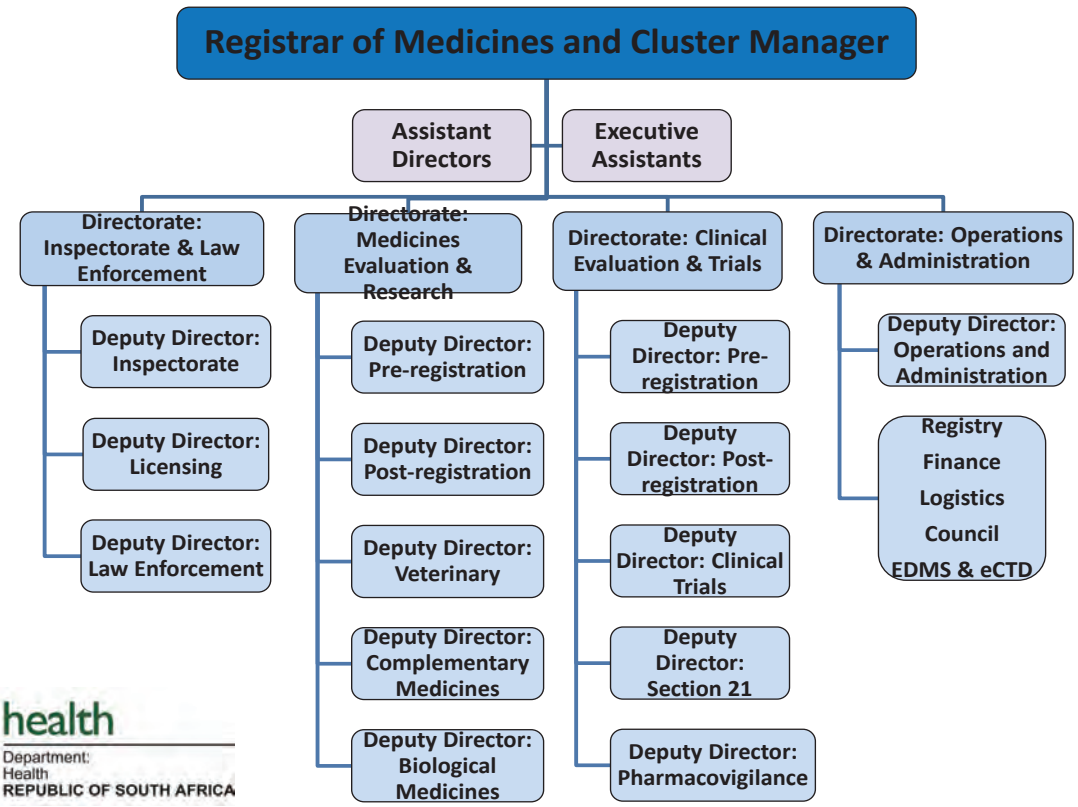
Sub- programme: Food Control Pharmaceutical trade and Product regulation (FCPT&PR)



Department: Health
REPUBLIC OF SOUTH AFRICA

5

Sub- programme: Food Control Pharmaceutical trade and Product regulation (FCPT&PR)



Department: Health
REPUBLIC OF SOUTH AFRICA

Legislation on Pharmaceutical administration

- **LEGISLATIVE AND OTHER MANDATES**
- The legislative mandate of the Department of Health is derived from the Constitution, the National Health Act, 61 of 2003, and several pieces of legislation passed by Parliament.

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

MEDICINES CONTROL COUNCIL

Constitutional Mandates

- In terms of the Constitutional provisions, the Department is guided by the following sections and schedules, among others:
- **The Constitution of the Republic of South Africa, 1996,** places obligations on the state to progressively realise socio-economic rights, including access to health care.
- **Schedule 4 of the Constitution** reflects health services as a concurrent national and provincial legislative competence
- **Section 9 of the Constitution** states that everyone has the right to equality, including access to health care services. This means that individuals should not be unfairly excluded in the provision of health care.
- **Section 27 of the Constitution states as follows**: with regards to Health care, food, water, and social security:

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

National Health Act, 61 of 2003

Provides a framework for a structured uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws on the national, provincial and local governments with regard to health services

The objects of the National Health Act (NHA) are to:

- unite the various elements of the national health system in a common goal to actively promote and improve the national health system in South Africa;
- provide for a system of co-operative governance and management of health services, within national guidelines, norms and standards, in which each province, municipality and health district must address questions of health policy and delivery of quality health care services;
- establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognised standards of research and a spirit of enquiry and advocacy which encourage participation;
- promote a spirit of co-operation and shared responsibility among public and private health professionals and providers and other relevant sectors within the context of national, provincial and district health plans; and
- create the foundations of the health care system, and must be understood alongside other laws and policies which relate to health.

Legislation falling under the Minister of Health's portfolio

- There are several legislations within the minister of healths portfolio, however only those relevant to the regulation of medicines, pharmacy and related activities have been listed below and are relevant both nationally and locally
- **Medicines and Related Substances Act, 101 of 1965**
- Provides for the registration of medicines and other medicinal products to ensure their safety, quality and efficacy, and also provides for transparency in the pricing of medicines.
- **Foodstuffs, Cosmetics and Disinfectants Act, 54 of 1972 (as amended)**
- Provides for the regulation of foodstuffs, cosmetics and disinfectants, in particular quality standards that must be complied with by manufacturers, as well as the importation and exportation of these items.
- **Pharmacy Act, 53 of 1974 (as amended)**
- Provides for the regulation of the pharmacy profession, including community service by pharmacists
- **National Health Laboratory Service Act, 37 of 2000**
- Provides for a statutory body that offers laboratory services to the public health sector.
- **Nursing Act, of 2005**
- Provides for the regulation of the nursing profession.

PIC/S

- SA MCC joined Pharmaceutical Inspectorate Co-operation scheme on 1 July 2007 and is strongly committed to the collaboration.

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Regulatory services

Drug Import/Export

- Systems

  Governance Issues

  Documents for importation

  Processes to be followed

  Roles of different stakeholders

    SARS

    Port Health

    MCC/NDoH

  Substandard Medicines

  Counterfeit Medicines

  Action to be taken

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Regulatory Import and Export

- Regulations-Imports and Exports controlled by

Section 27 of the Constitution (Act 108 of 1998)

Every citizen of the Republic of South Africa has the right to access to healthcare facilities

Medicines and Related Substances Act, 1965 (Act 101 of 1965)

Makes provision for the control and access to medicines

Provides for medicines registration.

Provides for the registration of facilities whereby medicines can be manufactured and stored

Provides for procedures to be adopted when selling medicines

Provides for dedicated port of entries for medicines

Provides for the appointment of Inspectors

Promotion of Administration Justice Act, 2000 (Act 2 of 2000)

Promotion of Access to Information Act, 2000 (Act

- Administered by- Medicines Control Council

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Regulatory services

Pharmaceutical Manufacturing

- Systems- Inspection programme drafted based on new sites; sites requiring renewal; complaints received. SOP's govern the processes followed
- Regulations
- Administered by MCC using the following references
- SA cGMP Guidelines can be accessed on www.mccza.com
- PIC/s Guidelines can be accessed from

http://www.picscheme.org/publication.php?id

- WHO Guidelines can be accessed from

http://www.who.int/publications/guidelines/en/

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Regulatory services

Marketing authorisation/ Registration Process

- Systems

Administrative Requirements

- Receiving and screening of amendments
- Human, biological, veterinary,

Technical Requirements

- Clinical safety and efficacy, Quality
- Good Manufacturing Practices (GMP)
- Good Clinical Practices (GCP)
- Names, Scheduling

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Registration Process

- **Admin**
  - **Reception & admin screening of application**
  - **Allocation of application number**
  - **Notification of number of copies required**
  -
- **Receipt of additional copies for evaluation**
- **Allocation of applications to Evaluators**
- **Evaluation & draft of evaluation report**
- **Peer review of report - Expert Committees**

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mcc
MEDICINES CONTROL COUNCIL

Registration Process cont

- Regulations: 14; 15; 15 (A); 22

Medicines and Related Substances Act, 1965 (Act 101/1965) [amended 16 times]

- Administered by: Medicines control Council

Guidelines for safety, efficacy and quality are based on WHO, EMA, FDA, TGA and recognized pharmacopoeia

E.g;Good Quality practice

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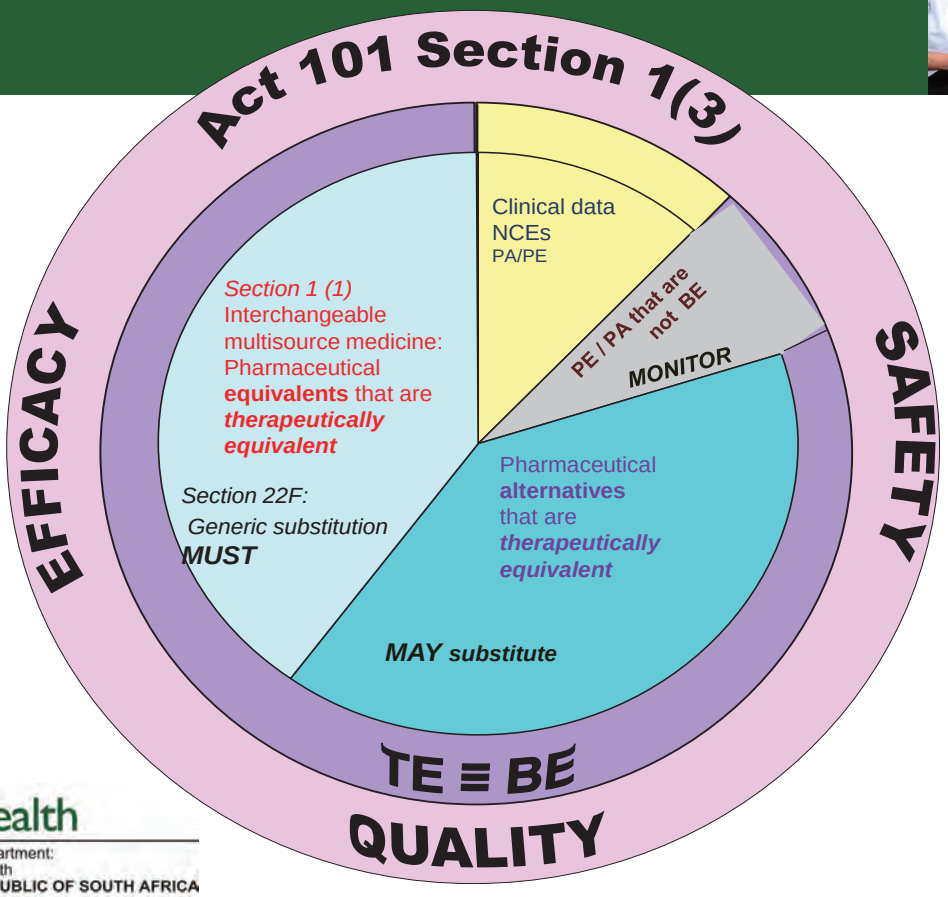

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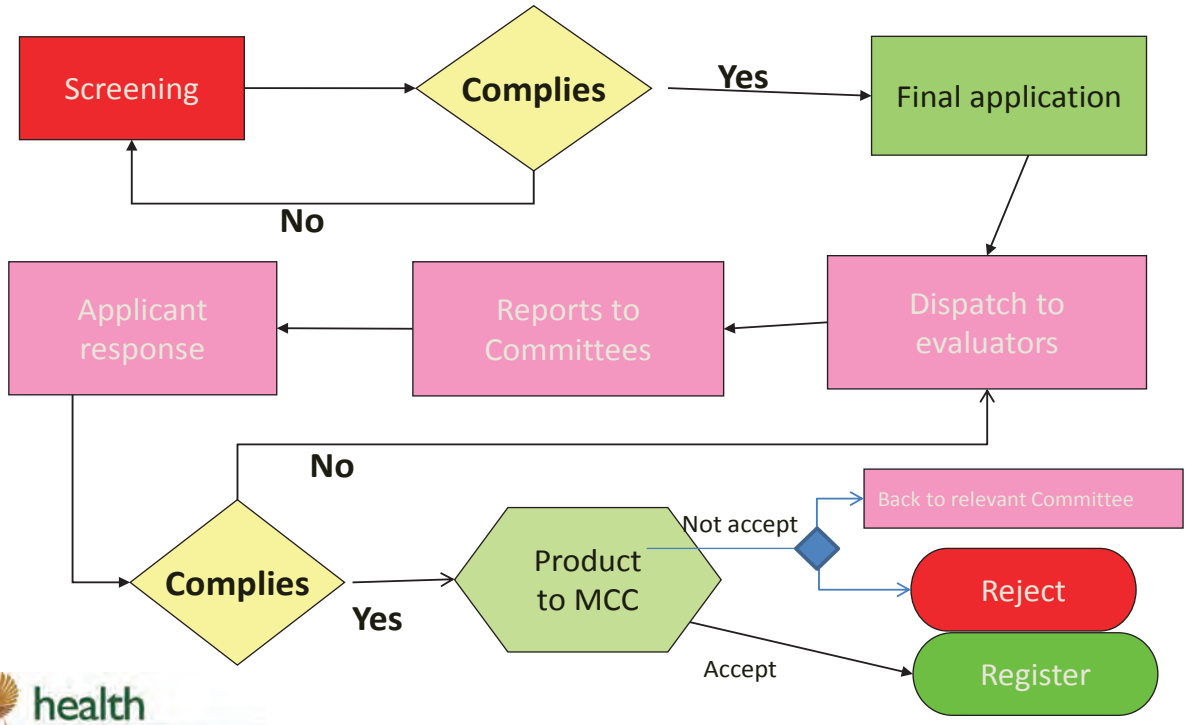
Registration Process

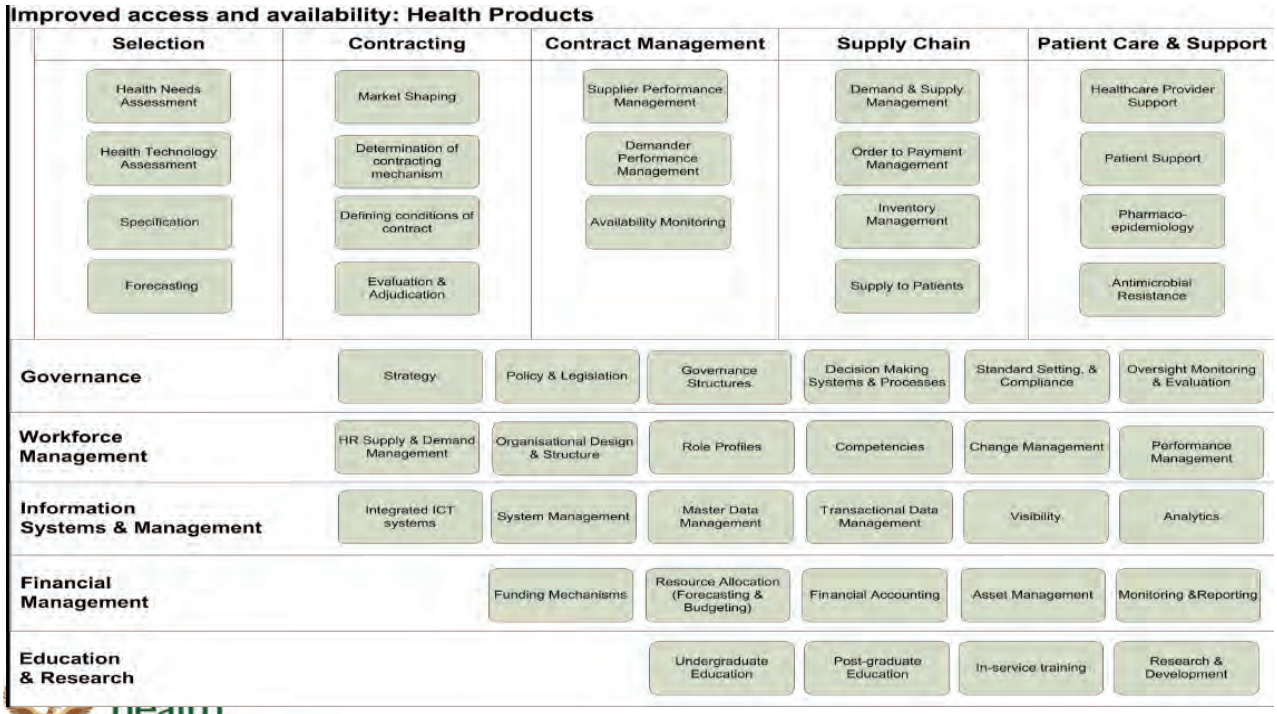


Regulatory services* not regulated by MCC

Drug Distribution including drug selection, procurement and sale

- Systems- Medicines Access Framework
- The WHO Medicine Access Framework defines access as a function of four elements.
- **Today's focus is on achieving a reliable supply chain**
- However, reforms are taking place across each of these areas.

Medicines Access Framework



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Regulatory services* not regulated by MCC

Drug Distribution including drug selection, procurement and sale

- Systems-
- Regulations: **Global & Local Imperatives**
- •Universal Declaration of Human Rights (1948), Article 25
- •The preamble to the Constitution of the WHO (1948)
- •The International Covenant of Economic, Social and Cultural Rights (ICESCR) Article 2
- •United Nations adopted 17 Sustainable Development Goals (SDGs) 25 September 2015 (Goal 3.8 of the SDGs)
- •South African Constitution and Bill of Rights , Section 27
- •National Health Act
- •National Development plan
- •National Health Insurance White Paper

- Administered by- NDoH Sector wide procurement Unit, separate from the MCC

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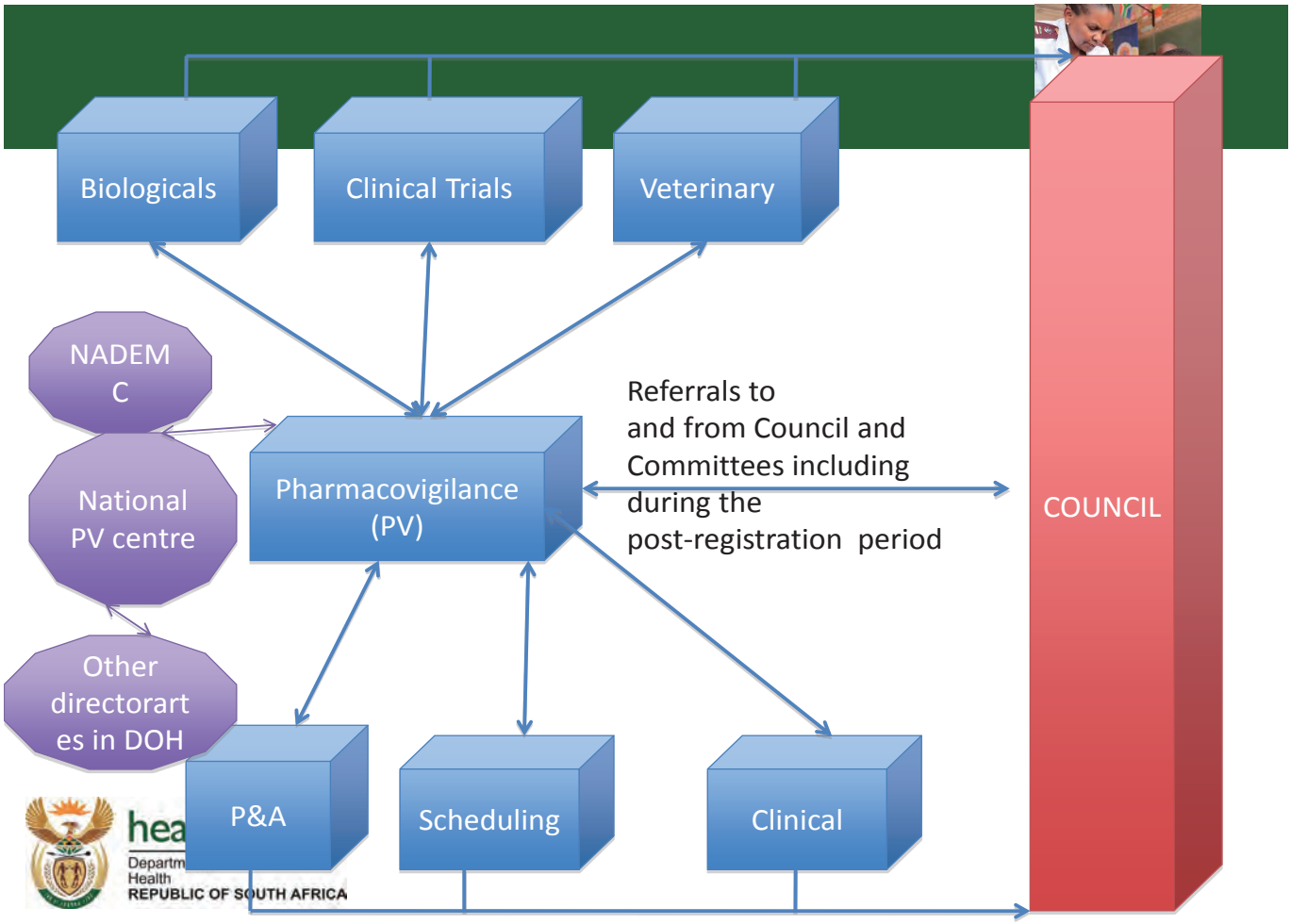
Medicine Safety (Post Marketing)

- **Systems - The following systems are used to manage ADRs**
- Adverse Drug Reaction Reporting Form (yellow form) used by Healthcare Professionals and consumers - Received via fax and post
- CIOMS forms from the applicants - Received via fax and post
- Use of the Vigiflow system for capturing of ADR reports and committing them into the Uppsala Monitoring Centre's Vigibase.
- All these forms are initially screened by technical staff (pharmacists), then captured by the administration clerks into the Vigiflow system and verified by pharmacist before committing them onto the UMC's Vigibase. On a weekly basis, causality is assessed for all serious cases before committing them.
- In the process of piloting the electronic submission of ADR reports in the E2B format directly into the Vigiflow system by the applicants.
- **Good Pharmacovigilance Practice**
- We have Pharmacovigilance inspections which are currently reactive and working towards being proactive. These inspections are done by qualified pharmacists who are GMP trained.

Regulatory services

Medicine Safety (Post Marketing)

- **Regulations -** Adverse Drug Reaction reporting is according to Regulation 37 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended.
- The applicant or holder of a certificate of registration or any authorized prescriber in respect of a medicine or Scheduled substance shall inform the Authority, in the manner and within the time frame as determined by the Authority, of suspected adverse drug reactions reported to him, her or it occurring as a result of the use of such a medicine or scheduled substance.
- Administered by- Medicines control Council



Regulatory services

Relief system for adverse drug reactions

- Systems- No relief systems in place from Regulatory agency

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Drug Pricing- Managed by NDoH Sector Wide Procurement

Basis is National Drug Policy in 1996-"to develop a pricing plan for drugs used in South Africa in the public and private sectors".

- multi-faceted series of interventions to reduce medicines prices and also improve prescribing and dispensing practices.
- a policy of mandatory offer of generic substitution

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Drug price control /drug price mechanism

A Pricing Committee with clearly defined functions to monitor and regulate drug prices will be established within the Ministry of Health

- • A pricing committee, to "monitor and regulate drug prices"
- • Total transparency in the pricing structure (at all points of the distribution chain)
- A non-discriminatory pricing system within the private sector
- • Replacing the wholesale and retail mark-up system with one based on a fixed professional fee
- • A database to monitor costs compared with other developing and developed countries
- • Regulation of price increases
- • Provision, in certain circumstances, of public sector stock to the private sector (e.g. supplying lower cost drugs bought by the State to private sector clinics in order to address a priority disease)

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Drug price control /drug price mechanism cont.

- • Promotion of generics (multi-source pharmaceutical products, generally cheaper than the originator's branded products), including generic substitution, while maintaining a negative list (a list of drugs that could not be substituted by the pharmacist at the patient's request, but where the prescribed brand would have to be supplied)
- • Measures to improve rational drug use, including establishing Pharmacy and Therapeutics Committees (PTCs) in all hospitals
- • Control of pharmaceutical marketing practices.

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Statistical Data

1. Number of pharmacists____ (year)
2. Number of GMP inspector (National & Local) 12 (year-2016)
3. Number of pharmaceutical manufacturers / manufacturing sites 77 (year-2016)
4. Number of traditional medicine manufacturers / manufacturing sites Not regulated byAct101 (year-2016)
5. Number of pharmaceutical importers 171 (year-2016)
6. Number of pharmaceutical wholesalers 187 (year-2016)

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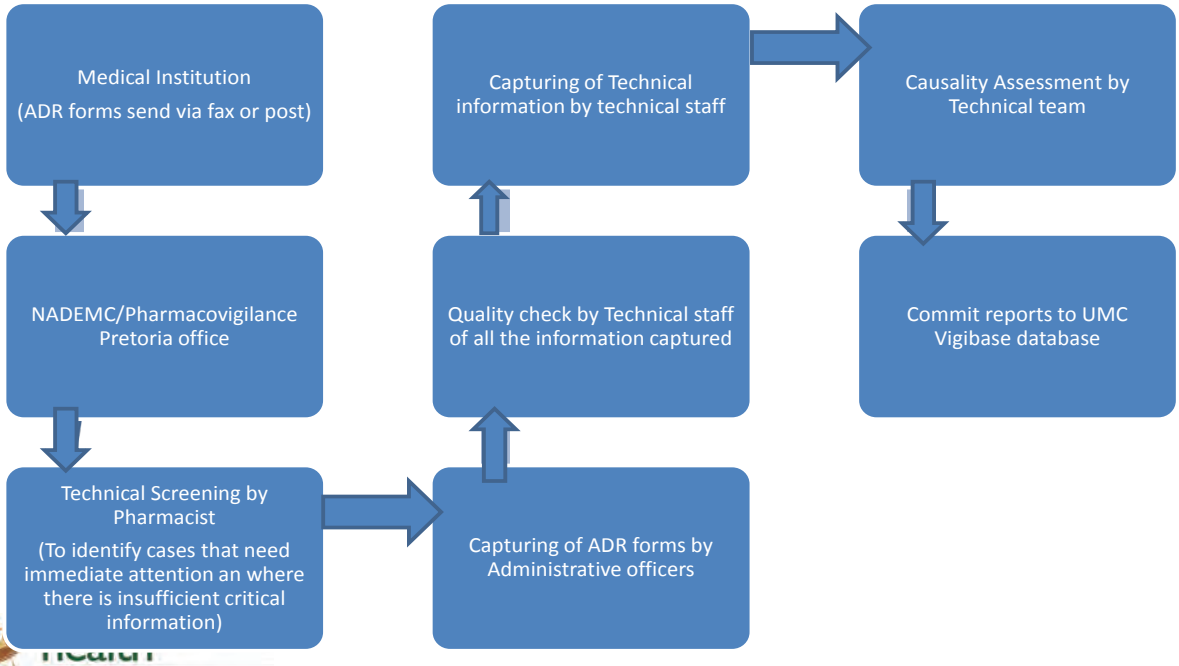
flow of reporting side effects-MCC perspective



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BRAZIL

Annex1

Roles of Regulatory Systems and Pharmacists
on Ensuring Proper Access to Quality Assured Medicines（JFY 2016）

Inception Report

Name: Dulcyane Neiva Mendes Fernandes
Country: Brazil

Organization/Department/Division: Brazilian Health Regulatory Agency (ANVISA)/GESI

As indicated in the General Information, all participants are requested to prepare an inception report (Part Ⅰ and Part Ⅱ) and send it to JICA TOKYO and JICWELS (E-mail: ticthd@jica.go.jp, jigyo@jicwels.or.jp) by 27 June, 2016. Please include 'the course title' and 'course number (J1604254)' in the e-mail title.

【Notes】

This report consists of two parts: Part I and Part I. The main purpose of this report is to collect information in regard to pharmaceutical regulatory services of your country and more to help each participant to understand and compare other countries' situations.
Your report given here will be shared with every participants to prepare for active discussions throughout the program.
In each part, "why, what, when and how"to be used is explained. Please follow the directions in each part.

Part I: INFORMATION SHARING

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

What? → *Information that overviews pharmaceutical administration framework/pharmaceutical management, services, relating laws and regulations in your country.*

When? → *Prepare your own reports before coming to Japan, and share them with other participants at the arrival in Japan.*

How? → *Collect necessary information in your country and prepare reports, and presentation materials. Deepen understanding by comparison with other countries through presentation and discussions.*

① **Organizational Chart: Attachment**
–Please attach the organizational chart 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 to focus on the position of the pharmacist in medical institutions.

② **Legislation on pharmaceutical administration**
–Please briefly bulletined major laws/acts

◆National Level

▪ Law 6360/1976 - Established the Marketing Authorization	administered by	Brazilian National Congress
▪ Law 6437/1977 - Violations and Penalties of Health Regulation	administered by	Brazilian National Congress
▪ Law 9782/1999 - Creation of National Agency of Sanitary Surveillance (ANVISA)	administered by	Brazilian National Congress
▪ Law 9787/1999 - Creation of Generics Medicines in Brazil	administered by	Brazilian National Congress
▪ RDC 17/2010 - Requirement of GMP in Brazil	administered by	ANVISA
▪ RDC 60/2014 - Requirement for Marketing Authorization in Brazil	administered by	ANVISA
▪ RDC 36/2013 - Mandatory report of adverse events	administered by	ANVISA
▪ RDC 4/2009 - Glossary of Pharmacovigilance	administered by	ANVISA
▪ Portaria 802/1998 - Requirement of Good Transportation Practice in Brazil	administered by	National Government
▪ Portaria 1660/2009 - Estabilished the Pharmacovigilance	administered by	National Government

◆Local Level
- As the regulation on medicines is done exclusively by the national level, there are no laws published by local level.

◆PIC/S
Yes OR [No] If yes, joined when

③ **Regulatory Services**
–Please describe pharmaceutical regulatory services of your country in response to each issues described below.
–It is recommended to add supplemental informations such as systems, regulations, responsible administrators, since you are expected to explain them to other participants.

◆ Drug Import/Export
- The activity of importing drugs is done by a system named SISCOMEX. This system is used not only by ANVISA, but also for all the institutions who deal with the process of importin
- RDC 74/2016 - Electronic petitioning Import of Goods and Products Subject to Health Surveillance.
- RDC 62/2016 - Informatization of petitioning Import and Export Authorization of substances and drugs subject to special control.

◆ Pharmaceutical Manufacturing
- After receiving the application requesting a good manufacture practice certificate, the site will be inspected. If aproved, the brazilian official gazette (DOU) will described the nam
- RDC 17/2010 - Drugs Good Manufacturing Practice;
- RDC 63/2009 - Radiopharmaceuticals Good Manufacturing Practice;
- RDC 69/2008 - Medical gases Good Manufacturing Practices;
- RE 899/2003 - Analytical Methods Validation;
- RDC 39/2013 - Certification process;
- RE 01/2005 - Drugs Stability studies;
- RE 45/2012 - Active Pharmaceutical Ingredient (IPA) Stability studies;
- RDC 69/2014 - API Good Manufacturing Practice.

◆ Marketing Authorization
- Marketing authorization is given after assessement of the medicines application where it is given proofs of eficacy and safety based on the resolution nº 60/2014. The assessement
- RDC 60/2014 - Criteria for concession and renewal of drugs registration (synthetics and semi-synthetics)
- RDC 55/2010 - Minimum requirements for the registration of new biopharmaceuticals and organic products in the country.
- RDC 26/2014 - Registration of phytotherapy and registration and notification herbal traditional products.

◆ Drug Distribution (including drug selection, procurement, sale)
- This activity is ruled by the Portaria nº 802/1998, published by the National Government. Although the authorization to conduct this activity is given by the ANVISA (based on the re
- Portaria 802/1998 - Instituting the Control and Supervision System in the whole chain of pharmaceutical products covering the stages of production, distribution, transport and disp
- RDC 320/2002 – Duties of companies distributing pharmaceuticals
- RDC 39/2013 – Criteria for granting of good manufacturing practices certification, fractionation, distribution and / or storage of medicines, pharmaceutical raw materials, heal

◆ Medicine Safety (post-marketing)

- Pharmaceuticals companies should develop a pharmacovigilance system in Brazil. They also should report and investigate all the serious adverse reactions relate
- RDC 04/2009 - refers to rules for pharmaceutical companies about farmacovigilance practices.

- RDC 36/2013 - determine that medical institutions should report to Anvisa all serious adverse reactions.
- IN 14/2009 - published guides to Pharmaceuticals companies: Good Pharmacovigilance Practices, Periodic Safety Reports Elaboration and Risk Management Plar
- System - Notivisa

◆ Relief System for Adverse Drug Reactions
- -

④ **Drug Pricing**

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

Anvisa monitors drug prices that are on the market and technically assists in the establishment of price of new drugs. One of its duties is to exercise the function of Executive Secretariat of the Drug Market Regulation Chamber (CMED), inter-ministerial body responsible for regulating the market and establish criteria for the definition and adjustmen of price. Moreover, Anvisa monitors the market for health products and, at the time of application or revalidation of registration, gathers economic information of some classes of these products.
Resolution 3/2011

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: 180.000 (2014) - Source: Federal Council of Pharmacy (CFF)
2: Number of GMP inspector (National & Local): 28 (2016)
3: Number of pharmaceutical manufacturers / manufacturing sites: 914 (2016)
4: Number of traditional medicine manufacturers / manufacturing sites: no available data
5: Number of pharmaceutical importers: 992 (2015) - Source: DATAVISA
6: Number of pharmaceutical wholesalers: 6583 (2015) - Source: DATAVISA

⑥ **Information on your hospital pharmacy** ※hospital pharmacy only

(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?
  _____ ㎡
- b. Does the pharmacy have a clean room or laminar flow hood?
  If "Yes", please describe it in detail
  Yes / No
  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:

⑦ **Education and License of Pharmacists in your** ※hospital pharmacy only

(1) Number of years in primary, secondary and high school education
Primary _____ years
Secondary _____ years
High school _____ years

(2) Number of years / weeks in the following categories during university or college.
University / college: _____ years
Professional education: _____ years
Practical training: _____ years
Duration of training by each facility:
Hospital pharmacy: _____ weeks
Community pharmacy: _____ weeks
Pharmaceutical company: _____ weeks
Others: _____ weeks
Age at graduation: _____ years old

(3) Are there any national examinations for pharmacists in your country?
Yes☐
Academic Exams _____ days
Clinical Exams _____ days
No

(4) Which of the followings must you fulfill to obtain a pharmacist's license?
* If practical training is mandatory, give the subjects and training period.

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

(5) Number of pharmaceutical university or college graduates:
_____ people / per year
The alumni's placement rate (%)
a. Hospital: _____ %
b. Community Pharmacy: _____ %
c. Government Organization: _____ %
d. Enterprise: _____ %
f. Others: _____ %

⑧**Side 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.

In Brazil, medical institutions should report to Anvisa all serious adverse reactions by a system called Notivisa, according to RDC 36/2013. Notivisa is a system designed for both the citizen and for the professional who wants to send notifications of incidents, adverse events and technical complaints related to the use of products and services under health surveillance. Some services, called sentinel hospitals, also has the responsability to make a previous investigation before report. When a report is received at Anvisa, it is analysed and the analyst can contact the reporter to get additional information, if necessary. The report is analysed according to seriousness and causality (the probability that an adverse reaction can be caused due the use of a drug). If the analyst detects a signal, an investigation should be performed. According to the investigation results, the agency should take a regulatory action, such as the withdrawal from the market of the product, the use and marketing restrictions, among other interventions.

Part II: INCEPTION REPORT PRESENTATION

Why? → *To make a presentations and discussions in order to understand each other and compare among the participants*

What? → *Report of the current situation about your work, your experiences to be shared and expectations to this program.*

When? → *Report presentation is held on the beginning of the program in Japan.(It is expected on July 15)*

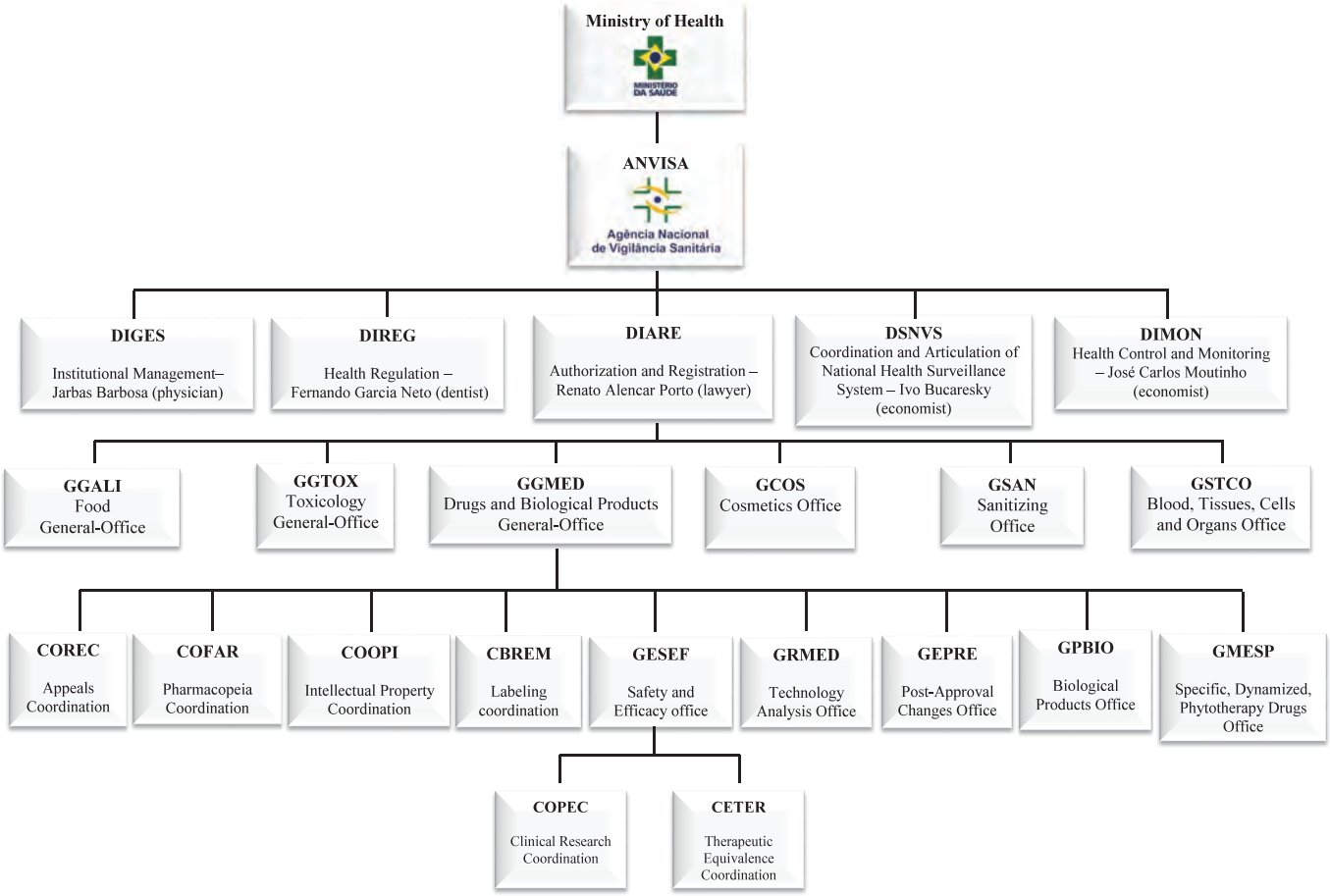
How? → *Refer to the outline described below. It is strongly recommended to prepare with Power Point (PPT).*

【Notes】・Please prepare presentation within 10 slides.

・Each presentation is allocated about 15 min. including Q/A.

◆Presentation OUTLINE

Category A	Introduction of your work —Organization & department that you belong to —Job tenure Role and position of pharmacists in your country, etc —Please describe your regulatory services that you are engaged in.
Category B	Good Practice —Please describe your experiences about Good Practices *(Examples)* ・Achievements ・Solutions for past problems ・On-going projects to deal with current problems ・Successful countermeasures against problems
Category C	Difficulties/Lessons Learned from Past Experience —Please describe your experiences you have faced difficulties, or struggled; *(Examples)* ・Problems that cannot be improved or solved ・Failed countermeasures to deal with the problems ・Emerging or Re-emerging Problems, if any
Category D	Your interests —Please describe issues you are expecting to this program.(at maximum 3(three)


Ministry of Health
ANVISA
Agência Nacional de Vigilância Sanitária
DIGES
Institutional Management– Jarbas Barbosa (physician)
DIREG
Health Regulation – Fernando Garcia Neto (dentist)
DIARE
Authorization and Registration – Renato Alencar Porto (lawyer)
DSNVS
Coordination and Articulation of National Health Surveillance System – Ivo Bucaresky (economist)
DIMON
Health Control and Monitoring – José Carlos Moutinho (economist)
GGALI
Food General-Office
GGTOX
Toxicology General-Office
GGMED
Drugs and Biological Products General-Office
GCOS
Cosmetics Office
GSAN
Sanitizing Office
GSTCO
Blood, Tissues, Cells and Organs Office
COREC
Appeals Coordination
COFAR
Pharmacopeia Coordination
COOPI
Intellectual Property Coordination
CBREM
Labeling coordination
GESEF
Safety and Efficacy office
GRMED
Technology Analysis Office
GEPRE
Post-Approval Changes Office
GPBIO
Biological Products Office
GMESP
Specific, Dynamized, Phytotherapy Drugs Office
COPEC
Clinical Research Coordination
CETER
Therapeutic Equivalence Coordination

"Roles of Regulatory Systems and Pharmacists on Ensuring Proper Access to Quality Assured Medicines （JFY 2016）"

Inception Report

Name: **CAROLINE YUKI NISHIKAWA NAGAYAMA**
Country: **BRAZIL**

Organization/Department/Division: **BRAZILIAN HEALTH REGULATORY AGENCY**

"

As indicated in the General Information, all participants are requested to prepare an inception report (Part Ⅰ and Part Ⅱ) and send it to JICA TOKYO and JICWELS (E-mail: ticthd@jica.go.jp, jigyo@jicwels.or.jp) by 27 June, 2016. **Please include 'the course title' and 'course number (J1604254)' in the e-mail title."**

【Notes】

・The report should be typed in English.

" This report consists of two parts: Part I and Part I. The main purpose of this report is to collect information in regard to pharmaceutical regulatory services of your country and more to help each participant to understand and compare other countries' situations.

Your report given here will be shared with every participant to prepare for active discussions throughout the program.

In each part, ""why, what, when and how" to be used is explained. Please follow the directions in each part."

Part I: ＩＮＦＯＲＭＡＴＩＯＮ　ＳＨＡＲＩＮＧ

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

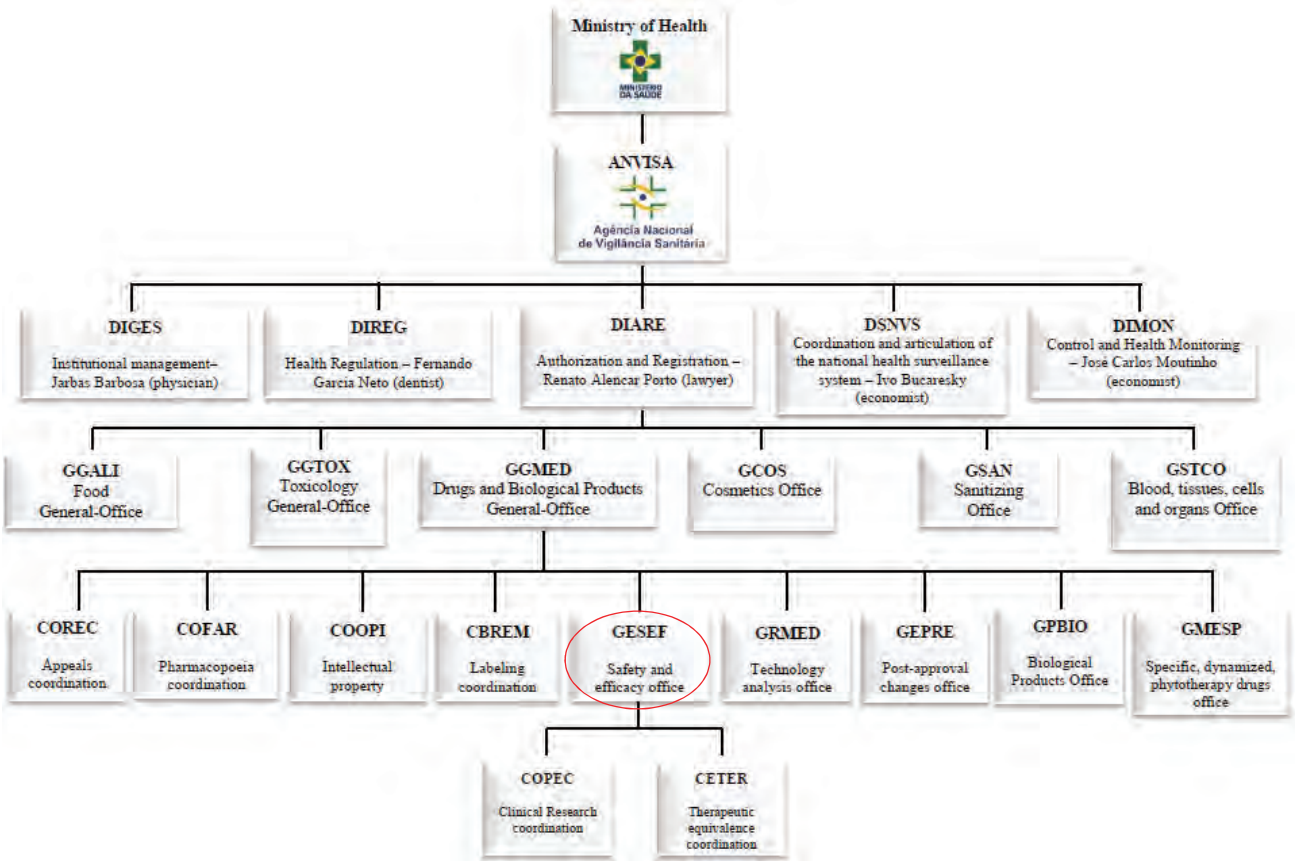
What? → Information that overviews pharmaceutical administration framework/pharmaceutical management, services, relating laws and regulations in your country.

When? → Prepare your own reports before coming to Japan, and share them with other participants at the arrival in Japan.

How? → Collect necessary information in your country and prepare reports, and presentation materials. Deepen understanding by comparison with other countries through presentation and discussions.

① Organizational Chart

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



ANVISA is the Brazilian Health Regulatory Agency, created in 1999 by a law (Lei nº 9782/1999). ANVISA was created to protect the population's health by the control of the production and the commercialization of services and products related to health. It's an autarchy indirectly linked to the Ministry of Health, which means that it has autonomy and economic independence.

ANVISA is structured in five board of directors called: 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).

I work in the safety and efficacy office (GESEF) which is subordinated to the Drugs and Biological Products General-Office. We are responsible for the analysis of clinical and non-clinical reports 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)

−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.

② Legislation on pharmaceutical administration

−Please briefly bulletined major laws/acts

◆National Level

Law 6360/1976 – it's about the health surveillance's rules that medicines, drugs, pharmaceutical ingredients, devices, cosmetics, sanitizing and other health related products are submitted to.

Decree 8077/2013 – regulates the activities described in the Law 6360.

Resolution RDC 60/2014 – provides the criteria required in order to grant a new marketing authorization for synthetic and semi synthetic drugs.

◆Local Level

Brazil has 27 state governments that have their own legislation, considering they don't differ or contradict the national laws.

◆PIC/S

Yes O R 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 informations such as systems, regulations, responsible administrators, since you are expected to explain them to other participants.

◆ Drug Import/Export

- Systems, Regulations, etc

DRUG IMPORT

The main Anvisa's resolution in drug import is the RDC nº 81/2008. Every drug must be registered at Anvisa in order to be imported by a company. This company must also have Anvisa's authorization to operate, and the imported drug must be approved in its country of origin.

On the other hand, natural persons are allowed to import drugs not approved in Brazil, just in quantity for personal use and provided they are not intended for resale (RDC nº 28/2011).

There is a list of drugs that are not approved in Brazil and can be imported exceptionally (IN nº 01/2014) for hospital use or under medical prescription, provided they are not intended for resale. To be included in the list of this normative instruction the drug should be unavailable in Brazil, it may not have others therapeutic options, the efficacy and safety of the drug should be demonstrated by indexed scientific journal articles, and the drug must be approved in its country of origin in the same administration route, strength, and therapeutic indications required.

The prohibited substances cannot be imported or exported.

DRUG EXPORT

There is no regulation for drug export. Anvisa issues export certificates to the companies that require a document of its products registered in Brazil.

◆ Pharmaceutical Manufacturing

- Systems, Regulations, etc

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. 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 the risk (population involved, disease studied…) and on the number of patients recruited (centers with a greater number of patients recruited are preferred). It is also requested an inspection after a complaint.

GOOD MANUFACTURING PRACTICE

The inspection of national pharmaceutical manufacturers is decentralized to the state and municipal government. When requested, Anvisa accompanies the local inspectors during these inspections. Anvisa is mainly responsible for the international manufacturers' inspections.

The inspections in international pharmaceutical manufacturers are performed with the purpose of certifying the good manufacturing practice (certificado de boas práticas de fabricação – CBPF). The inspection comprehends visits to the productive area, to quality control laboratories and to pharmaceutical critical utility system's sections (for example, HVAC, water for pharmaceutical use, clean steam, compressed air, etc). Additionally, there is a random evaluation of the GMP technical documents, related, for instance, to quality assurance, quality control, sanitation and hygiene, qualification and validation, calibration. The non-compliances are informed to the manufacturer during the inspection in order to adopt corrective actions in accordance to GMP requirements.

The inspection conclusion is classified in one of the three following status: satisfactory (it may be detected minor non-compliances with no likelihood of affecting population's health), unsatisfactory (it was detected critic non-compliances or recurrence of minor non-compliances) or on-demand (it was detected minor non-compliances or a low number of major non-compliances, that are unlikely to cause harm to population's health).

The GMP certificate is valid for two years. The inspection frequency is based on risk-assessment.

The main resolution is RDC 17/10 (GMP for drugs).

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

◆ Marketing Authorization

Nowadays, for new synthetic drugs the process is petitioned electronically. Older processes are still received physically. The system is called electronic registration (Registro Eletrônico - RE), where the companies upload the dossier.

A new drug application is analyzed by different areas in the agency. There is an office responsible to the analysis of the pharmaceutical technology (GRMED), which involves the assessment of the manufacturer data, manufacturers documents (CBPF) synthesis route, contaminants

and impurities, quality control methods, active pharmaceutical ingredient (API), stability testing of API (RDC 45/2012), stability data of the final product (RE 01/2005), in-process control system, packaging, labeling analysis. The major resolutions used by GRMED office are RDC 16/2007 (for generic drugs), RDC 17/2007 (for similar drugs), RDC 31/2010 and RDC 37/2011 (bioequivalence for generic and similar drugs) and RDC 60/2014 (for new drugs).

The safety and efficacy of the new synthetic drug is analyzed by another office called GESEF, where I work. We are responsible for the analysis of the clinical trials reports as well as the non-clinical reports. We also evaluate the labeling. The major resolution is RDC 60/2014.

The majority of the clinical studies applied to grant a drug registration are conducted in foreign countries. Therefore sometimes we face difficulties in analyzing these dossiers, considering that brazil has a very mixed population. For instance, to determine when should we ask for some complementary studies, in order to have a representative result of the clinical studies.

When there is some unanswered question about the dossier Anvisa 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.

It is also required a pharmacovigilance plan, which is analyzed by Pharmacovigilance Office (Gerência de Farmacovigilância – GFARM). When it is identified a notable risk for the new drug, the agency requires a risk management plan, which is also analyzed by GFARM.

・ Systems, Regulations, etc

※Example: Good Quality Practice

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

・ Systems, Regulations, etc

In Brazil everybody has 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.

In the public service this is not Anvisa's scope. Once marketed, the drug selection, procurement and distribution to the population is a Ministry of Health's attribution.

※Example: Good Distribution Practice

◆ Medicine Safety (post-marketing)

・ Systems, Regulations, etc

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 health surveillance reporting system is called NOTIVISA. The adverse events' reports are also collected by the ombudsman service.

Brazil is a WHO member (http://who-umc.org/DynPage.aspx?id=100653&mn1=7347&mn2=7252&mn3=7322&mn4=7442), following its guidelines, and Anvisa is the national pharmacovigilance center, a WHO approved pharmacovigilance center of countries participanting in the WHO Programme for International Drug Monitoring.

Source: http://www.who.int/medicines/areas/quality_safety/safety_efficacy/nat_centres/en/

The main national regulations in pharmacovigilance are RDC nº 04/2009, regulates how the pharmacovigilance should be done by the marketing authorization holders (MAH), and RDC nº36/2013, which establishes rules for the patient's safety in health care system.

The pharmacovigilance is one of the fields that we have to improve, as we don't have a good reporting system and culturally our population don't have the habit of reporting.

※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.

- Systems, Regulations, etc

④ Drug Pricing

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

In Brazil it was created in 2003 the Drug Market Regulation Chamber (Câmara de Regulação do Mercado de Medicamentos – CMED) by the law 10.742. The CMED is responsible for drug market regulation and for establishing criteria of drug prices definition and their adjustments. Anvisa has the attribution of the Executive Secretariat in the CMED, managing price controls of pharmaceutical drugs commercialized in Brazil by setting price-cap standards.

It's available at Anvisa's website (http://portal.anvisa.gov.br/consulta-lista-de-preco-de-medicamento) a list with the ceiling prices, the maximum price allowed for a drug.

There is also a price-cap established for the public sector. The state and municipal governments have some tools to acquire drugs by lower prices, for instance electronic trading, annual drug acquisition with installment delivery, and establishment of consortium among the states.

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: 176.963 pharmacists in Brazil (Source: http://ictq.com.br/portal/estatisticas-do-setor-farmaceutico/censo-demografico-farmaceutico, January, 2014)

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 statistic number. We only have the total number of pharmaceutical manufacturers.

5: Number of pharmaceutical importers: (YEAR)

992 importers (Source: Datavisa - Anvisa, 2015)

6: Number of pharmaceutical wholesalers : (YEAR)

6583 wholesalers (Source: Datavisa – Anvisa, 2015)

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 MAH 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). In case of death or risk of death, the SAE 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.

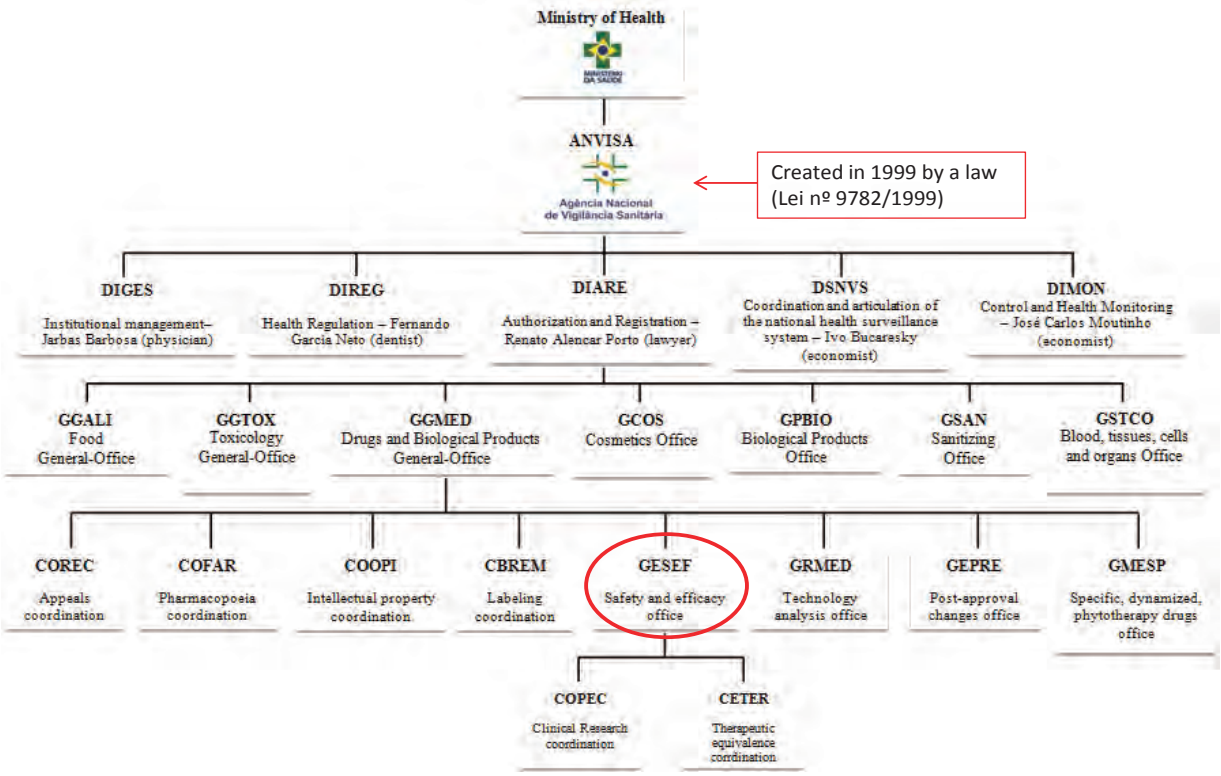
Roles of Regulatory Systems and Pharmacists on Ensuring Proper Access to Quality Assured Medicines

Caroline Yuki Nishikawa Nagayama
Specialist in Regulation and Health Surveillance
Brazilian Health Regulatory Agency (ANVISA)

July, 2016

Agência Nacional de Vigilância Sanitária

ANVISA Organizational Chart



Agência Nacional de Vigilância Sanitária

Legislation on pharmaceutical administration

- National level

Law 6360/1976

Decree 8077/2013

Resolution RDC 60/2014

- Local level

27 state governments that have their own legislation, considering they don't differ or contradict the national laws

- PIC/S

GMP – 2018/2019

GCP – 2015/2016: inspections with England and Austria

Agência Nacional de Vigilância Sanitária

Drug Import and Export

DRUG IMPORT

- Every drug must be registered at Anvisa (RDC 81/2008)
- The company must have Anvisa's authorization to operate
- The imported drug must be approved in its country of origin
- Natural persons are allowed to import drugs not approved just for personal use (RDC 28/2011)

DRUG EXPORT

- There is no regulation for drug export
- Anvisa issues export certificates that the product is approved in Brazil

Agência Nacional de Vigilância Sanitária

Pharmaceutical Manufacturing

GOOD CLINICAL PRACTICE

- RDC 09/2015: regulates the conduction of clinical trials with drugs in Brazil. Incorporates ICH E6 guideline
- The inspections evaluate the clinical research centers' systems, the ethical documents, the case report forms.
- Based on the risk, the number of patients recruited and after a complaint

GOOD MANUFACTURING PRACTICE

- National pharmaceutical manufactures – decentralized inspections
- International pharmaceutical manufacturers – CBPF (GMP certificate) valid for 2 years. Frequency: risk-based.
- RDC 17/2010 (GMP for drugs)

Agência Nacional de Vigilância Sanitária

Marketing Authorization

SYSTEM

- Electronic registration (Registro eletrônico – RE)

DOSSIER ANALYSIS

- GRMED: pharmaceutical technology
  - RDC 16/2007 (for generic drugs)
  - RDC 17/2007 (for similar drugs)
  - RDC 31/2010 and RDC 37/2011 (bioequivalence for generic and similar drugs)
  - RDC 60/2014 (for new synthetic and semi-synthetic drugs)
- GESEF: safety and efficacy (clinical and non-clinical trials reports)
  - RDC 60/2014

Agência Nacional de Vigilância Sanitária

Drug Distribution and Drug Pricing

DRUG DISTRIBUTION

- Unified Health System (Sistema Único de Saúde – SUS)
- Ministry of Health's attribution

DRUG PRICING

- Law 10.742/ 2003: created the Drug Market Regulation Chamber (CMED)
  - CMED establishes criteria of drug prices definition and adjustments
  - ANVISA has the attribution of the Executive Secretariat in the CMED
  - It's available at Anvisa's website (http://portal.anvisa.gov.br/consulta-lista-de-preco-de-medicamento) a list with the ceiling prices, the maximum price allowed for a drug
  - There is a different price-cap established for the public sector

Agência Nacional de Vigilância Sanitária

Medicine Safety

POST-MARKETING PHARMACOVIGILANCE

- Voluntary reporting of AE by health practitioners and patients
- Web form available at Anvisa's website
- The health surveillance reporting system is called NOTIVISA
- Anvisa is a WHO member, being the national pharmacovigilance center
- RDC 04/2009: regulates how the pharmacovigilance should be done by the marketing authorization holders (MAH)

RELIEF SYSTEM FOR ADVERSE DRUG REACTIONS

- Anvisa's website
- MAH's letter to the health practitioners

Agência Nacional de Vigilância Sanitária

Statistic Data

1. **Number of pharmacists**

   176.963 pharmacists in Brazil (Source: http://ictq.com.br/portal/estatisticas-do-setor-farmaceutico/censo-demografico-farmaceutico, January, 2014)

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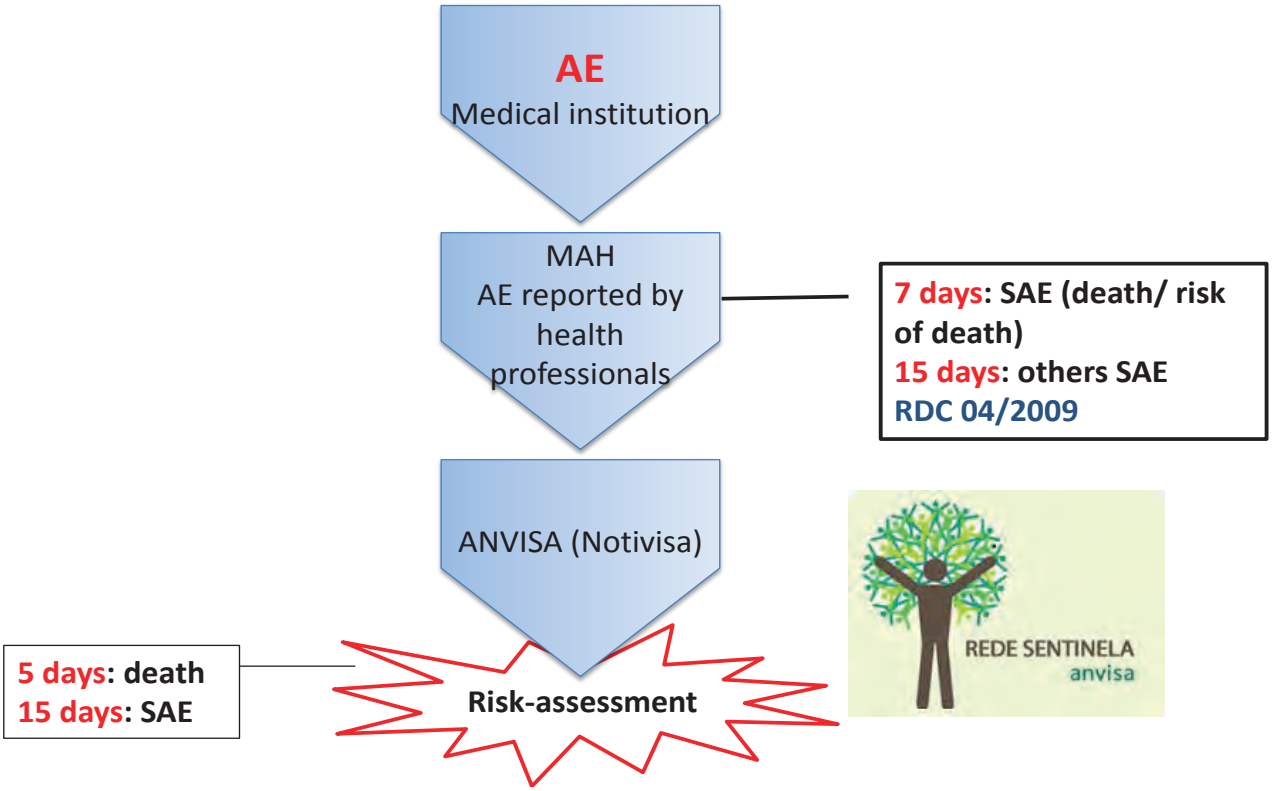
Agência Nacional de Vigilância Sanitária

Side Effect Report



GHANA

Roles of Regulatory Systems and Pharmacists on Ensuring Proper Access to Quality Assured Medicines (JFY 2016)

DANIEL NII AMOO ANKRAH

KORLE-BU TEACHING HOSPITAL

ACCRA, GHANA

BACKGROUND OF THE KORLE-BU TEACHING HOSPITAL

The Korle-Bu Teaching Hospital was established in 1923 as a 192 bed hospital. This was under the direction of Sir Gordon Guggisberg, the then British governor of the Gold Coast, now Ghana. The Hospital became a teaching hospital as a result of the establishment of the Ghana Medical School in 1962.

Today the Hospital has a bed capacity of 2000 and 21 clinical and diagnostic departments. It has three centers of excellence namely National Cardiothoracic Center, National Center for Radiotherapy and Nuclear Medicine, and National Reconstructive Plastic Surgery and Burns Center. It has a staff capacity of about 4000 at the moment.

The Hospital is guided by a board appointed by the president of Ghana and is managed by a chief executive and seven directors.

Mission and Vision statement of KBTH

Mission: “We are committed to provide quaternary health care facilities and services, training, research, outreach and advocacy for clients within and outside Ghana”.

Vision: “To become the preferred center of excellence and innovation for specialist health care provision, training, research and advocacy in Ghana and West Africa”.

HEALTH SYSTEM IN GHANA - 1

Ministry of Health

Responsible for:

A. Policy Formulation

B. Monitoring and Evaluation

C. Resource Mobilization

D. Regulation of the Health Services Delivery.

Its autonomous agencies are responsible for implementation of national policies through their governing Councils.

- The agencies receive public funds and thus remain within the public sector

HEALTH SYSTEM IN GHANA 2

Ministry of Health Agencies

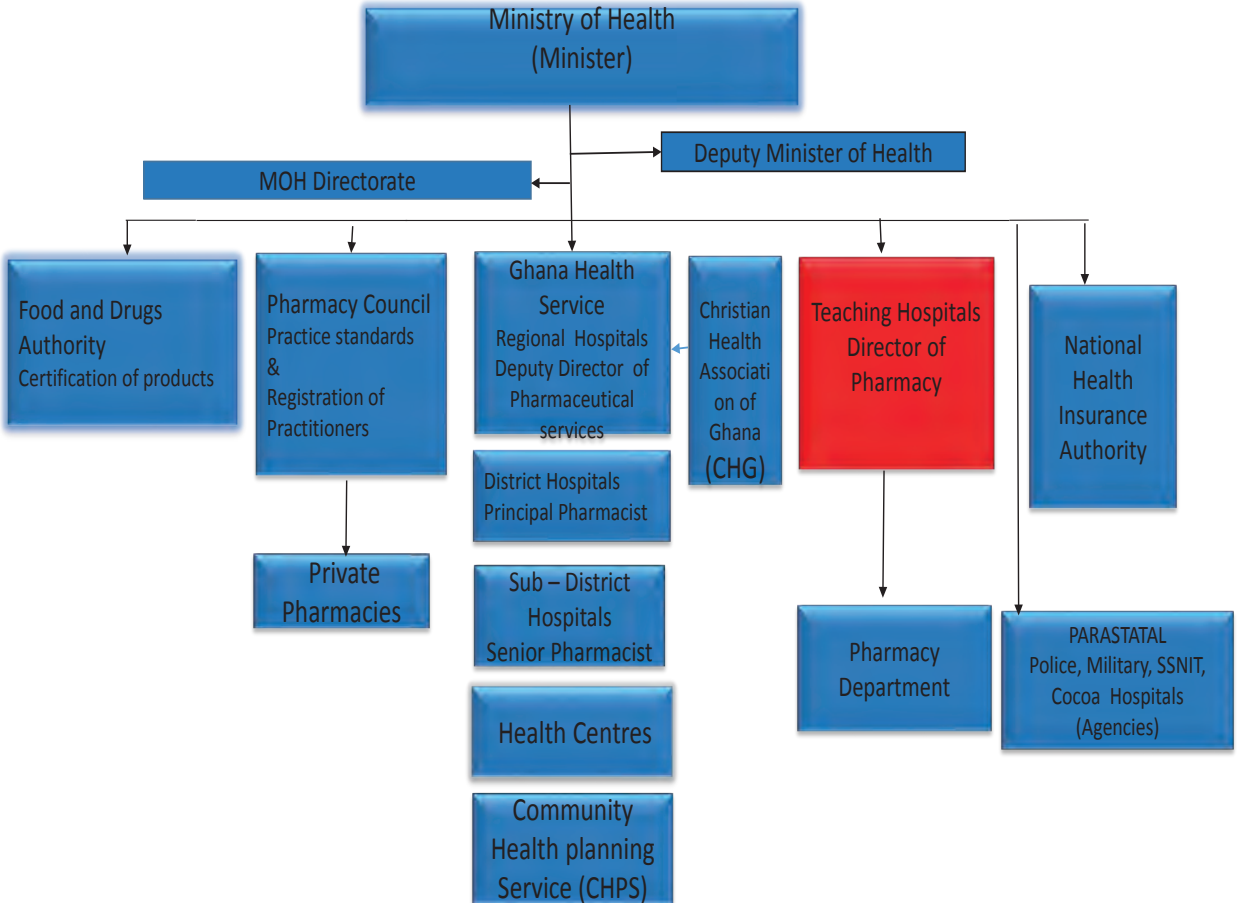
- Ghana Health service
- National Health Insurance Authority
- National Ambulance service
- Teaching Hospitals - 4 in the country
- Christian Health Association of Ghana
- Health Regulatory Bodies on professional standards
  - Pharmacy Council,
  - Food and Drug Authority
  - Medical and Dental Council
  - Nurse and Midwives Council
  - Health Facilities Regulatory Agency
  - Traditional and Alternate medicine Council
  - Psychology Council
  - Allied Health Council
- The centre for scientific research into plant medicine (CSRPM)

HEALTH SYSTEM IN GHANA 3

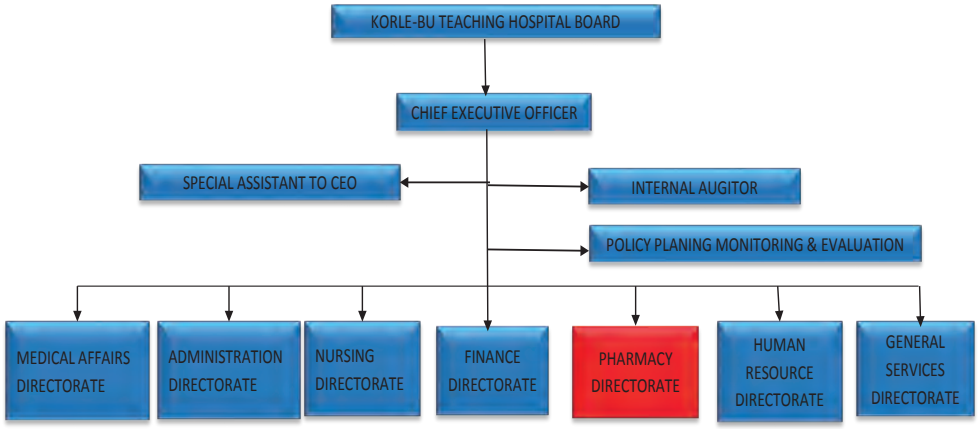
Some Ghana's development Partners in Health

- WHO
- UNICEF
- Japan International Cooperation Agency -JICA
- Department for International Development - DFID
- Danish International Development Agency - DANIDA
- GLOBAL FUND
- World Health Organisation - WHO
- United Nation Development Programme – UNDP
- UNAIDS, USAID

Administrative Structure of Pharmaceutical Services - 1.0



Administrative organogram of Korle-Bu Teaching Hospial



Administrative Structure of Pharmaceutical Services - 1.1

- In the Public sector, Medicines are categorised into level of care and are accessed accordingly: from the lower level Community Health planning Services (CHPS), Health Centre, sub district health facility, District hospital, Regional, and Referral/Teaching hospitals in ascending order.
- Mostly non- prescription medicines are available at the sub district level and in the rural areas
- No person deals in restricted medicines unless he/she is registered with Pharmacy Council
- The Pharmacy Council licenses the private pharmacies

ROLES OF PHARMACISTS IN MEDICINE REGULATION 1.2

It is recognised that certified medicine by Food and Drugs Authority that are safe , efficacious, and of good quality in the hands of unqualified persons can pose risk to the public, thus the role of a pharmacist in medicine regulation is vital;

- Detecting, identification of substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medicines in supply and distribution chains and reporting to Food and Drugs Authority for appropriate action
- Post – marketing safety issues: Detecting and reporting ADR to Food and Drugs Authority
- Manage properly supply chain and inventory control of medicines to ensure constant availability of Essential Medicines

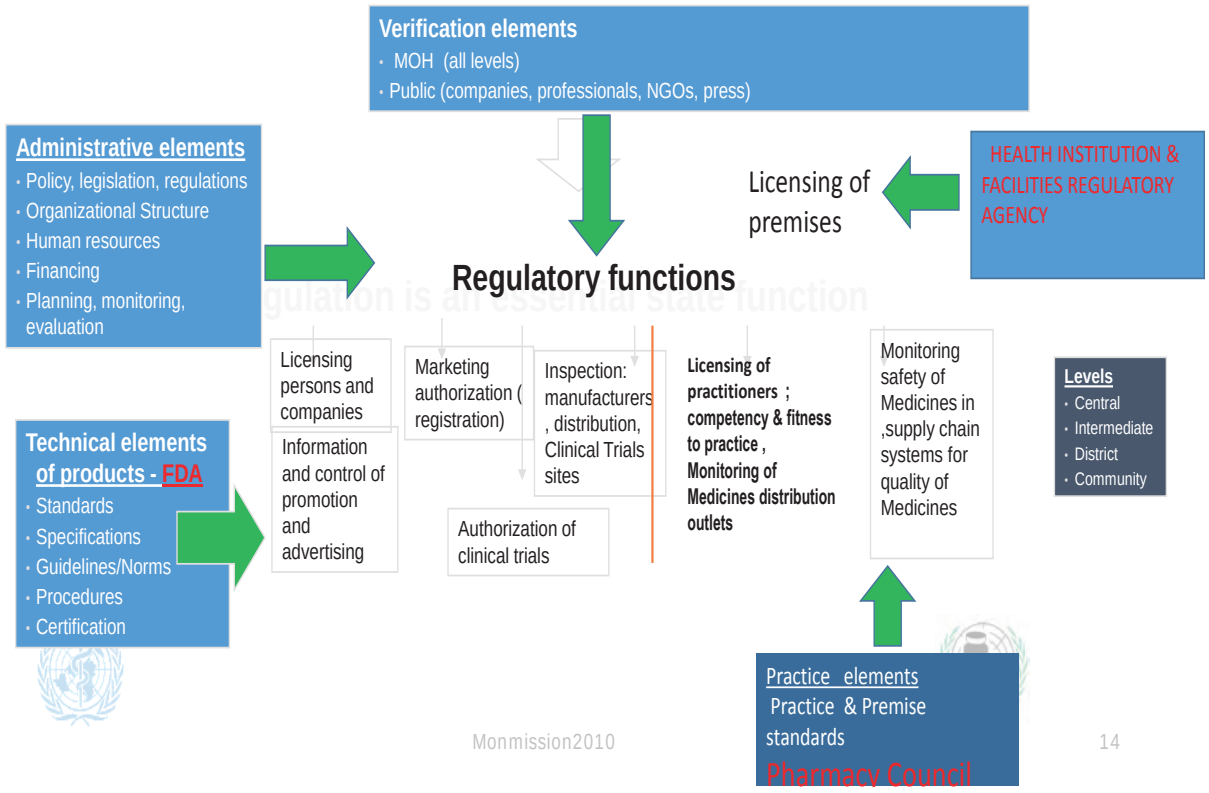
ROLES OF PHARMACISTS IN MEDICINE REGULATION - 1.3

- They take into custody, preparation and dispensing of medicines
- Selection and provision of prescription and non-prescription medicines to patients from private retail pharmacies
- Ensure safe and rational use of medicines
- Lead in medicine Policy and hospital formulary formulation
- Provide information on medicine to other health professionals
- Provide clinical service to all deserving patients
- Play an active role on Drugs and Therapeutic Committees
- Perform operational research, involve in clinical trials

LEGISLATIONS REGULATING ACCESS TO MEDICINES IN GHANA - 2

legislation /Act	CONSTITUENT	STATUS OF LI
The Health Professions Regulatory Bodies Act, 2013 (Act 857)	Pharmacy Council	LI Pending
Traditional Medicine Practice Act 2000 (Act 575)	Traditional and Alternative Medicine Council	
Public Health Act 2012, Act 851	Food and Drug Authority	Outstanding
Health Institutions and Facilities Regulatory Act 2011 (Act 829)	Health facilities Regulatory Agency	Submitted to AG Depart
National Insurance Authority Act 2012 (Act 852)	National Health Insurance Authority	Pending to submitted to AG Depart
Specialist Health Training & Plant Medicines Research Act 833	Ghana college of Pharmacist & Centre for plant Medicine Research	Pending completed
Ghana National Medicine policy (GNDP) 3rd edition	GNDP & Ministry of Health	Submitted to Cabinet

REGULATORY FUNCTIONS – 3



MEDICINE REGULATION IN GHANA

Food and Drugs Authority (FDA)

- By the law medicines must be registered by FDA before distribution and use in Ghana
- Product assessment and registration programme thus constitute the hub of FDA regulatory function:
  - Evaluation of technical and administrative data associated with products
  - Laboratory testing or analysis
  - Decision to approve or disapprove of products
  - Issuance of market authorisation
  - Issuance of import permit
  - Conducting ADR monitory on medicines

  This is to ensure that registered products have been adequately tested and evaluated for safety, efficacy and quality that information provided to the patients is accurate and not misleading

MEDICINE REGULATION IN GHANA

Pharmacy Council

By Health Professions Regulatory Bodies Act, 857 part V & VI, any person who practice pharmacy in Ghana must be registered. This is to ensure in the public interest the highest standards of pharmacy practice in the country, Thus:

The primary regulatory functions of the Pharmacy Council includes:

- Register pharmacist and Pharmaceutical support staff
- Set standards for continuous professional development for Pharmacists
- Ensure the equitable and accessible distribution of pharmaceutical premises
- Set and maintain standards for pharmacy practice and professional conduct
- Register , Monitor and evaluate medicines distribution outlet to ensure that set standards /quality of medicines are complied with
- Exercise disciplinary power over pharmacists and pharmaceutical support staff

Drug import/export 3.1

Drug (including active pharmaceutical ingredients) importation and exports are regulated and controlled by:

- The FDA
- Ministry of Trade
- Customs Excise and Preventive Service.

Where narcotic drug importation is involved, the Narcotics Control Board is also involved. For example, the KBTH imports Morphine for the preparation of Morphine Sulphate solution.

Pharmaceutical Manufacturing 3.2

The manufacturing premises as well as production and process are regulated by the FDA Ghana. The FDA Ghana trains personnel on Good Clinical practice (see below). They also ensure that Good Manufacturing Practices (GMP) are adhered to by all manufacturers.

The Ghana Standards Authority inspects equipment through their Metrology Division and maintains standards.

The qualified personnel to register the manufacturing facility is regulated by the Pharmacy Council.


FOOD AND DRUGS BOARD

Certificate

This is to certify that

Daniel Ankrah

has successfully participated in the Good Clinical Practice (GCP)Workshop Organized by the Food & Drugs Board 28-30 March ,2011

Chief Executive
Food and Drugs Board
DR. STEPHEN K. OPUNI

WHO Country Representative


International Workshop

on

Good Manufacturing Practice(GMP)

Accra, Ghana, 24th - 26th July, 1997

Certificate of Participation Awarded to

Daniel Ankrah.

Sponsors:

WHO IFPMA FIP CPA WAPF

WAPF President
Prof. K. Boakye-Yiadom

Workshop Chairman
Prof. J.S.K. Ayim

Marketing Authorization (MA) 3.3

The FDA Ghana has a separate division for Safety Monitoring and Clinical Trials of products. They regulate all phases of clinical trials involving medicines in Ghana. The FDA is the only body in Ghana responsible for issuing MA to any pharmaceutical manufacturer or importer.

Drug selection, procurement and sale 3.4

Drug selection is done by the Ghana National Drugs Programme in collaboration with all health stakeholders (clinicians, pharmacists, nurses).

Drug procurement is done with the guidance of the Public Procurement Act, Act 663 (2003).

Ghana has an open market system and there is no price control on the sale of medicines.

.

Medicine Safety (post-marketing surveillance) 3.5

· 1. Safety Monitoring and Clinical Trail Division of the Food and Drugs Authority responsible for post marking surveillance.

2. Two Technical advisory committees on: i. Medicines and ii. vaccines and biologicals products which review ADR cases reported.

3. Systems of reporting by filling the Blue form and returning them (it is voluntary)

- Health professional in health facilities – ADR
- Patients – side effects of medicines

4. Feed back in writing to reporters/institutions

Relief System for Adverse drug Reaction 3.6

Drug-related iatrogenic diseases, when they occur, are reported to FDA Ghana. The reporting institution takes care of the patient naturally (as if it were a normal disease occurrence).

If the person has registered with the National Health Insurance Authority, free services are provided.

There is no special relief package in the form of regulation in Ghana at the moment for such situations.

MEDICINES PRICING - 4.0

- The Ministry of Health (MOH) has no pricing policy
- MOH Centrally Procures Anti –retroviral (ARVs), psychotropic, family planning products, anti-tuberculosis drugs and vaccines through voluntary pooled procurement from Global Fund and Global Drug Facility (GDF) and supply them supplied free. (Programme medicines)
- Essential medicines are procured by the Central and Regional Medical Stores, Tertiary and district facilities directly
- National Insurance Scheme coverage is about 80 – 95 % of consultations in public facilities
- Over 50 % National Insurance Scheme expenditure is on medicines
- Affordability 62 % of the population
- Facilities prices tends drift towards the reimbursement price of National Insurance Scheme
- The proportion of uninsured patients that are willing to pay extra for non . EML is about 2 %

MEDICINES PRICING IN GHANA 4.1

PRICE C0MPONET OF MEDICINES (OUT – POCKET PAYMENT & NHIS)

- ✓ In public facilities the mark up is 12% - 20%
- ✓ Import duty 10 % of CIF and VAT 17.5 %,
- ✓ Tariffs; port rent, handling and clearing agent fees
- ✓ Mark-up ; importers typically added up 36 % ex – factory price. medicines and retailers - 30 %,
- ✓ a levy of 2.5 % on goods and services are charge for NHIS
- ✓ Paediatric formulations are more expensive than adult formulations . Paracetamol syrup is 400 % more expensive than the respective tablet

STATISTICAL DATA – 5.0

Facility	Number As at 31 Dec. 2015
Pharmacist (Practising)	2578
GMP inspectors	27
Pharmaceutical manufactures	39
Traditional medicine manufactures	100
Importers	38
Pharmaceutical wholesalers	235

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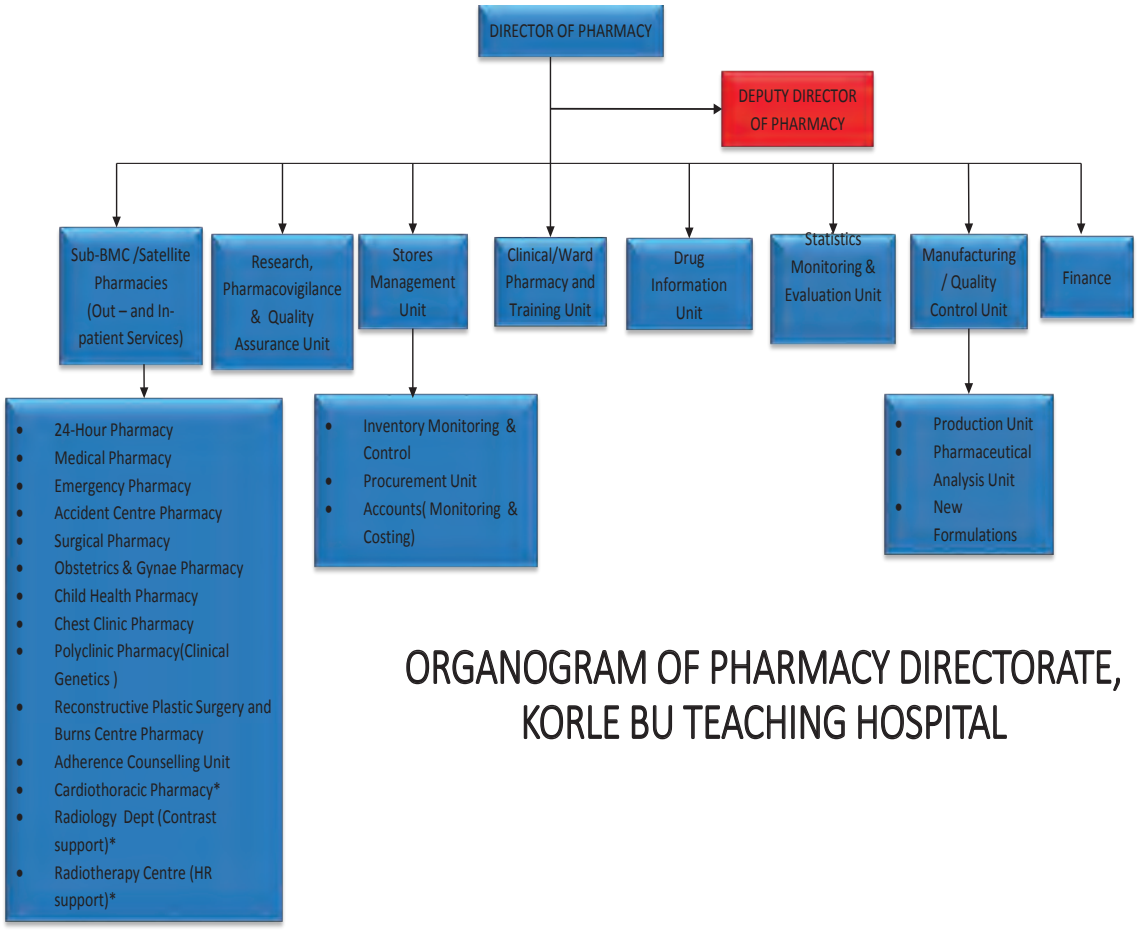
INFORMATION ON PHARMACISTS AND PHARMACY PRACTICE AT THE KORLE-BU TEACHING HOSPITAL 6.0

Mission and Vision Statement of the Pharmacy Department

Mission: "To ensure acquisition and supply of safe medicines, promote cost-effective medication use, and work synergistically with health care colleagues to stimulate optimal drug therapeutic outcomes through the development of integrated quality programs in patient care, research and education".

Vision: "To ensure that the Pharmacy Directorate is envisaged as a leader in providing optimal pharmaceutical expertise, innovation and personalized care to (patients) clients who visit the Korle-Bu Teaching Hospital".



ORGANOGRAM OF PHARMACY DIRECTORATE, KORLE BU TEACHING HOSPITAL

PHARMACY MANAGEMENT STAFF 6.1

Director of Pharmacy	1
Deputy Director of Pharmacy	1
Pharmacy Managers	17

Number of Pharmacy Staff 6.2

Number of Pharmacists (Total)	84
Number of clinical pharmacists	20
Number of Public Health Pharmacists	7
Number of Pharmacy Technicians	34

Number of kinds of drugs managed at the Korle-Bu Teaching Hospital 6.3

Oral medicines (tablets, syrups and suspensions)	**385**
Injections (including anaesthetic agents)	**156**
Medicines for external use (eye, ear, nose, creams and ointments)	**71**

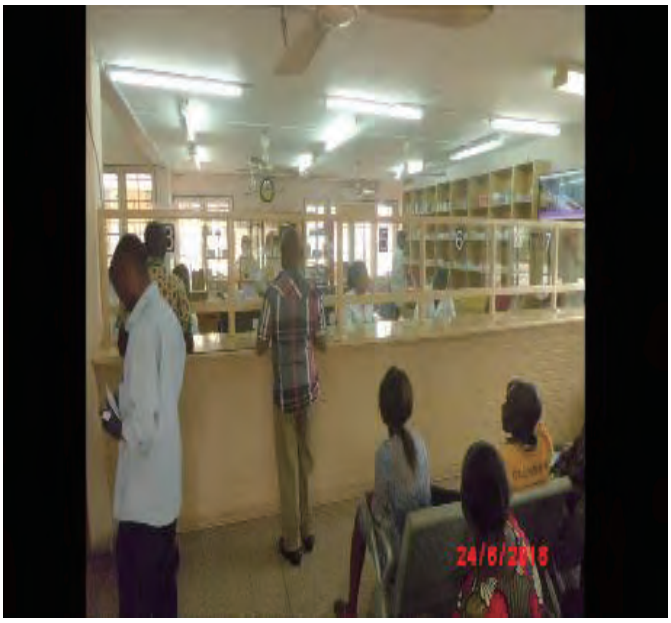
Number of prescriptions dealt with per day 6.4

For in-patients	**137**
For out-patients	**1,091**

Equipment of the Pharmacy at the Korle-Bu Teaching Hospital 6.5

A/ Presence of dispensary room • **8 dispensaries in all**	**Yes**	**18-150 m^3** (smallest to largest)
B/ Presence of lamina flow	Yes	3 a. Oncology admixtures b. Radiopharmacy c. Manufacturing Unit
C/ Presence of computers **All the dispensaries use computers**	Yes	• Inventory control • Drug billing • Dispensing • Internet access
D/ Therapeutic drug monitoring	No	
E/ Preparation of Total Parenteral Nutrition (TPN)	No	We use preformed TPN
F/ Internet at the pharmacy	Yes	• For drug information purposes • Computer communication • Accounting purposes

Pictures of the largest pharmacy at the KBTH



EDUCATION AND LICENSING OF PHARMACISTS GHANA -7.0

School	years	Total years in school
Primary school	6	17 (19 for doctorate in Pharmacy)
Junior secondary	3	
Senior secondary school	3	
University	4 For Bsc 6 For doctorate in Pharmacy	
Internship training A. *Accredited Public hospital for clinical practical training* *B. Accredited Private pharmacy* Proposed Internship for Doctorate of pharmacy	9 months 3 months } BSc Pharmacy to be phased out by 2018 40 weeks in hospital for graduates of doctorate in Pharmacy. (students in the fourth year)	
Ghana Pharmacy Professional Qualifying Examination	December and April annually	Twice in a year

PHARMACY TRAINING INSTITUTIONS -7.1

Name of university	An average turn out of graduates per year
Kwame Nkrumah University of Science & Technology	250
University of Ghana School of Pharmacy	40
Central University College	90
Ghana Post – Graduate college of Pharmacists for specialist training	First 150 graduates are expected in 2018
Total	380

PHARMACISTS LICENSED FOR THE PAST THREE YEARS - 7.2

year	Number licensed
2014	207
2015	199
2016	350
Total	**756**
Average per a year	**252**

Side effect report at the Korle-Bu Teaching Hospital 8.0

In the event of a severe side effect of a drug or herbal preparation, there are two ways to report. The first is that the reporting health personnel (doctor, pharmacist or nurse) fills the approved "blue form" (see next slide). This form is then submitted to the Safety Monitoring and Clinical Trials Division of the Food and Drugs Authority (FDA) Ghana. The form is submitted either by direct posting to FDA (their address is behind the form) or by informing them via telephone, and someone will be sent to collect it as soon as possible. The second option is to submit the report online. Online submission is done by visiting the FDA's website (www.fdaghana.gov.gh). However, one needs a username and password to send a form online. This username and password is provided by the FDA upon application. When the FDA receives the form, they give two responses. Firstly, a letter of acknowledgement is written to sender. At the FDA, a preliminary assessment of the report is made. For serious reports an investigation is made within 48 hours of receiving it. The details of the report is then entered into the national database. Then the form is sent to the Technical Advisory Committee (TAC) on safety of medicines of the FDA for causality assessment. When findings are made, a second letter is sent to the sender of the form informing him/her on the outcome of the report. After causality assessment by the TAC, the form is submitted to the Vigiflow database. This is a web-based Individual Case Safety Report (ICSR) management system that is specially designed for use by national centres in the World Health Organization (WHO) Programme for International Drug Monitoring. The center is at Uppsala in Sweden. A flow chart of the process is attached.

Reporting form and flow chart for reporting adverse reactions in Ghana by health professionals.

FDA/SMC/SMD/GL-RAR/2013/01

APPENDIX I- Adverse Reaction Reporting Form

Age/Date of Birth (dd/mm/yyyy): / / Gender: M ( ) F ( ) Wt: .....kg
Name/Folder Number: ..... Telephone No: .....
Hospital/Treatment Centre: .....

(B) DETAILS OF ADVERSE REACTION AND ANY TREATMENT GIVEN (Attach a separate sheet when necessary)

Date reaction started (dd/mm/yyyy): / / Date reaction stopped (dd/mm/yyyy): / /

(C) OUTCOME OF ADVERSE REACTION:

Recovered ( ) Not yet recovered ( ) Unknown ( )
Did the adverse reaction result in any untoward medical condition? Yes ( ) No ( ) If yes, specify.....
SEVERITY: Death ( ) Life threatening ( ) Disability ( ) (specify)..... Hospitalization ( )
Others (specify).....

(D) SUSPECTED PRODUCT(S) (Attach sample or product label if available)

Brand name	Generic name	Batch no.	Expiry date	Manufacturer

Reasons for use (Indication)	Daily dose:	Route of Administration:
Date started:	Date stopped:	
Did the adverse reaction subside when the drug was stopped (de-challenge)? Yes ( ) No ( )		
Was the product prescribed? Yes ( ) No ( )	Source of Drug:	

Was product re-used after detection of adverse reaction (re-challenge)? Yes ( ) No ( )
Did adverse **reaction** re-appear upon re-use? Yes ( ) No ( )

(E) CONCOMITANT DRUGS INCLUDING HERBAL MEDICINES TAKEN PRIOR TO THE ADVERSE REACTION
(Attach a separate sheet when necessary)

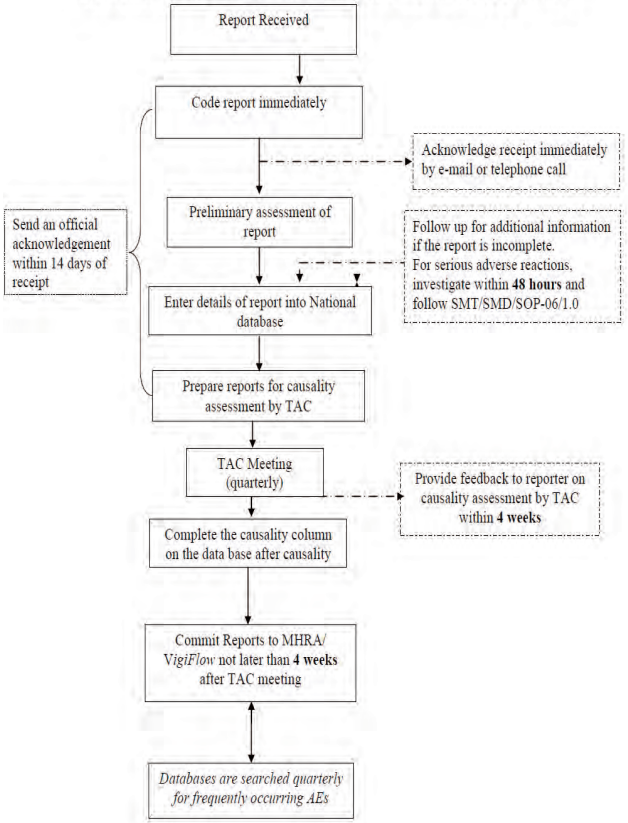
Name of Drug	Daily dose	Date started	Date stopped	Reasons for use

Attach all relevant laboratory tests/data

(F) DETAILS OF REPORTER

Name of Reporter: .....
Address: .....
Profession: .....
Signature: .....
Tel: .....
E-mail: .....
Date (dd/mm/yyyy): / /

FLOW CHART FOR PROCESSING OF INDIVIDUAL CASE SAFETY REPORTS



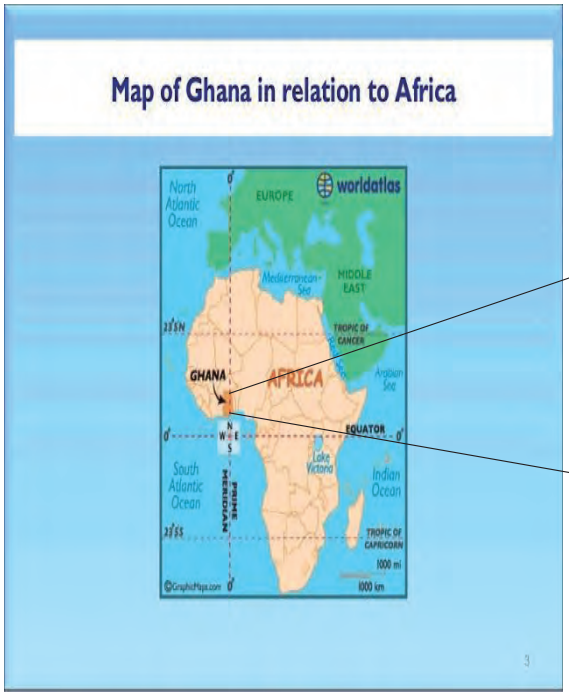
Roles of Regulatory Systems and Pharmacists on Ensuring Proper Access to Quality Assured Medicines （JFY 2016）
PART 2

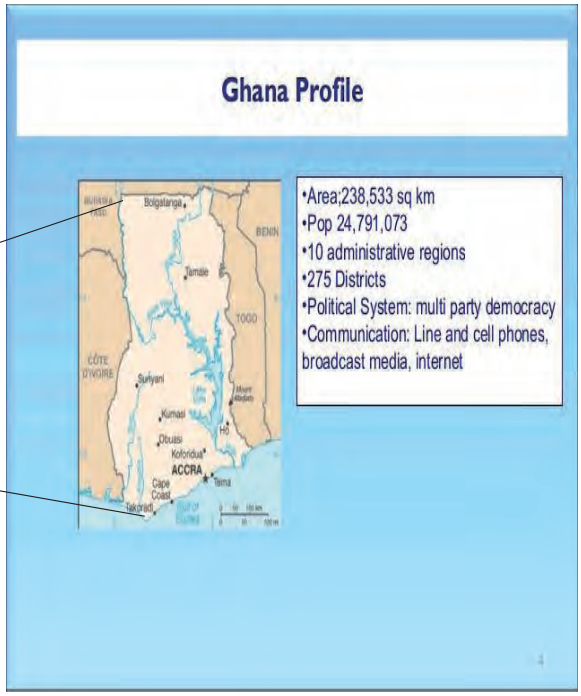
Name: Daniel Ankrah

Country: Ghana

Organization/Department: Korle-Bu Teaching Hospital

Demography of Ghana



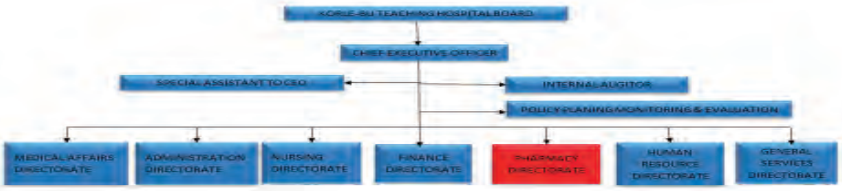


Organization and department

Korle-Bu Teaching Hospital (1923) established by the British

- A 2000 bed hospital with 17 clinical and diagnostic departments including the department of pharmacy
- 3 Centres of clinical excellence
  - ❖National Cardiothoracic Centre
  - ❖National Centre for Radiotherapy and Nuclear Medicine
  - ❖National Reconstructive Plastic Surgery and Burns Centre

Administrative organogram of Korle-Bu Teaching Hospial



Organization and department cont.

Pharmacy department

Job tenure : 1/10/1991 – Houseman pharmacist

1/01/1993 – Assistant pharmacist

1/02/1996 – Pharmacist

1/03/2001 – Senior pharmacist

4/03/2006 – Principal pharmacist

4/03/2011 – Deputy Director of Pharmaceutical Services

4/01/2016 – Ag Deputy Director of Pharmacy

15/07/2016 – Still at post

Role and position of pharmacists in Ghana

Government employee

Academia – lecturer/researcher

Health programme

- Mental Health
- National Malaria Drugs Program
- National AIDS Control Programme
- National tuberculosis control programme
- Expanded programme on immunization

Hospital

- Ghana Health Service
- Teaching Hospital

Regulatory agency

- FDA Ghana/Pharmacy Council

Any of the United Nation's bodies (WHO)

Private employee/employer

Community (retail) practice

Industry

Medical Representative

Wholesale supplier/distributor

Regulatory services performed

- Institutional contact person for safety of medicines
- Member of the Technical Advisory Committee on Biological Products and Vaccines, FDA Ghana
- Member of the Korle-Bu Teaching Hospital Ethical Review Committee
- Oversees the Local Manufacturing Unit of the KBTH
- Heads the Pharmacy Practice Research Unit of the Pharmacy Department


HONOR CODE CERTIFICATE

edX MITx

Daniel Ankrah

successfully completed and received a passing grade in

10.03x: Making Biologic Medicines for Patients: The Principles of Biopharmaceutical Manufacturing

a course of study offered by MITx, an online learning initiative of The Massachusetts Institute of Technology through edX.

J. Christopher Love
Associate Professor, Department of Chemical Engineering
Massachusetts Institute of Technology

Anthony J. Sinskey
Professor, Department of Biology
Massachusetts Institute of Technology

Stacy L. Springs
Director, Biomanufacturing Program
Center for Biomedical Innovation
Massachusetts Institute of Technology

Paul W. Barone
Assistant Director for Programs,
Center for Biomedical Innovation
Massachusetts Institute of Technology

Sanjay Sarma
Dean of Digital Learning
Massachusetts Institute of Technology

HONOR CODE CERTIFICATE
Issued September 07, 2015

Verify the authenticity of this certificate at
https://verify.edx.org/cert/29144e4bc1e141199507 7cacc5ae9751


International Workshop
on
Good Manufacturing Practice(GMP)
Accra, Ghana, 24th - 26th July, 1997
Certificate of Participation Awarded to
Daniel Ankrah.
Sponsors:
WHO IFPMA FIP CPA WAPF
WAPF President
Prof. K. Bodiley-Tladom
Workshop Chairman
Prof. J.S.K. Ayim


FOOD AND DRUGS BOARD
Certificate
This is to certify that
Daniel Ankrah
has successfully participated in the Good Clinical Practice (GCP) Workshop Organized by the Food & Drugs Board 28-30 March, 2011
Chief Executive
Food and Drugs Board
DR. STEPHEN K. OPUNI
WHO Country Representative

.Good practices: Achievements, solutions for the past


Drug Saf
DOI 10.1007/s40264-013-0037-7
ORIGINAL RESEARCH ARTICLE

Incidence of Adverse Events Among Healthcare Workers Following H1N1 Mass Immunization in Ghana

A Prospective Study

Daniel N. A. Ankrah · Aukje K. Mantel-Teeuwisse · Marie L. De Bruin · Philip K. Amoo · Charles N. Ofei-Palm · Irene Agyepong · Hubert G. M. Leufkens


Ankrah et al. BMC Health Services Research (2016) 16:198
DOI 10.1186/s12913-016-1459-6

BMC Health Services Research

RESEARCH ARTICLE Open Access

Insufficient access to oral paediatric medicines in Ghana: A descriptive study

Daniel N A Ankrah[1,2*], Joseph T Turkson[2], Edith B Boateng[3], Frank T T Amegavie[2] and Elizabeth Bruce[2]

Good practices: On-going projects to deal with current problems

- Reporting of adverse events following immunizations in Ghana - Using disproportionality analysis reporting ratios – Research
- Audit of the new prescription form to improve access to medicines through rational prescribing - Research

.Difficult lessons learned from past experience

- Hospital Drugs and Therapeutic Committees (DTC) and FDA Ghana have trained health care professionals on identification and reporting of spontaneous adverse events but the outcomes are not improving

- Availability of a hospital formulary, Essential Medicines list and Standard Treatment Guidelines; training on the use of these documents are provided periodically. However, we still see prescriptions that are not in these documents. What are we not doing right? Communication?

Expectations by the end of this program

1. To learn best practices that will encourage spontaneous reporting of adverse events of medicines by health care professionals

2. To learn what other countries doing right in generic prescribing, because it reduces cost and improves access to medicines. “Generic paradox”

3. Find out more on off-label prescribing of medicines since there is evidence that it is associated with unknown adverse events.

PART I

Roles of regulatory systems and pharmacists on ensuring proper access to quality assured medicines (JFY 2016)

HENRY SAJA MADEN

GHANA

PHARMACY COUNCIL, GHANA

GHANA - 1

Ghana, officially called the Republic of Ghana is a sovereign, unitary presidential constitutional democracy

- located along the Gulf of Guinea , in the sub region of West Africa with land mass of 238,535 square km
- Ghana is bordered by the Ivory Coast in the west, Burkina Faso in the north, Togo in the east and Atlantic Ocean in the south.
- Ghana has a population of approximately 27 million
- Ghana is one of the world's largest producer of gold and second producer of cocoa.
- Religiously, 5.2% of the population is traditional religion, 71.2% are Christian and 17.6% of the total are Muslim.

GHANA ON THE WORLD MAP

GHANA ON WEST AFRICA MAP

MAP OF GHANA

PHARMACY COUNCIL, GHANA

VISION

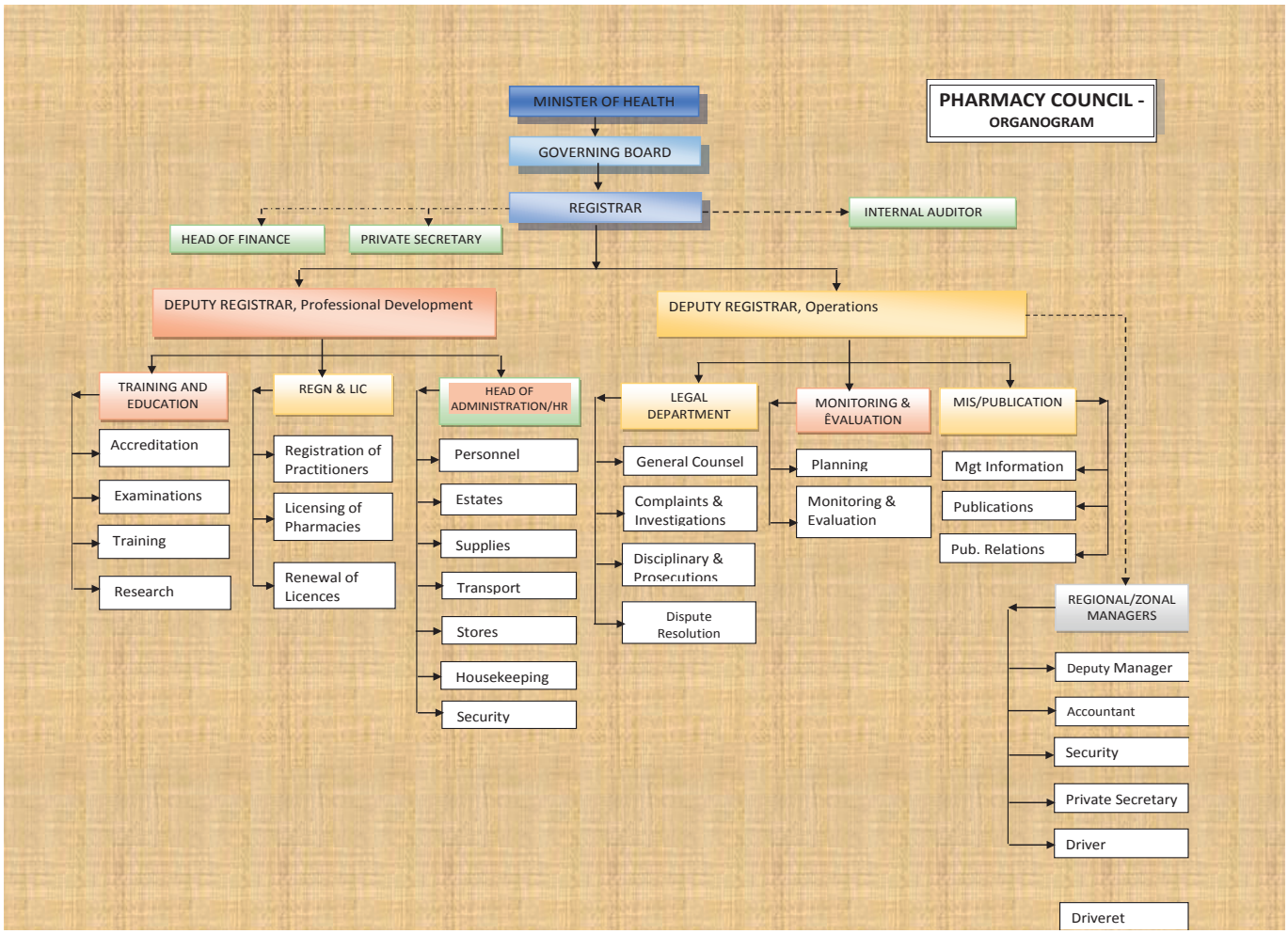
To guarantee the highest levels of pharmaceutical care

MISSION STATEMENT

The mission of the Pharmacy Council, Ghana is to secure the highest level of pharmaceutical care by ensuring competent pharmaceutical care providers who practice within agreed standards and are accessible to the whole population. In addition we shall collaborate with related local agencies and international pharmaceutical organizations to enhance our effectiveness and our contribution to rational medicine use in the nation. This mission shall be carried out with dedication, integrity, and professionalism.

PHARMACY COUNCIL, GHANA

The Pharmacy Council of Ghana is a statutory regulatory body established by an act of parliament , the Health Professions Regulatory Act , 2013 (Act) 857 , part 4 and 6 . The objective of the Council is to secure in the public's interest, the highest standards of pharmaceutical care in Ghana.



Induction of New Pharmacists

HEALTH SYSTEM IN GHANA - 1

Ministry of Health

Responsible for:

A. Policy Formulation

B. Monitoring and Evaluation

C. Resource Mobilization

D. Regulation of the Health Services Delivery.

Its autonomous agencies are responsible for implementation of national policies through their governing Councils.

- The agencies receive public funds and thus remain within the public sector

HEALTH SYSTEM IN GHANA 2

Ministry of Health Agencies

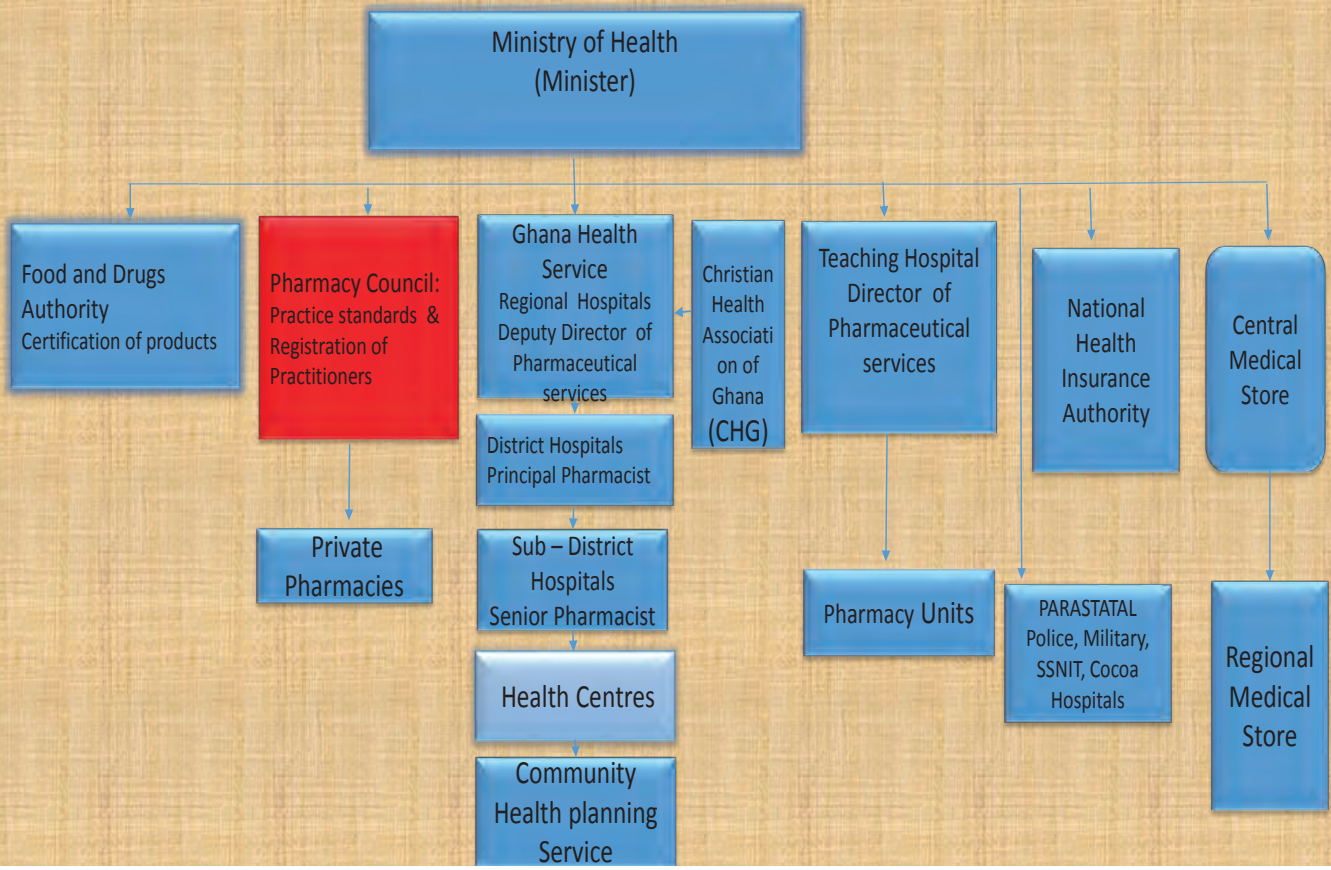
- Ghana Health service
- National Health Insurance Authority
- National Ambulance service
- Teaching Hospitals - 4 in the country
- Christian Health Association of Ghana
- Health Regulatory Bodies on professional standards
  - Pharmacy Council,
  - Food and Drug Authority
  - Medical and Dental Council
  - Nurse and Midwives Council
  - Health Facilities Regulatory Agency
  - Traditional and Alternate medicine Council
  - Psychology Council
  - Allied Health Council
- The centre for scientific research into plant medicine (CSRPM)

HEALTH SYSTEM IN GHANA 3

Some Ghana's development Partners in Health

- WHO
- UNICEF
- Japan International Cooperation Agency -JICA
- Department for International Development - DFID
- Danish International Development Agency - DANIDA
- GLOBAL FUND
- World Health Organisation - WHO
- United Nation Development Programme – UNDP
- UNAIDS, USAID

ADMINISTRATIVE STRUCTURE OF PHARMACEUTICAL SERVICES - 1.0



ADMINISTRATIVE STRUCTURE OF PHARMACEUTICAL SERVICES - 1.1

- In the Public sector, Medicines are categorised into level of care and are accessed accordingly: from the lower level Community Health planning Services > Health Centre > sub district health facility > District hospital > Regional > Referral/Teaching hospitals the highest level
- only Non- prescription medicines are available at the sub district level and in the rural areas
- No person deals in restricted medicines unless he/her is registered with Pharmacy Council
- The Pharmacy Council licenses the private pharmacies

ROLES OF PHARMACISTS IN MEDICINE REGULATION 1.2

It is recognised that certified medicine by Food and Drugs Authority to be Safe , efficacious, and of good quality in the hands of unqualified persons can pose risk to the public, thus the role of a pharmacist in medicine regulation is vital;

- Detecting, identification of falsified and sub standard medicines in supply and distribution chains and reporting to Food and Drugs Authority for appropriate action
- Post – marketing safety issues: Detecting and reporting ADR to Food and Drugs Authority
- Manage properly supply chain and inventory control of medicines to ensure constant availability of Essential Medicines

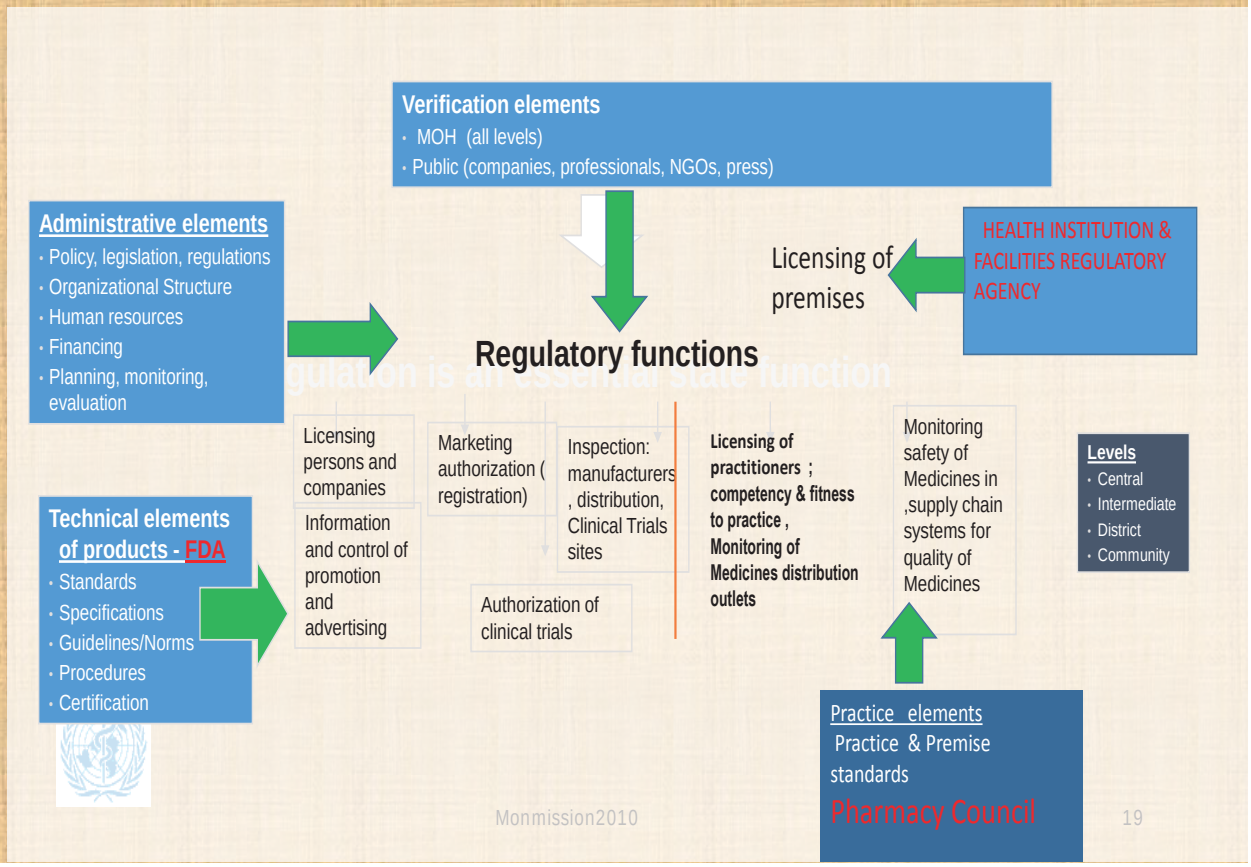
ROLES OF PHARMACISTS IN MEDICINE REGULATION - 1.3

- The take into custody, preparation and dispensing of medicines
- selection and provision of non-prescription medicines to patients from private retail pharmacies (2,165 in the country)
- Ensure safe and rational use of medicines
- Lead in medicine Policy formulation
- Provide information on medicine to other health professionals

LEGISLATIONS REGULATING MEDICINES SUPPLY IN GHANA - 2

legislation /Act	CONSTITUENT	STATUS OF LI
The Health Professions Regulatory Bodies Act, 2013 (Act 857)	Pharmacy Council	LI Pending
Traditional Medicine Practice Act 2000 (Act 575)	Traditional and Alternative Medicine Council	
Public Health Act 2012, Act 851	Food and Drug Authority	Outstanding
Health Institutions and Facilities Regulatory Act 2011 (Act 829)	Health facilities Regulatory Agency	Submitted to AG Depart
National Insurance Authority Act 2012 (Act 852)	National Health Insurance Authority	Pending to submitted to AG Depart
Specialist Health Training & Plant Medicines Research Act 833	Ghana college of Pharmacist & Centre for plant Medicine Research	Pending completed
Ghana National Medicine policy third edition	GNDP & Ministry of Health	Submitted to Cabinet

REGULATORY FUNCTIONS – 3



MEDICINE REGULATION IN GHANA – 3.1

Food and Drugs Authority (FDA)

- By the law medicines must be registered by FDA before distribution and use in Ghana
- Product assessment and registration programme thus constitute the hub of FDA regulatory function:
  - Evaluation of technical and administrative data associated with products
  - Laboratory testing or analysis
  - Decision to approve or disapprove of products
  - Issuance of market authorisation
  - Issuance of import permit
  - Conducting ADR monitory on medicines

  This is to ensure that registered products have been adequately tested and evaluated for safety, efficacy and quality that information provided to the patients is accurate and not misleading

MEDICINE REGULATION IN GHANA – 3.2

Pharmacy Council (PC)

By Health Professions Regulatory Bodies Act, 857 part V & VI, any person who practice pharmacy in Ghana must be registered. This is to ensure in the public interest the highest standards of pharmacy practice in the country, Thus:

The primary regulatory functions of the Pharmacy Council includes:

- Register pharmacists and Pharmaceutical support staff
- Set standards for continuous professional development for Pharmacists
- Ensure the equitable and accessible distribution of pharmaceutical premises
- Set and maintain standards for pharmacy practice and professional conduct
- Register , Monitor and evaluate medicines distribution outlet to ensure that set standards /quality of medicines are complied with
- Exercise disciplinary power over pharmacists and pharmaceutical support staff
- Ensure that the education and training of pharmacists and pharmaceutical support staff are carried out in approved educational institutions

DRUG IMPORT/EXPORT 3.3

- ❖Drug (including Active Pharmaceutical Ingredients (API) importation and exports are regulated and controlled by:
- ❖The FDA in collaboration with Ministry of Trade and Customs Excise and Preventive Service.
- ❖Where narcotic drug importation is involved, the Ghana Narcotics Control Board is also involved.

PHARMACEUTICAL MANUFACTURING 3.4

- ❑The manufacturing premises as well as production and process are regulated by the FDA Ghana. The FDA Ghana trains personnel on Good Clinical practice (see below). They also ensure that Good Manufacturing Practices (GMP) are adhered to by all manufacturers.
- ❑The Ghana Standards Authority inspects equipment through their Metrology Division and maintains standards.
- ❑The qualified personnel to register the manufacturing facility is regulated by the Pharmacy Council.

MARKETING AUTHORIZATION (MA) 3.5

The FDA is the only body in Ghana responsible for issuing MA to any pharmaceutical manufacturer or importer.

The FDA Ghana has a separate division for Safety Monitoring and Clinical Trials of products. They regulate all phases of clinical trials involving medicines in Ghana.

GOOD DISTRIBUTION PRACTICES - 3.6

- Any person who practice pharmacy in Ghana must be registered.
- Availability of non prescription medicines outlets in the rural areas
- No medicine is offered for dispensing in Ghana unless it is registered by Food and Drugs Authority
- The current policy of MOH allows herbal medicines to be prescribed and dispensed in the hospitals
- Medicines are permitted to be dispensed from only registered premises

DRUG SELECTION, PROCUREMENT AND SALE 3.7

- Medicines selection is done by the Ghana National Drugs Programme in collaboration with all health stakeholders (clinicians, pharmacists, nurses).
- medicines procurement is done with the guidance of the Public Procurement Act, Act 663 (2003).
- Ghana has an open market system and there is no price control on the sale of medicines.

MEDICINES PRICING - 4.0

- The Ministry of Health (MOH) has no pricing policy
- MOH Centrally Procures Anti –retroviral (ARVs), psychotropics, family planning products and vaccines through voluntary pooled procurement from Global Fund and Global Drug Facility (GDF) and supply them supplied free. (Programme medicines)
- Essential medicines are procured by the Central and Regional Medical Stores, Tertiary and district facilities directly
- National Insurance Scheme coverage is about 80 – 95 % of consultations in public facilities
- Over 50 % National Insurance Scheme expenditure is on medicines
- Affordability 62 % of the population
- Facilities prices tends drift towards the reimbursement price of National Insurance Scheme
- The proportion of uninsured patients that are willing to pay extra for non . EML is about 2 %

MEDICINES PRICING IN GHANA 4.1

PRICE COMPONET OF MEDICINES (OUT – POCKET PAYMENT & NHIS)

- ✓ In public facilities the mark up is 12% - 20%
- ✓ Import duty 10 % of CIF and VAT 17.5 %,
- ✓ Tariffs; port rent, handling and clearing agent fees
- ✓ Mark-up ; importers typically added up 36 % ex – factory price. medicines and retailers - 30 %,
- ✓ a levy of 2.5 % on goods and services are charge for NHIS
- ✓Paediatric formulations are more expensive than adult formulations . Paracetamol syrup is 400 % more expensive than the respective tablet

Ghana National Medicines Policy 3rd Edition 2016-2020

STATISTICAL DATA – 5.0

Facility	Number As at 31 Dec. 2015
Pharmacist (Practising)	2578
GMP inspectors	27
Pharmaceutical manufactures	39
Traditional medicine manufactures	100
Importers	38
Pharmaceutical wholesalers	235

REGIONAL DISTRIBUTION OF PRIVATE PHARMACIES – 5.1

NO.	Region	Number On Register	Retail	Wholesale	Wholesale/Retail	Manufacture with wholesale outlets
1	Ashanti	478	286	51	98	6
2	Brong Ahafo	55	8	3	44	0
3	Central	55	27	5	27	0
4	Eastern	71	22	7	35	1
5	Greater Accra	1371	670	141	152	10
6	Northern	30	13	10	12	0
7	Upper East	13	5	1	6	0
8	Upper West	7	2	0	4	0
9	Volta	31	11	3	16	0
10	Western	78	30	14	33	0
TOTAL		2189	1074	235	437	17

Pharmacy Council annual report 2015

PHARMACY COUNCIL , INSPECTORS – 5.2

Inspectors	Number at post
Registrar	**1**
Ag. Deputy Registrar	1
Deputy Chief Inspecting Pharmacist	3
Principal Inspecting Pharmacist	8
Senior Inspecting Pharmacist	16
Inspecting Pharmacist	3
Total	32

EDUCATION AND LICENSING OF PHARMACISTS GHANA -7.0

School	years	Total years in school
Primary school	6	17 (19 for doctorate in Pharmacy)
Junior secondary	3	
Senior secondary school	3	
University	4 For Bsc 6 For doctorate in Pharmacy	
Internship training A. *Accredited Public hospital for clinical practical training* *B. Accredited Private pharmacy* Proposed Internship for Doctorate of pharmacy	9 months BSc Pharmacy to be phased out by 2018 3 months 40 weeks in hospital for graduates of doctorate in Pharmacy. (students in the fourth year)	
Ghana Pharmacy Professional Qualifying Examination	December and April annually	Twice in a year
Registration and issue of number Continuous Professional Development & Re – licensure (minimum 10 credit point)	Once annually	

PHARMACY TRAINING INSTITUTIONS -7.1

Name of university	An average turn out of graduates per year
Kwame Nkrumah University of Science & Technology	250
University of Ghana School of Pharmacy	40
Central University College	90
Ghana Post – Graduate college of Pharmacists for specialist training	First 150 graduates are expected in 2018
Total	380

PHARMACISTS LICENSED FOR THE PAST THREE YEARS - 7.2

year	Number of Pharmacists licensed
2014	207
2015	199
2016	350
Total	**756**
Average per a year	**252**

POST - MARKETING SURVEILLANCE - 8 .0

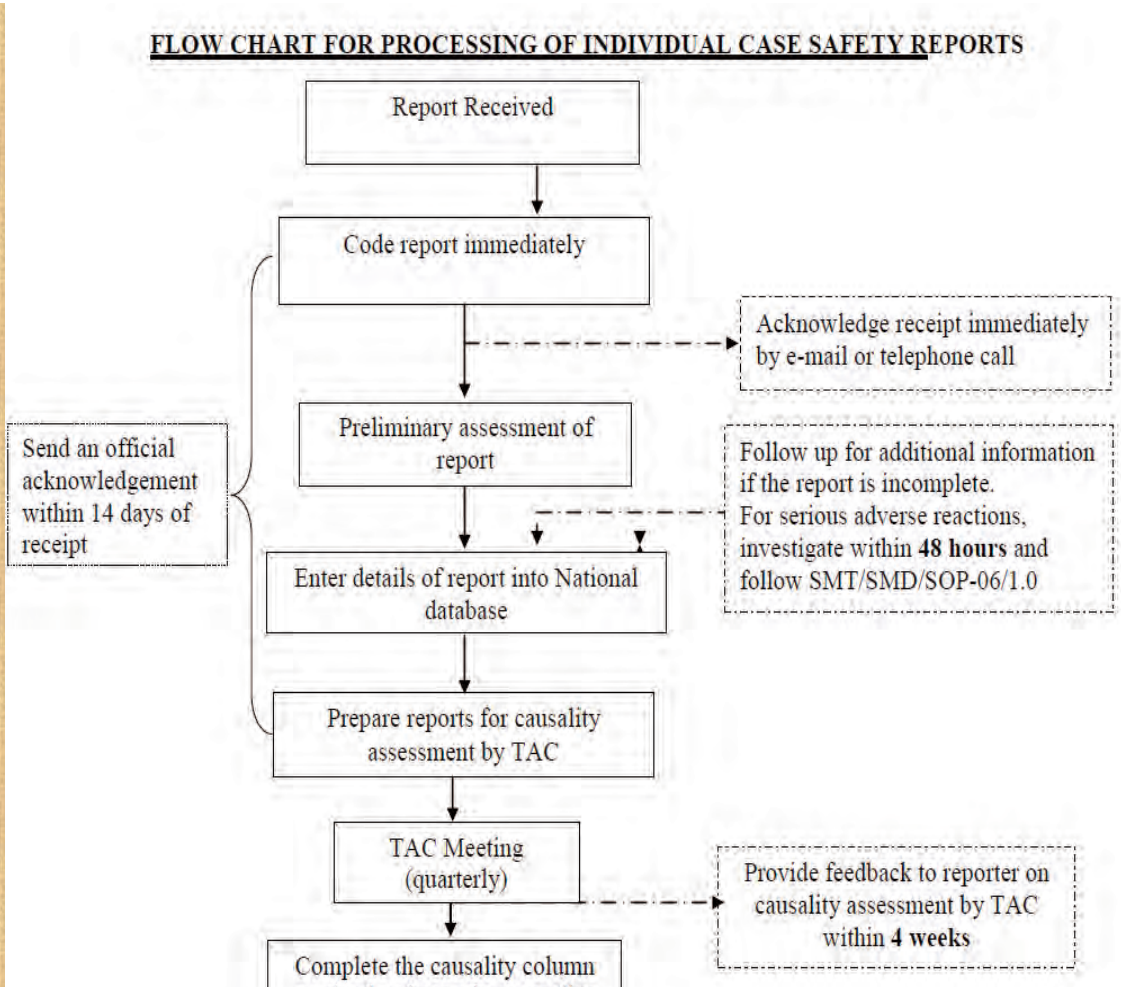
1. Safety Monitoring and Clinical Trail Division of the Food and Drugs Authority responsible for post marking surveillance.
2. Two Technical advisory committees on ; 1. Medicines 2. vaccines and biologicals products which review ADR cases reported.
3. Systems of reporting by filling the Blue form and returning them (it is voluntary)

- Health professional in health facilities – ADR
- Patients – side effects of medicines

4. Feed back in writing to reporters/institutions

RELIEF SYSTEM FOR ADVERSE DRUG REACTION 8.1

- Medicines -related iatrogenic diseases, when they occur, are reported to FDA Ghana. The reporting institution takes care of the patient naturally (as if it were a normal disease occurrence).
- If the person has registered with the National Health Insurance Authority, free services are provided.
- There is no special relief package in the form of regulation in Ghana at the moment for such situations.



GOOD PHARMACOVIGILANCE PRACTICES 8.2

- A division at FDA for Safety Monitoring
- Safety Monitoring of facilities by team of FDA inspectors
- Involvement of Patients in reporting side effects of medicines to the regulators
- Feed back on cases to reporters/institutions
- Contact persons in health institutions who liaise with FDA

PART II

Roles of regulatory systems and pharmacists on ensuring proper access to quality assured medicines (JFY 2016)

HENRY SAJA MADEN

GHANA

PHARMACY COUNCIL, GHANA

GHANA - 1

Ghana, officially called the Republic of Ghana is a sovereign, unitary presidential constitutional democracy

- located along the Gulf of Guinea , in the sub region of West Africa
- Ghana has a population of approximately 27 million with a variety of ethnic, linguistic and religious groups.
- Ghana is one of the world's largest producer of gold and second producer of cocoa.
- National capital Accra

GHANA ON THE WORLD MAP

MAP OF GHANA

PHARMACY COUNCIL , GHANA

VISION: to guarantee the highest levels of pharmaceutical care in Ghana

Post : Head of Monitoring and Evaluation Department.

Title : Deputy Chief Inspecting Pharmacist

(Equivalent of Deputy Director of pharmaceutical services)

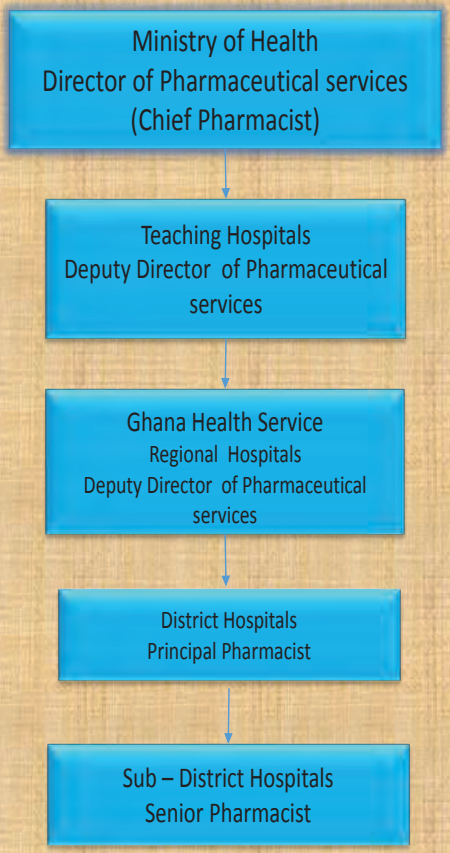
Job functions and responsibilities:

- ❑ Monitor and Evaluate Pharmacy Council's inspections and enforcement activities and report to the Governing Board
- ❑Recommend and prepare concept paper in the areas of operational research
- ❑Liaise with other departments and regional offices to prepare annual plans of work and budget

ROLES OF PHARMACISTS IN MEDICINE REGULATION

- Detecting, identification of falsified and sub standard medicines in supply and distribution chains and reporting to Food and Drugs Authority for appropriate action
- Post – marketing safety issues: Detecting and reporting ADR to the appropriate Authorities
- The take into custody, preparation and dispensing of medicines
- selection and provision of non-prescription medicines to patients from private retail pharmacies (2,165 in the country)
- Ensure safe and rational use of medicines
- Lead in medicine Policy formulation
- Provide information on medicine to other health professionals
- Manage properly supply chain and inventory control of medicines to ensure constant availability of Essential Medicines

POSITIONS OF PHARMACISTS IN GHANA



REGULATORY SERVICES DIRECTLY ENGAGED

lead in monitoring and evaluation of inspection/enforcement activities in medicines distribution outlets to drive improvement in set standards for access to quality medicines in Ghana

GOOD PRACTICES 1

- TRANSPARENCY : guidelines that explains how our services can be accessed and helping duty holders to understand what is expected of them and what they should expect from the Council.

The problem: Prospective pharmaceutical service providers turn to middle men for help to obtain permit . These Men pose as staff of the Council thus undermine the credibility of our inspectors

led in the review of guidelines (including application forms) detailing how to obtain pharmacy operating licence. The Procedures , processes, requirement and the responsibility and role of pharmacist. For both private and public pharmacies/dispensary and made it available free of charge at the regional office and at our website. Before then, they were been sold

GOOD PRACTICES - 2

- CONSISTENCY in Enforcement : taking a similar approach in similar circumstances to achieve similar outcomes

- The problem: Regional variation in approaches to inspections and response to incidents and breaches.

In February 2015 , Led in development of standard operating procedures for Routine , site, Processing of applications for permits

DIFFICULTIES/LESSONS FROM THE PAST EXPERIENCE

- The risk management and control approach to regulation have no effective mechanism for demonstration improvement in standards –

In January 2016. led in redesigning checklist used for inspections in cooperating action plans for improving poor standards & in service training... Tracking what is needed to be improved. Emphasis on optimum outcome. That is improvement rather then minimum standards

- Effective pharmacist direct personal control of private pharmacies had been our problem.

Measures such suspensions, fines , Reprimand had not worked in the past

- Emerging problems- Regulating internet pharmacy

INTEREST

To understudy the international best regulatory practices as it pertains in developed and developing nations and adopt them to Ghanaian situation.

This will strengthen our capacity to modernise inspection and enforcement activities at medicines distribution outlets to ensure continuous improvement in access to quality medicines .

NIGERIA

Annex1

Roles of Regulatory Systems and Pharmacists
on Ensuring Proper Access to Quality Assured Medicines（JFY 2016）

Inception Report

Name:
Country:
Organization/Department/Division:

As indicated in the General Information, all participants are requested to prepare an inception report (Part Ⅰ and Part Ⅱ) and send it to JICA TOKYO and JICWELS (E-mail: ticthd@jica.go.jp, jigyo@jicwels.or.jp) by 27 June, 2016. Please include 'the course title' and 'course number (J1604254)' in the e-mail title.

【Notes】

This report consists of two parts: Part I and Part I. The main purpose of this report is to collect information in regard to pharmaceutical regulatory services of your country and more to help each participant to understand and compare other countries' situations.
Your report given here will be shared with every participants to prepare for active discussions throughout the program.
In each part, "why, what, when and how"to be used is explained. Please follow the directions in each part.

Part I: INFORMATION SHARING

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

What? → *Information that overviews pharmaceutical administration framework/pharmaceutical management, services, relating laws and regulations in your country*

When? → *Prepare your own reports before coming to Japan, and share them with other participants at the arrival in Japan.*

How? → *Collect necessary information in your country and prepare reports, and presentation materials. Deepen understanding by comparison with other countrie through presentation and discussions.*

① **Organizational Chart**
—Please attach the organizational chart 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 to focus on the position of the pharmacist in medical institutions.

vent drug misuse. The roles of pharmacy is diverse in Nigeria. Besides the hospital functions, a lot of phramacists are into the commu

② **Legislation on pharmaceutical administration**
—Please briefly bulletined major laws/acts

◆National Level
- mandatory 1 year internsh administered by Pharmaceutical Cou uncil of Nigeria
- License to Practice administered by Pharmaceutical Cou uncil of Nigeria

◆Local Level
License to Practice administered by Pharmaceutical Council of Nigeria
mandatory annual renewal c administered by Pharmaceutical Council of Nigeria

◆PIC/S
Yes OR No If yes, joined when NO

③ **Regulatory Services**
—Please describe pharmaceutical regulatory services of your country in response to each issues described below.
—It is recommended to add supplemental informations such as systems, regulations, responsible administrators, since you are expected to explain them to other particip

◆ Drug Import/Export
- Systems, Regulations, etc

WHO Guidelines on Distribution of Pharmaceuticals	administered by	WHO/NAFDAC
NAFDAC Guid elines on Good Distribution Prac ctices, 2016	administered by	NAFDAC

◆ Pharmaceutical Manufacturing
- Systems, Regulations, etc

WHO Guidelines on Good Manufacturing Practices	administered by	WHO/NAFDAC
NAFDAC Guid elines on Good Manufacturing Practices , 2016	administered by	NAFDAC

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

◆ Marketing Authorization
- Systems, Regulations, etc

NAFDAC Guidelines on Good Manufacturing Practices, 2016	administered by	NAFDAC
NAFDAC Guidelines on Good Distribution Practices, 2016	administered by	NAFDAC

※Example: Good Quality Practice

◆ Drug Distribution (including drug selection, procurement, sale)
- Systems, Regulations, etc

NAFDAC Guidelines for Good Distribution Practices, 2016	administered by	NAFDAC
	administered by	NAFDAC

※Example: Good Distribution Practice

◆ Medicine Safety (post-marketing)

・ Systems, Regulations, etc

WHO Guide to good Pharcovigilance Practices	administered by	WHO/NAFDAC
NAFDAC Guidelins to Good Pharmacovigilance Practice, 2016	administered by	NAFDAC

※Example: Good Pharmacovigilance Practice

◆ Relief System for Adverse Drug Reactions

・ Systems, Regulations, etc

NAFDAC Guidelines to Good Pharmacovigilance Practice, 2016	administered by	NAFDAC

④ **Drug Pricing**

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

⑤ **Statistic Data**

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

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

1: Number of pharmacists about 26,(-2015
2: Number of GMP inspector (National & Loc 120 inspe -2016
3: Number of pharmaceutical manufacturers / manufacturing sites about 250 -2015
4: Number of traditional medicine manufacturers / manufacturing sites (YEAR)
5: Number of pharmaceutical importers (YEAR)
6: Number of pharmaceutical wholesalers (YEAR)

⑥ **Information on your hospital pharmacy** ※hospital pharmacy only N/A

(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?
_____ ㎡

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

⑦ Education and License of Pharmacists in your country ※hospital pharmacy only

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

Primary	6	years
Secondary	6	years
High school	N/A	years

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

University / college:	5	years
Professional education:	optional	years
Practical training:	1	years
Duration of training by each facility:		
Hospital pharmacy:	48	weeks
Community pharmacy:	(optional)	weeks
Pharmaceutical company:	nil	weeks
Others:	nil	weeks
Age at graduation:	23	years old

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

Academic Exams	15-30	days
Clinical Exams	nil	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.

Pass marks must be obtained in Pharmacology, Pha

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

is internship is undergone, not to prepare for exams b

(5) Number of pharmaceutical university or college graduates:
>2000 people / per year

The alumni's placement rate (%)

a. Hospital:	30	%
b. Community Pharmacy:	20	%
c. Government Organization	20	%
d. Enterprise:	5	%
f. Others:	25	%

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.

division documents it and re-emphasize the possiblity of this occurence to the public. If not listed in the drug leaflet, the PV

Part II: INCEPTION REPORT PRESENTATION

Why? → *To make a presentations and discussions in order to understand each other and compare among the participants*

What? → *Report of the current situation about your work, your experiences to be shared and expectations to this program.*

When? → *Report presentation is held on the beginning of the program in Japan.(It is expected on July 15)*

How? → *Refer to the outline described below. It is strongly recommended to prepare with Power Point (PPT).*

【Notes】・Please prepare presentation within 10 slides.

・Each presentation is allocated about 15 min. including Q/A.

◆Presentation OUTLINE

Category A	Introduction of your work —Organization & department that you belong to —Job tenure Role and position of pharmacists in your country, etc —Please describe your regulatory services that you are engaged in.
Category B	Good Practice —Please describe your experiences about Good Practices *(Examples)* ・Achievements ・Solutions for past problems ・On-going projects to deal with current problems ・Successful countermeasures against problems
Category C	Difficulties/Lessons Learned from Past Experience —Please describe your experiences you have faced difficulties, or struggled; *(Examples)* ・Problems that cannot be improved or solved ・Failed countermeasures to deal with the problems ・Emerging or Re-emerging Problems, if any
Category D	Your interests —Please describe issues you are expecting to this program.(at maximum 3(three)

出典：平成 ２８年度 JICA 課題別研修カントリーレポート
- 平成 28 年度 JICA 課題別研修「水道管理行政（A）」
- 平成 28 年度 JICA 集団研修「水道管理行政（B）」
- 平成 26 年度 JICA 課題別研修「薬事行政」

Japan International Corporation of Welfare Services (JICWELS) was established with the sanction of the Minister for Health, Labour and Welfare in July 1983 and implements international technical cooperation programmes with purpose of contributiing to the promotion of health and social welfare activities in the friendly nations.

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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

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