Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

Country Reports

Japan International Corporation of Welfare Services (JICWELS)

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Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

BRAZIL

Japan International Cooperation Agency

The Scope of Pharmaceutical Administration in the Federal District, Brazil

Mr. de OLIVEIRA CARNEIRO, Emmanuel
Manager of Medicine Purchase Planning
Pharmaceutical Administration Bureau

Agenda

- The Federal District, Brazil;
- Pharmaceutical Assistance in Brazil;
- Pharmaceutical Assistance in the Federal District, Brazil.

The Federal District, Brazil

Area: 5,779.999 Km^2
Population: 2,914,830 (2015)
Capital: Brasilia

15 Hospitals

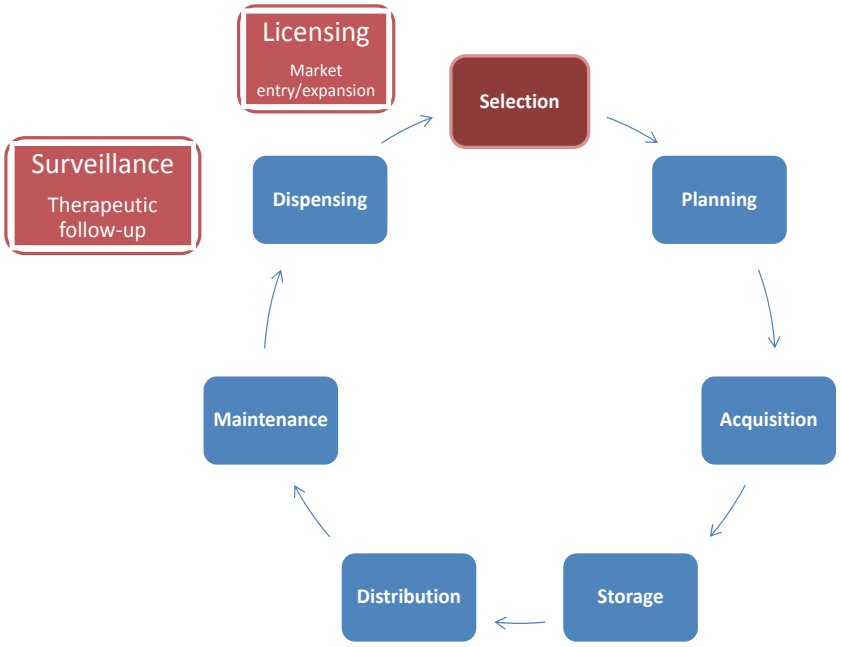
7 Pharmacies

116 Primary Care Centers

Pharmaceutical Assistance in Brazil

- Brief history
  - Following the creation of Brazilian Unified Health System, in 1990, the new National Medicines Policy was designed to promote, regulate and develop several medicine-related issues;
  - The reorientation of Pharmaceutical Assistance was one of those issues.

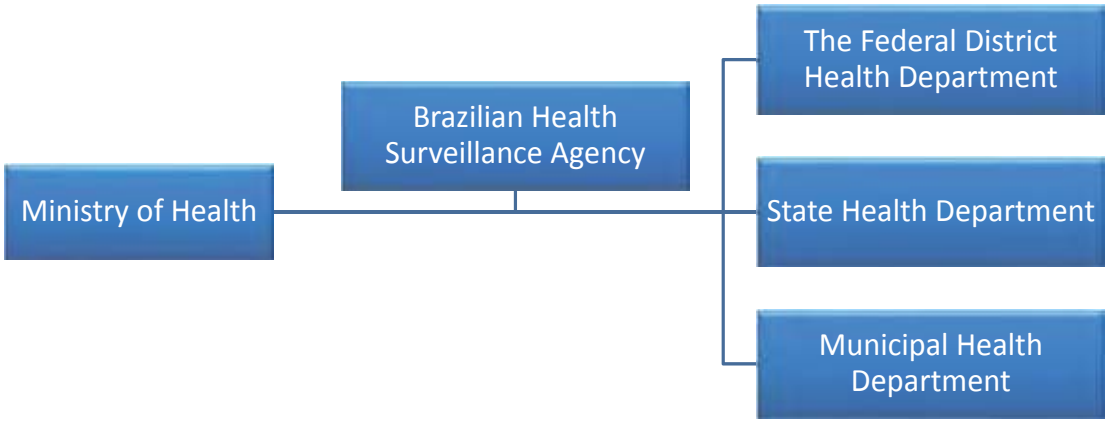
The Pharmaceutical Assistance Cycle



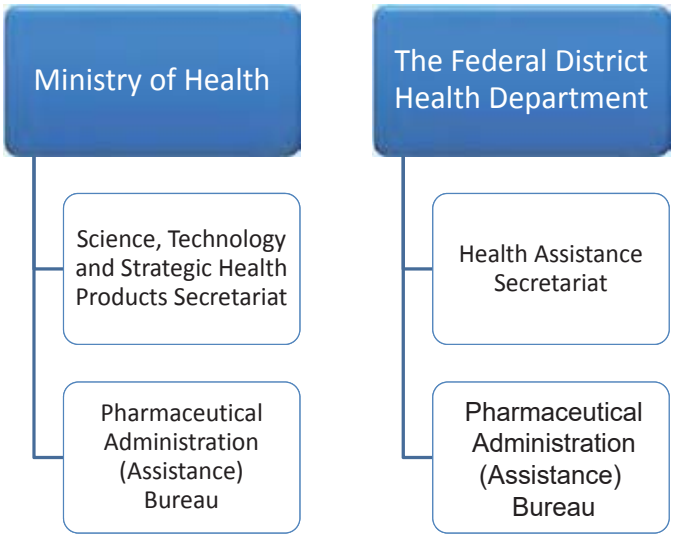
Pharmaceutical Assistance in Brazil

- The new proposed Pharmaceutical Assistance is based on:
  - Decentralization of services;
  - Promotion of rational use of medicines;
  - Optimization of the cycle-based activities;
- Drug funding is supported by the 3 government levels.

Organizational Chart



Organizational Chart



Pharmaceutical Assistance in Brazil

- Major strengths
  - Visualizes most of pharmacy practice and includes not just patient-centered practices, but drug logistics also;
  - Decentralized services promote greater efficiency;
  - Service is universal and free-for-all;
  - Its legislation is clear and concise regarding aspects of pharmaceutical assistance.

Pharmaceutical Assistance in Brazil

- Major limitations
  - Outside Brazil, the term “Pharmaceutical Assistance” is not well-known;
  - In North America it refers to financial support of medicines (e.g., Medicare’s Pharmaceutical Assistance Program);
  - Public funding is three-tiered (federal, state, and municipal), unclear and inefficient;
  - Private funding is market/profit driven leading to characteristics of unnecessary drug use and prescription-free drug access.

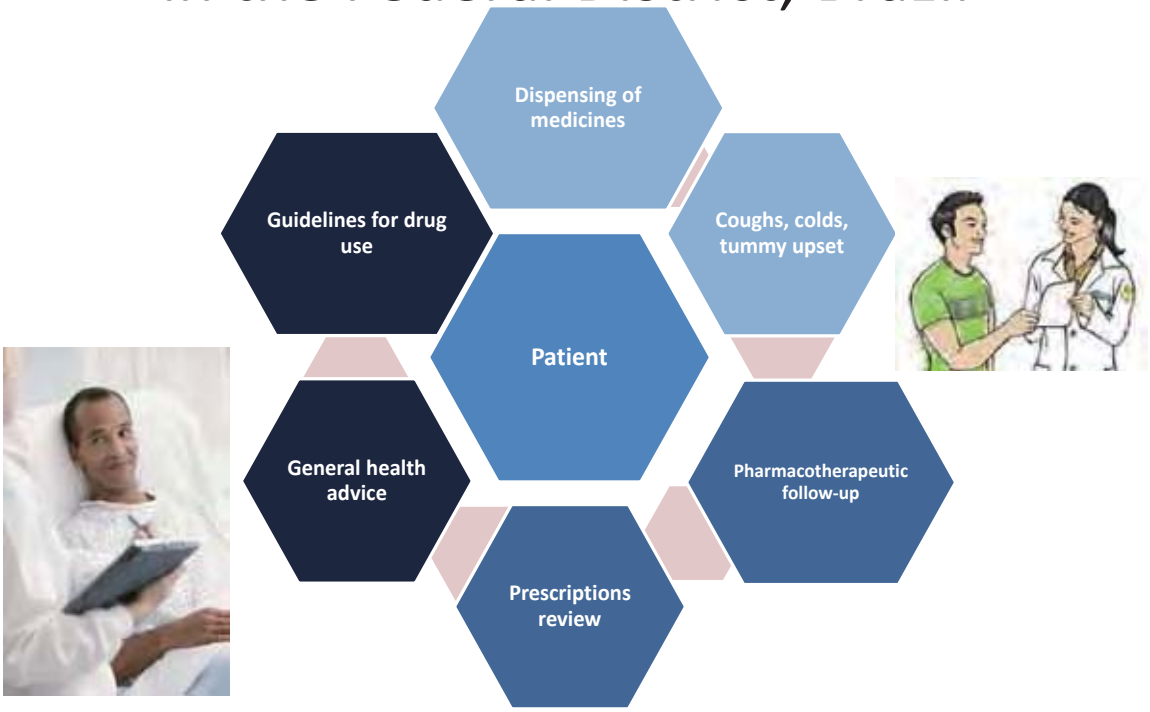
Pharmaceutical Assistance in the Federal District, Brazil

- Overview:
  - Shares State and Municipality Assignments
  - Drug selection is made by a Comission named “Pharmacy and Therapeutic Comission”:
    - If a medicine is found cost-effective and feasible for purchasing, it is included in the “Standardized Drug List”;

Pharmaceutical Assistance in the Federal District, Brazil

- Overview:
  - Planning involves a budget impact analysis and estimation of drug utilization:
    - Eligible number of patients and correspondent doses are determined;
    - The budget is projected for the current year;
  - Drug purchase is performed by Tendering Process or Licitation;
  - Drug storage and distribution in a Central Warehouse.

Pharmaceutical Assistance in the Federal District, Brazil



Pharmaceutical Assistance in the Federal District, Brazil

Challenges

Pharmaceutical Assistance in the Federal District, Brazil

Provide computers and web availability in all community and hospital pharmacies

Pharmaceutical Assistance in the Federal District, Brazil

Provide suitable structure and furniture

Pharmaceutical Assistance in the Federal District, Brazil

Central Warehouse: Present

Pharmaceutical Assistance in the Federal District, Brazil

Central Warehouse: Future??

Pharmaceutical Assistance in the Federal District, Brazil

Budget availability for drug purchase

2015 - REQUIRED

R$ 270.690.357,54 ~ US$ 71,241,804.16

2015 - FIRSTLY AUTHORIZED

R$ 150.684.565,00

55%

DEFICIT:

R$ 120.005.792,54

Pharmaceutical Assistance in the Federal District, Brazil

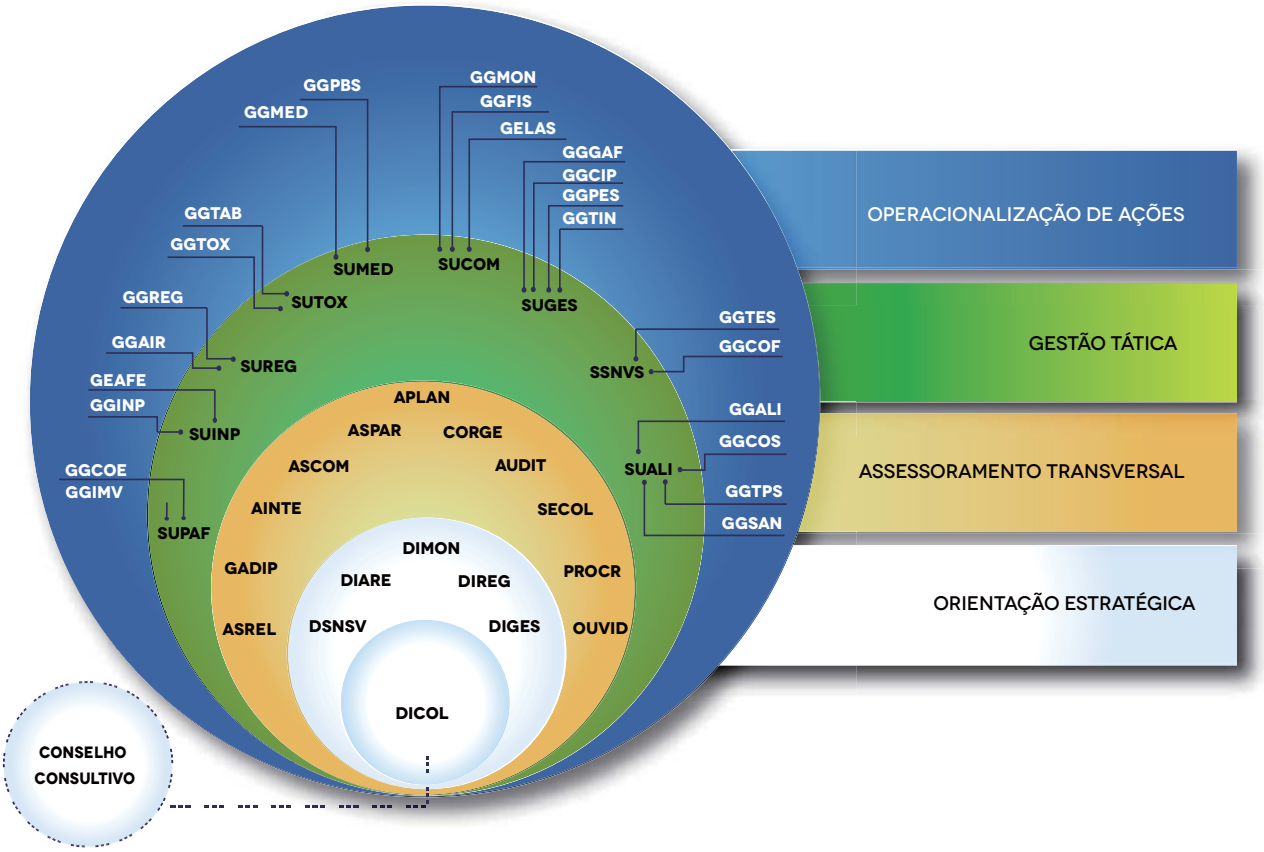
Cycle Actions

\+

$

Universal access and Rational use of Medicines

Target


GGPBS
GGMED
GGMON
GGFIS
GELAS
GGGAF
GGCIP
GGPES
GGTIN
GGTAB
GGTOX
GGREG
GGAIR
GEAFE
GGINP
GGCOE
GGIMV
SUMED
SUCOM
SUTOX
SUGES
SUREG
SUINP
SUPAF
GGTES
GGCOF
SSNVS
GGALI
GGCOS
SUALI
GGTPS
GGSAN
APLAN
ASPAR
CORGE
ASCOM
AUDIT
AINTE
SECOL
DIMON
GADIP
DIARE
DIREG
PROCR
ASREL
DSNSV
DIGES
OUVID
DICOL
CONSELHO CONSULTIVO
OPERACIONALIZAÇÃO DE AÇÕES
GESTÃO TÁTICA
ASSESSORAMENTO TRANSVERSAL
ORIENTAÇÃO ESTRATÉGICA

Japan International Cooperation Agency

Inception report presentation

Eduardo Agostinho Freitas Fernandes
MSc. Health Sciences
Regulation and Sanitary Surveillance Expert

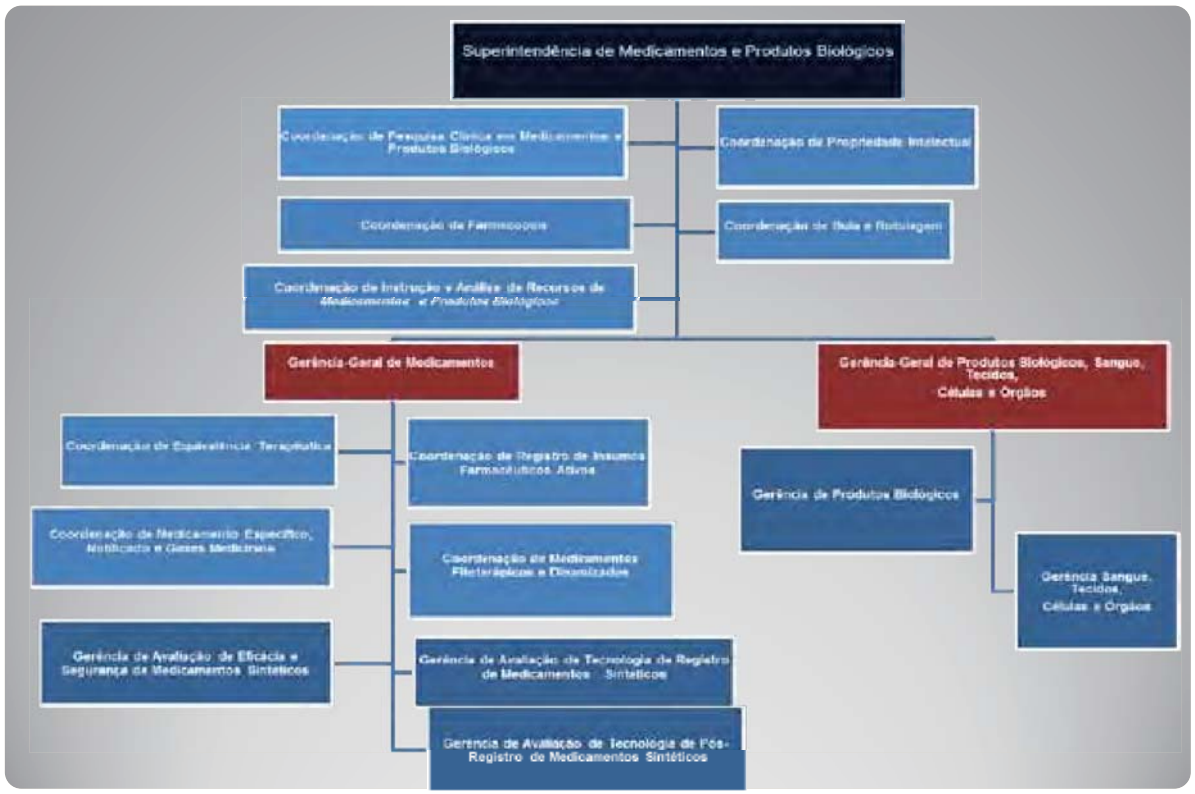
Location of Anvisa`s Office in Brazil

Brazilian Health Surveillance Agency (ANVISA)

- Brief history
  - 1998 – National Important Case of SSFFC product (Microvlar® - contraceptive)
  - Jan/1999 - Creation of Brazilian Health Surveillance Agency (ANVISA);
  - Fev/1999 – Establishment of Generic Medicines in Brazil.

Brazilian Health Surveillance Agency (ANVISA)

Organogram of ANVISA



Inception report presentation

- Coordination of Therapeutic Equivalence (CETER)

  - Conduct inspections on Bioequivalence Centers (GCP and GLP)
  - Assess of bioequivalence studies
  - Conduct inspection on Pharmaceutical Equivalence Centers (GLP)
  - Others: Reviewing regulations, etc

Inception report presentation

- Good Practice
  - Problem: Problems with different information during the inspection and evaluation of the bioequivalence studies
  - Solution: Transform the inspectors and assessors in only one team.

Inception report presentation

- Good Practice
  - Problem: Competition for the submission
  - olution: Create codes in order to allow the submission to be divided in pieces and to be delivered to the department responsible

Inception report presentation

- Problem to tac le

  - Problem: Lac of Comparator Product (Reference)

  - easures ta en: n this case, we have assumed as the new comparator the product with the most similar P profile But as the new comparator doesn t show efficac and safet in an clinical trials, can ou do it

  - Obs : e cannot choose an international comparator which is not available in the Bra ilian mar et and from what we do not have an information regarding clinical trials and pharmacovigilance

Brasília - Brazil

CHINA

Inception Report

DONG Wei-hua (CHINA)

Introduction of my hospital

* **The First Affiliated Hospital of Xi'an JiaoTong University**
  * a large comprehensive (first-rate of Level three) hospital in Xi'an,China
  * belonging to National Health and Family Planning Commission of the People's Republic of China
  * 2497 beds
  * It occupies the leading position in medical technology in the northwest of China

Introduction of my work

* I have been a pharmacist for 19 years
  * The job I have experienced:
    * drug purchasing
    * drug dispensing
    * drug quality control
    * TDM
    * clinical pharmacy
  * Now my job: pharmaceutical management
* **In China, Pharmacists is in the secondary position In hospital, but the status of pharmacists is getting higher and higher.**

3

Good Practice

* The situation of the Pharmaceutical Department in my hospital
  * more than 160 employees
  * 6 divisions
    * outpatient pharmacy
    * inpatient pharmacy
    * traditional Chinese medicine pharmacy
    * drug warehouses
    * pharmacy intravenous admixture service (PIVAS)
    * clinical pharmacy

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Good Practice

* The business of the pharmaceutical department
  * drug purchasing
  * drug dispensing
  * stock control
  * pharmacy intravenous admixture service
  * patient counseling
  * therapeutic drug monitoring
  * Clinical pharmacy

Outpatient pharmacy hall

Automatic dispensing system

PIVAS

Single dose dispensing delivery system

Drug storehouse

TDM instruments

Group photo of Pharmaceutical Department

Good Practice

* My experiences about Good Practices
  * **Past problems**: There are emergency medicines reserved in wards. Because they do not be often used, sometimes seldom of them will exceed the validity period.
  * **Methods:** The pharmacists check all of the medicines in ward every month. If invalid medicines are found, the duty nurse and head-nurse will be punished by nursing department.
  * **Achievements:** Since then, the invalid medicines are almost never seen in wards.

Bad Practice

* My experiences about bad Practices
  * **Past problems:** The prescription was filled and the patient took away the medicines, but for some reasons, the patient asked to return some expensive oral medicine. The pharmacist can not accept it because the medicine was unsafe.
  * **Methods:** We establish the rule : oral medicines can not be returned.
  * **Problems existing:**
    * Some patients do not obey the rule, they insist to return the medicine.
    * Returned medicines are unsafe.

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My interests

* 1. Are drugs sold in the pharmacy need to be tested for the quality by the pharmaceutical department?
* 2. How can we conduct research work and publish papers in pharmacy department?
* 3. How to ensure the quality and safety of intravenous admixture?

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INDONESIA

Category A

- Introduction of your work
- Organization & Department that you belong to
- Job tenure
- Please describe your regulatory services that you are engaged in

VISION AND MISSION

Vision:

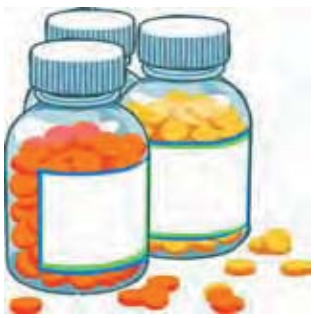
Safe Food and Medicine to Improve Public Health and National Competitiveness

Mission:

1. **Protecting public health by strengthening risk-based food and drug control system**
2. **Ensuring the resilience of business operator to provide medicine and food safety assurance, strengthening partnerships with stakeholders**
3. **Improving institutional capacity of Badan POM**

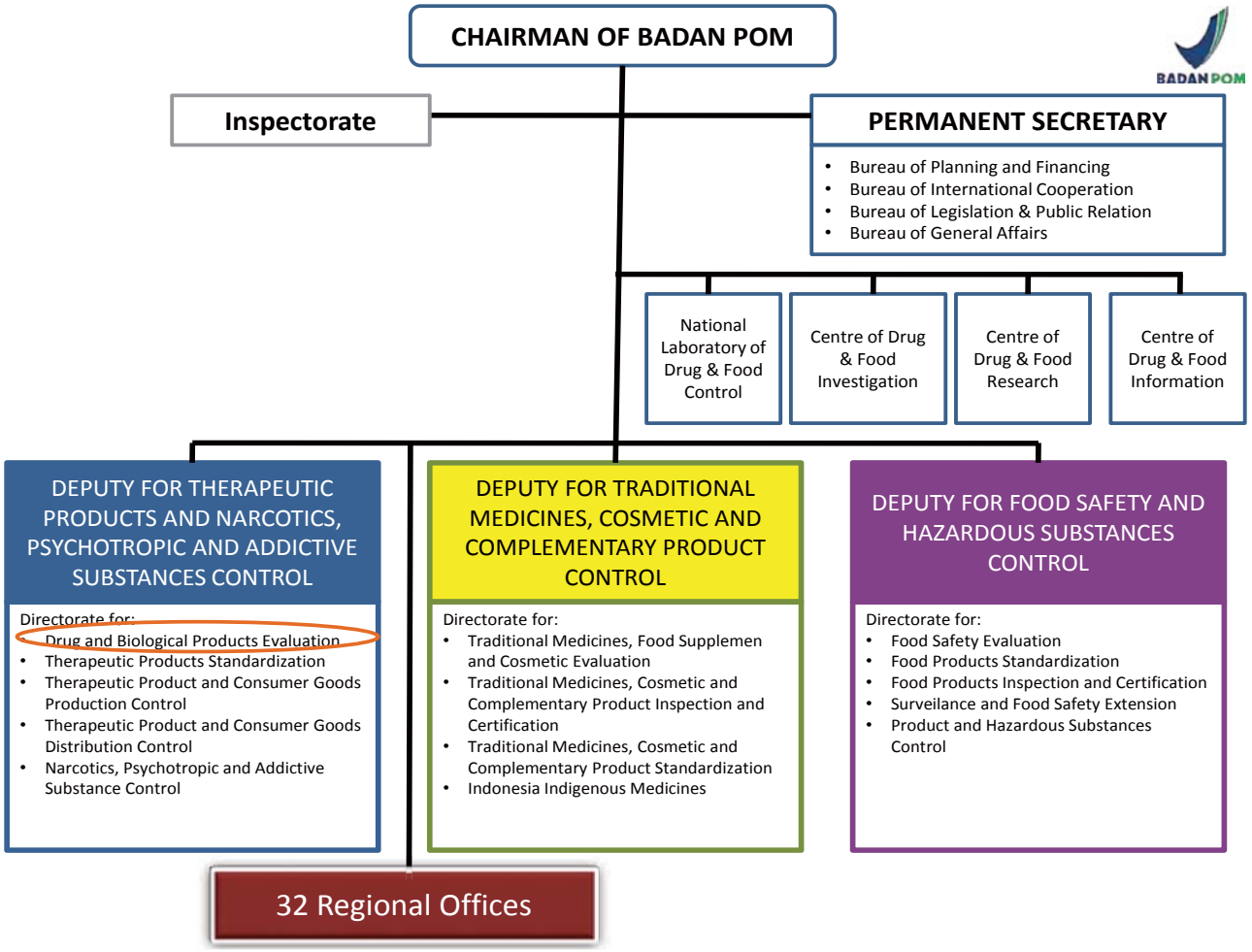
GOALS OF BADAN POM
2015 - 2019

1. Ensuring safety, efficacy, and quality of food and drug to increase public health
2. Improving food and medicine competitiveness nationally and globally through quality assurance and innovation.

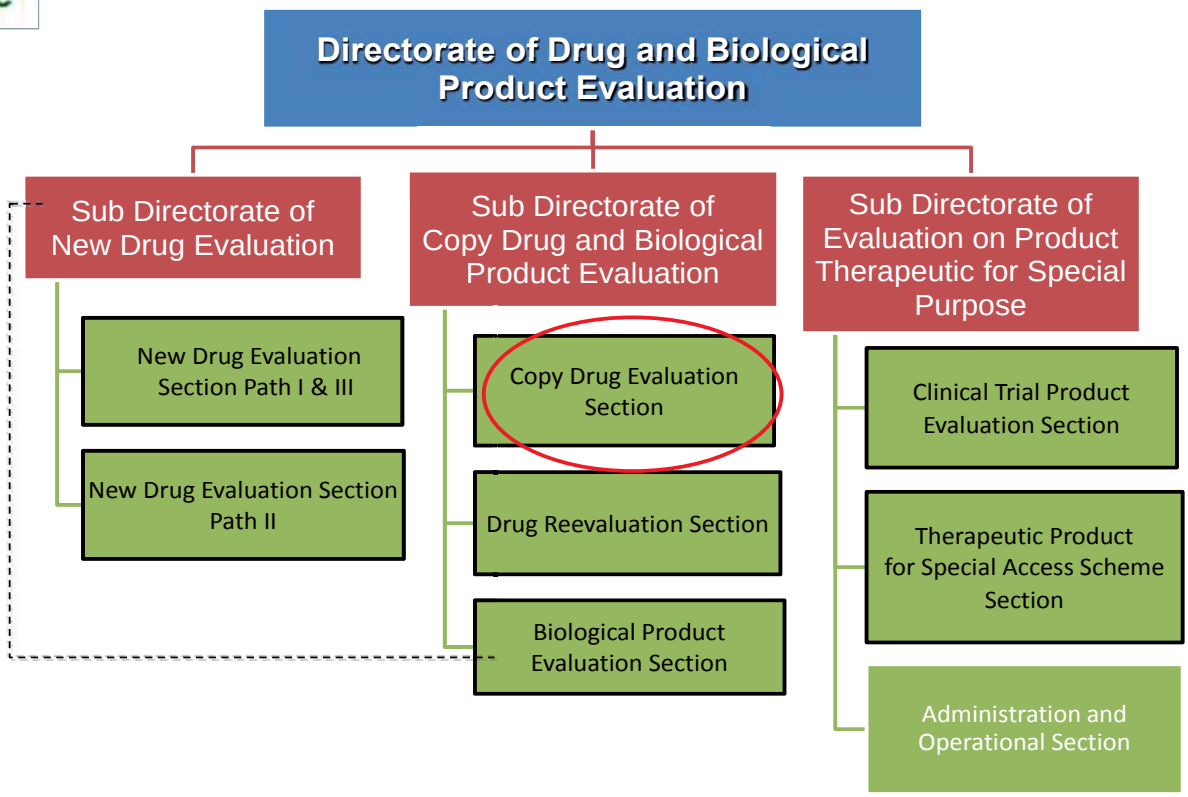


STRATEGIC OBJECTIVES

1. Food and drug regulatory system enhanced
2. The resilience of business operator and stakeholder partnership strengthened
3. Institutional capacity of Badan POM improved



Organization of Directorate Of Drug And Biological Product Evaluation

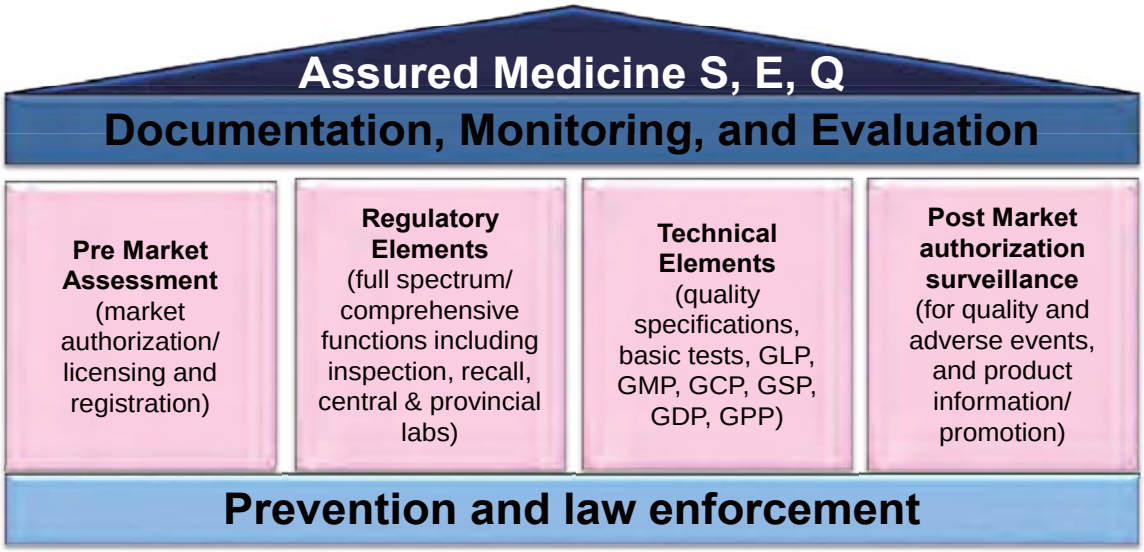


7

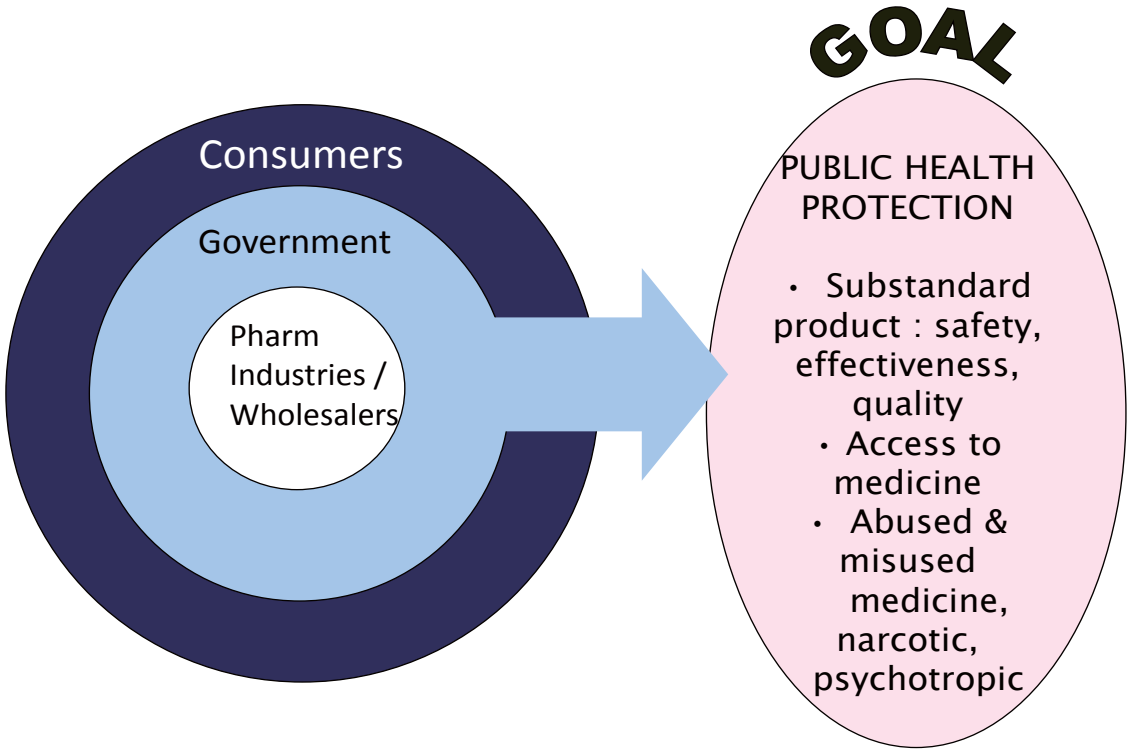
Drug Regulatory System in Indonesia

REGULATORY FRAMEWORK ON ENSURING S, E, Q OF MEDICINE

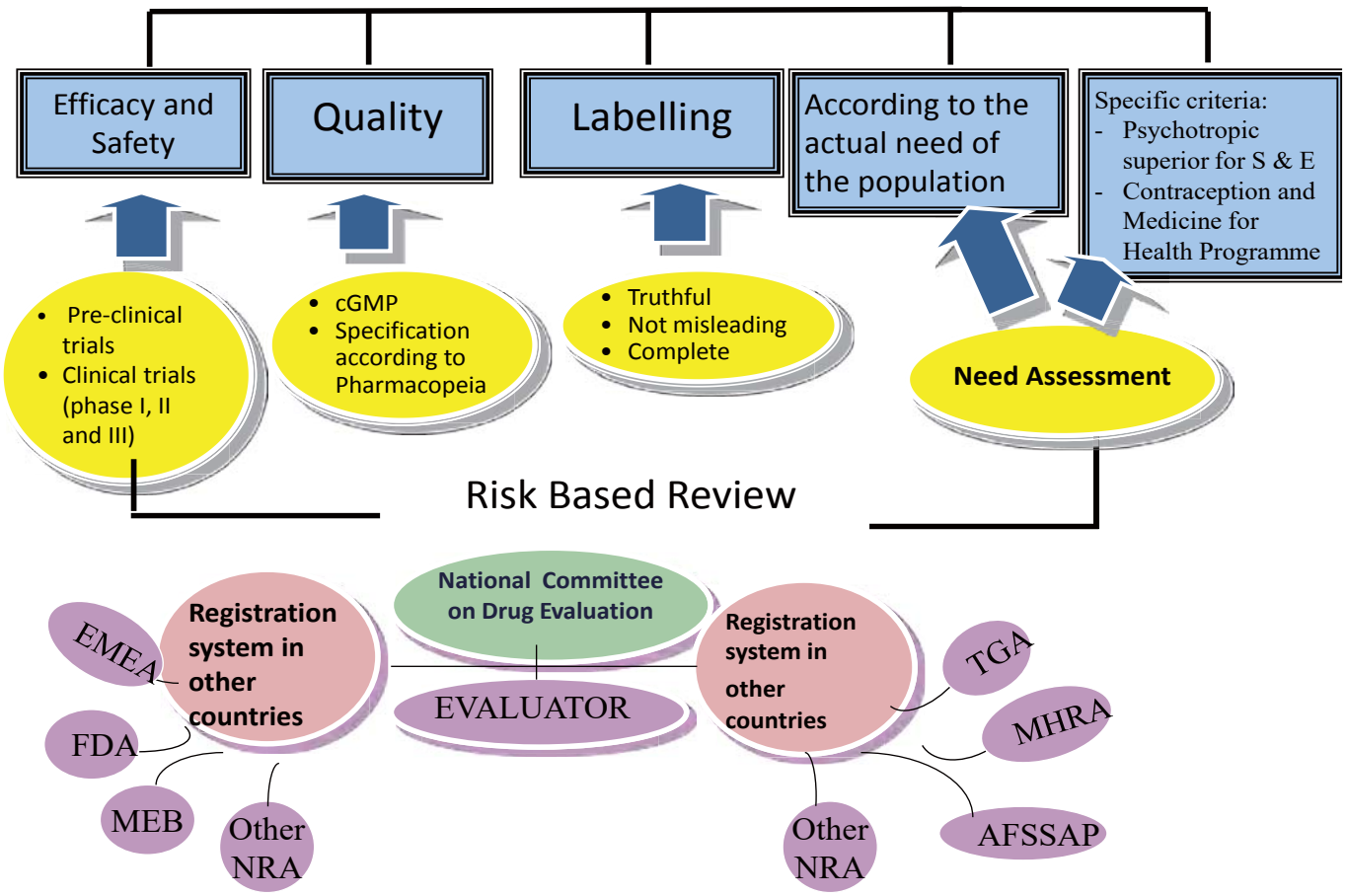
Medicine Quality Assurance Structural Components



MEDICINE CONTROL SYSTEM IN INDONESIA



CRITERIA FOR MEDICINE EVALUATION



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

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*

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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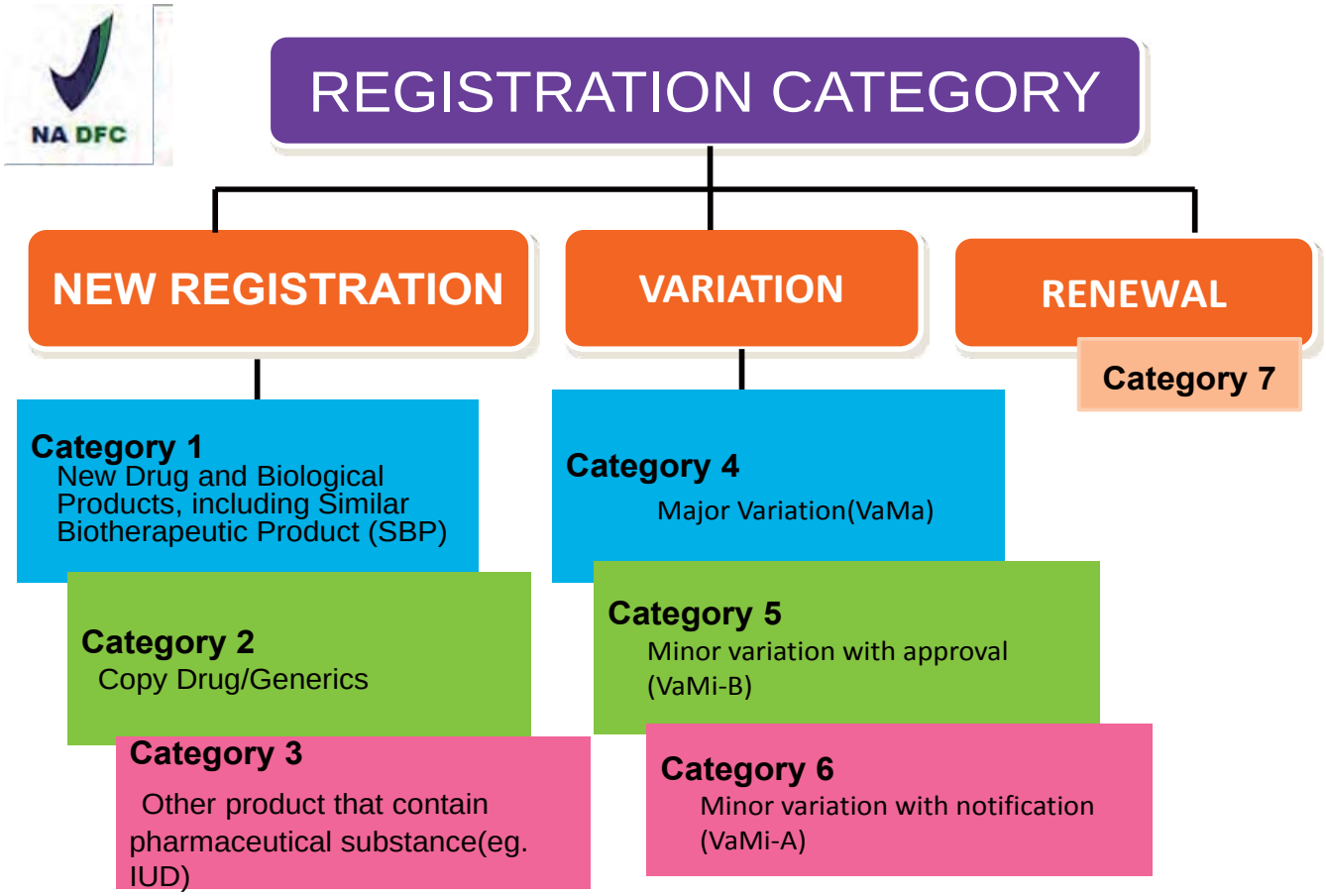
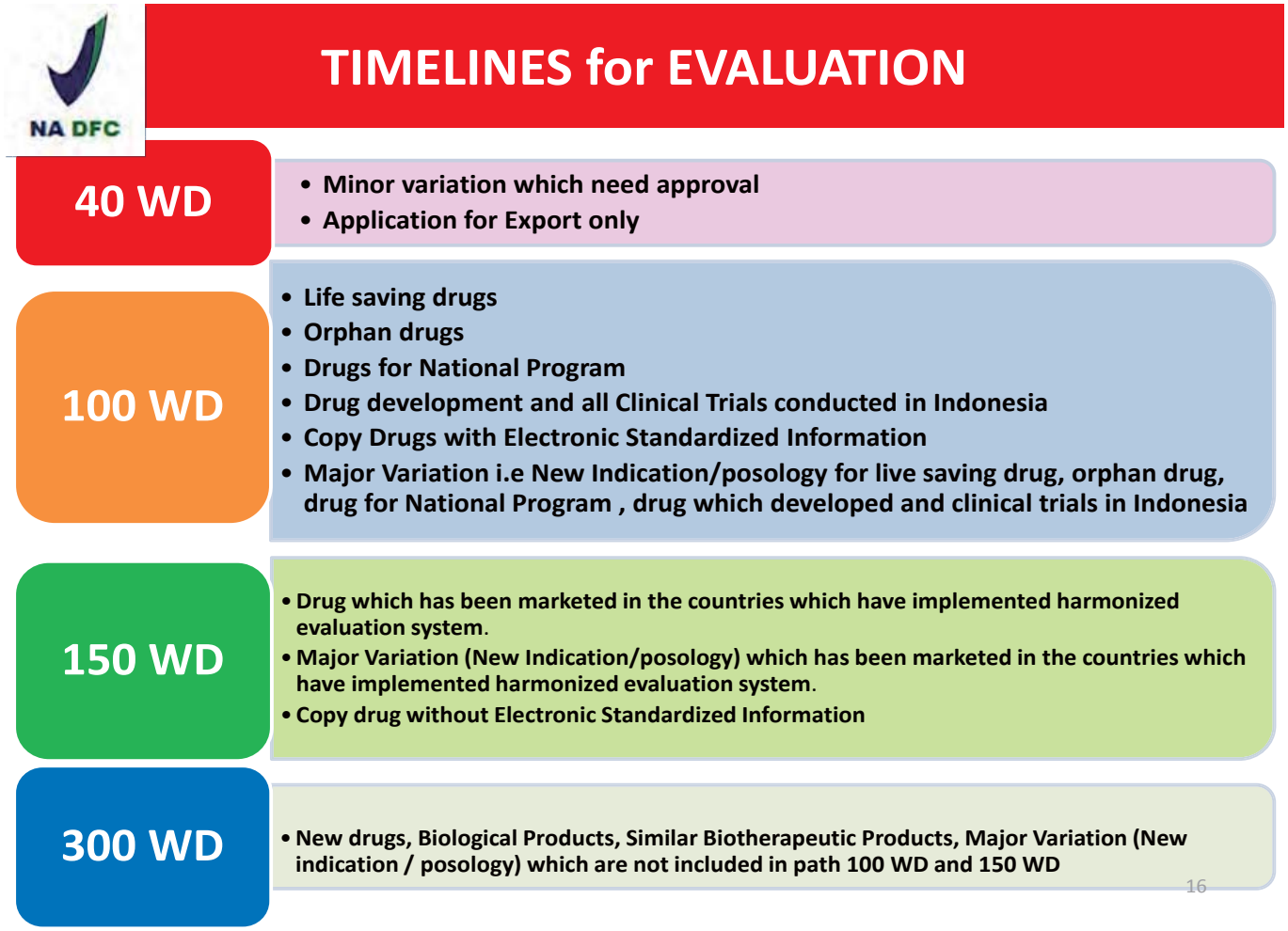

REGISTRATION CATEGORY
NEW REGISTRATION
VARIATION
RENEWAL
Category 7
Category 1
New Drug and Biological Products, including Similar Biotherapeutic Product (SBP)
Category 2
Copy Drug/Generics
Category 3
Other product that contain pharmaceutical substance(eg. IUD)
Category 4
Major Variation(VaMa)
Category 5
Minor variation with approval (VaMi-B)
Category 6
Minor variation with notification (VaMi-A)

15


TIMELINES for EVALUATION
40 WD
• Minor variation which need approval
• Application for Export only
100 WD
• Life saving drugs
• Orphan drugs
• Drugs for National Program
• Drug development and all Clinical Trials conducted in Indonesia
• Copy Drugs with Electronic Standardized Information
• Major Variation i.e New Indication/posology for live saving drug, orphan drug, drug for National Program , drug which developed and clinical trials in Indonesia
150 WD
• Drug which has been marketed in the countries which have implemented harmonized evaluation system.
• Major Variation (New Indication/posology) which has been marketed in the countries which have implemented harmonized evaluation system.
• Copy drug without Electronic Standardized Information
300 WD
• New drugs, Biological Products, Similar Biotherapeutic Products, Major Variation (New indication / posology) which are not included in path 100 WD and 150 WD

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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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Validity of Marketing Authorization

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Category B—Good Practice

- Please describe your experiences about good practices

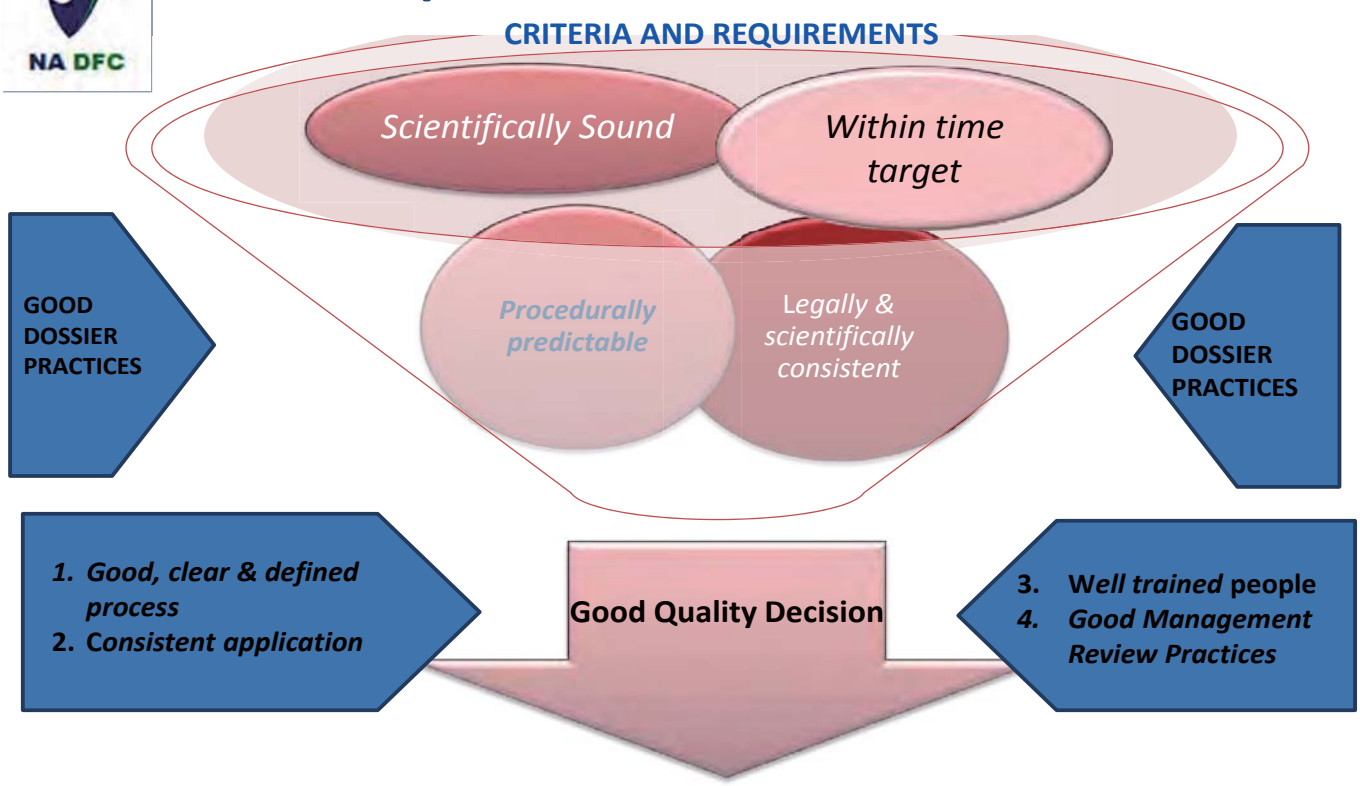
Examples

a. Achievements
b. Solutions for past problems
c. On-going projects to deal with current problems
d. Successful countermeasures against problems

PRE MARKET CONTROL

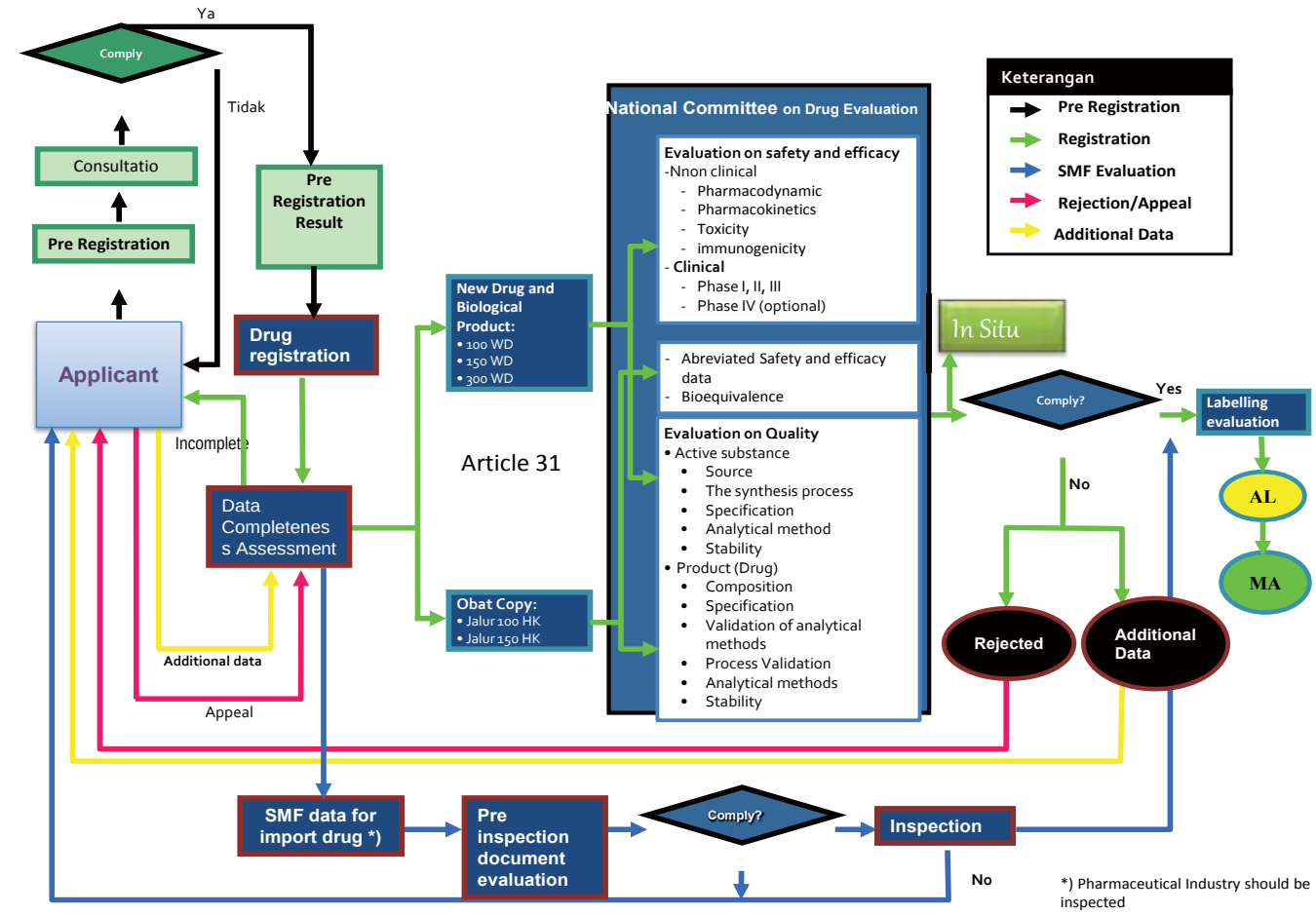
DRUG EVALUATION/REGISTRATION

Concept of Pre-Market Evaluation



PRODUCTS WITH REGISTRATION NUMBER

DRUG REGISTRATION AND EVALUATION FLOWCHART



What is Generic Drug?

Drugs contain active pharmaceutical ingredients that have the same :

- composition/quantity
- stregth
- dosage form
- route of administration
- indication
- posology

as the originator

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Production Status

- Local Product
  - Produced by marketing authorization holder
  - Toll manufactured product
  - License product
- Import Product

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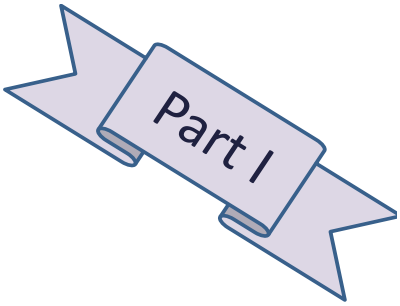
Generic Dossier

Part I Administrative Document	• Administrative Data • Product Information
Part II Quality Document	• Drug Substance • Drug Product

Administrative Document



- **Administrative data**

  such as : industry license, GMP certificate, the latest inspection report,CPP and SMF* for import product, license/contract agreement

  *** Latest Site Master File for overseas pharmaceutical industry that has not had a product with the same type and dosage forms that approved to be marketed in Indonesia**

- **Product Information**

  → labelling and summary product characteristic/ brochure/leaflet

Quality Document

QUALITY OVERALL SUMMARY

S. DRUG SUBSTANCE

- S.1. General information (Nomenclature, Structural formula, General properties)
- S. 2 Manufacturing process and Manufacturer(s) (manufacturer, description of manufacturing process and process control, control of material, controls of critical steps and intermediates)
- S.3 Characterisation
- S. 4 Control of drug substances : specification & analytical procedures include validation of analytical procedures, batch analyses, and justification of specification
- S. 5 Reference standards or material
- S.6 Container closure system
- S.7 Stability

APIMF

P. DRUG PRODUCT

- P.1. Description and composition
- P.2.Pharmaceutical development
  - Information on development studies
  - Component of drug product
  - Finished product
  - Manufacturing process development
  - Container closure system
  - Microbiological attributes
  - Compatibility
- P.3 Manufacture
  - Batch formula
  - Manufacturing process and process control
  - Controls of critical steps and intermediates
  - Process validation and/or evaluation
- P. 4 Control excipients : specification and analytical procedures, result of internal test
- P.5 Control of finished product : specification, analytical procedures, validation of analytical procedures, batch analyses, characterization of impurities, justification of specification
- P. 6 Reference standards or materials
- P.7 Container closure system
- P8. Stability
- P.9 Equivalence evidence

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Current situation in Indonesia

- About 96% of APIs are imported
- About 90% of drug substances are imported

  Top 5 source of API:
  - China
  - India
  - Korea
  - Japan
  - Europe

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Quality Requirement

New

Active Pharmaceutical Ingredient Master File (APIMF) requirement data :

1. A Valid quality Certificate of Suitability of European Pharmacopeia (CEP)
   - With all appendices
   - Provide information, which may not be covered by the CEP

   or
2. An API MF (API Master File)
   - Submitted by API manufacturer
   - Contains all information requested in section 2.S. Drug substance

Requirement for 1st Generic started in 2010 on voluntary basis

Quality Requirement

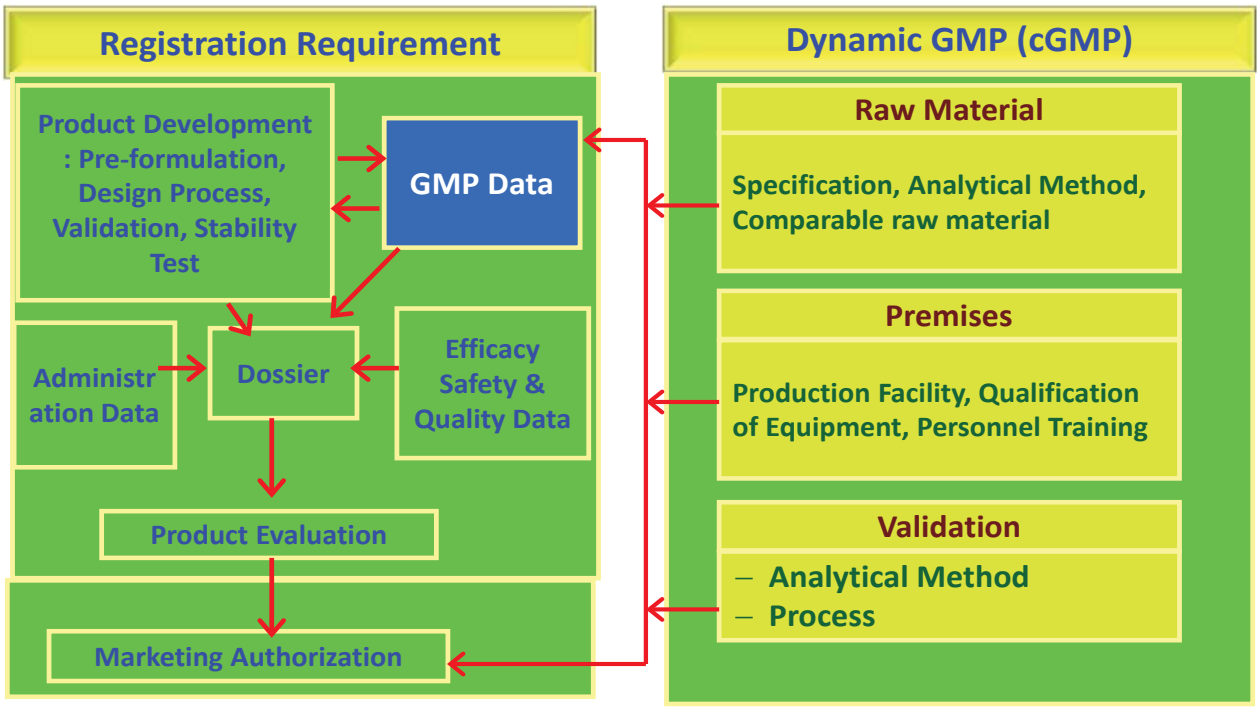
On site evaluation at the facility of product manufacture (*in-situ*)

- ❑ To support the quality of products
- ❑ For mapping the suitability of the quality of data submitted in the dossier with the documentation in the production of medicines in facility.
- ❑ To ensure the validity of information written in documents of Quality as well as to check the GMP inspection

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**

Relationship Between Dynamic GMP and Registration Requirements



Category C---Bad Practice

- Please describe your experiences about Bad practices

Examples

a. Problems that cannot be improved or haven't been improved
b. Failed countermeasures to deal with past problems
c. Emerging problems because past problems haven't been solved

1. **Challenges** in the implementation part includes among other **different interpretation from the perspective of the government and the stakeholders by many functions and hierarchies**. Regulatory improvement is needed for more effective and efficient implementation to support pharmaceutical trade.
2. **Obstacles** in regulating medicines and medical devices to facilitate trade are among other :
   i. **Different level of maturity** in understanding and implementing the regulation and guidance amongst the industries and the regulator staffs
   ii. **Inefficiency** in implementing the regulation and guidelines
   iii. **Limited resources**, for example, well trained staffs and need-improved IT, infrastructure and capability

MARKETING AUTHORIZATION FOR MEDICINE & CLINICAL TRIAL

FINDINGS	DISCUSSION
1. Guideline for MA & Technical requirements are available, based on WHO & International Standard 2. MA Dossier & Requirements follow ASEAN formats (ACTD &ACTR) 3. Transfer of Technology requirements is included in the Regulation on MA (imported products)	1. The Guideline needs to be supported with clear technical directive, e,g Questions and Answer documents 2. No publicly written procedure on special cases commonly faced with the application & how the evaluation being done 3. MA decision process should be more publicly transparant, including hearing & appeal

PRODUCTION/MANUFACTURING PROCESS CONTROL

FINDINGS	DISCUSSION
1. Regulation & Guidance for cGMP are available to ensure that product are consistently manufactured to meet specified Q appropppriate to their intended use. 2. Indonesia is the 41st PIC/s member 3. The GMP based on PIC/S and other International Std will provide protection from defects products & recall so that sustainability of availability product of assured QSE is ensured 4. Adoption of new regulatory practices or new technology may affect product price at the begining, but if it is done efficiently, it could lead to more affordable product	1. Implementation of cGMP needs technical directive, in particular for transfer of technology 2. Additional investment may be needed in order to reach & increase the bar of product QC / standard, & the manufacturer capability need to be strengthen as well. 3. Government's support is needed e.g, GMP inspection being consistently done, availability of raw material , strategy on centralizing production, insentive scheme for transfer of technology etc

FINDINGS	DISCUSSIONS
1. **To support local capacity of manufacturing, Transfer of Technology is stated in regulation related to MA and GMP (imported products)** 2. **Transfer of Technology covers (i) product development, (ii) technical and method or process of production and (iii) Quality Assurance**	1. **Critical issue of Transfer of Technology is economics of scale for new investment, effort for R&D, stringent regulatory requirement.** 2. **Incentive scheme is needed, e.g regulation & technical GL to speed up the process, facilitation for funding/loan facility, deffered import tax for capital goods, etc**

Category D

Your interests

- Please describe topics you look forward to most in this program (at maximum three topics)

- Better understanding of regulatory management for access to quality-assured medicines including inspection system, as well as trends of international collaboration among regulatory authorities
- Critical issue of Transfer of Technology
- Counterfeit medicine's distribution and the problems related which may lead to public health issue.

Roles of Regulatory Systems and Pharmacists on Ensuring Proper Access to Quality Assured Medicines (JFY 2015) - J1504386

Inception Report for Government Officials

Name : Ratna Juwita

Country : Indonesia

Organization : National Agency of Drug and Food Control (NADFC)

Part I INFORMATION SHARING

Why? → To share the basic information related to pharmaceutical administration in each country.

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

Introduction

Vision of NADFC: Safe Food and Medicine to Improve Public Health and National Competitiveness.

Mission:

1. Protecting public health by strengthening risk-based food and drug control system
2. Ensuring the resilience of business operator to provide medicine and food safety assurance, strengthening partnerships with stakeholders
3. Improving institutional capacity of Badan POM

B. Procedure of drug registration
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 regisration that are pre-registration, and then registration.

a. **Pre-registration**

Pra registration should be done before registration. This step has some purposes to determine the registration category, timeline, and registration fee. At this step, the applicant can also consult to the officers about the requirement 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 seven registration categories that divided into 3 types of registration.

a. New registration type, including new registraton for originator product, generic and other.
   1. Category 1
      New Drug and Biological Products, including Similar Biotherapeutic Product (SBP)
   2. Category 2
      Copy Drug/Generics
   3. Category 3
      Other product that contains pharmaceutical substance (eg. IUD)

b. Variation registration, this type registration is to register product that have already had approval but there are some changes in their product, such as labelling, production, source of material, etc.
   4. Category 4
      Major Variation (VaMa)
   5. Category 5
      Minor variation with approval (VaMi-B)
   6. Category 6
      Minor variation with notification (VaMi-A)

c. Renewal that is type of registration for product that the registration number has expired.
   7. Category 7
      Renewal

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 dossier including:

- Part I (Administrative Data and Product Information).
  Not only ACTD dossier in registration document, it is also a country specific document for administrative data. Then for this, the documents is depend on the requirement in each country.

- Part II (Quality) applied from Pharmaceutical Industry consists:
  1. S. Drug Substance
     - Nomenclature, Structure, general Properties, Manufacture, GMP, Control of Materials, Validation of Analytical Procedures, and Stability.
  2. P. Drug product
     - Description and Composition, Pharmaceutical development, Batch Formula, Manufacturing Process and Process Control; Control of Critical Steps and Intermediates), Process Validation and/or Evaluation Control of Excipients, Control of Finished Product, Reference standard Materials, Container Closure System, Stability and Equivalence Evidence.

Criteria On Drug Evaluation (Risk Based Assessment):

- For efficacy and safety aspects, we have to evaluate non clinical study and clinical study, including phase I, II, and III, but this is only for originator product and biological drug registration.
- In quality aspect, we should evaluate manufacturing process according to GMP, product spesification, stability study and also bioequivalence study for generic. Then in labelling/product information concern, product information should be correct and objective to ensure the rationality of drug using. Beside that, there's also a specific criteria aspects such as drug for national program needing local clinical trial.

When we evaluate the document we have timeline to finish the evaluation. We have 4 types timeline of evaluation depend on the category of registration. They are:

a. 40 WD for evaluating of Minor variation which need approval; Application for Export only.

b. 100 WD for evaluating of Life saving drugs, Orphan drugs, Drugs for National Program, Drug development and all Clinical Trials conducted in Indonesia, Copy Drugs with Electronic Standardized Information, Major Variation i.e New Indication/posology for live saving drug, orphan drug, drug for National Program, drug which developed and clinical trials in Indonesia

c. 150 WD for evaluating of Drug which has been marketed in the countries which have implemented harmonized evaluation system, Major Variation (New Indication/posology) which has been marketed in the countries which have implemented harmonized evaluation system, Copy drug without Electronic Standardized Information

d. 300 WD for evaluating of New drugs, Biological Products, Similar Biotherapeutic Products, Major Variation (New indication / posology) which are not included in path 100 WD and 150 WD

The product who has already had approval have a validity of marketing authorization not more than 5 years. It means, the validity can be less than 5 years, for example licensed or import 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 renewal their product if the product is still kept marketing.

What? Information that overviews each-other situations in regard to pharmaceutical laws, regulations, and etc.

These are some regulations in Indonesia related to drug:

- Law No. 36 of 2009 on Health
- Law No. 35 of 2009 on Narcotics
- Law No. 8 of 1999 on Customer Protection
- Law No. 5 of 1997 on Psychotropics
- Regulation of the Minister of Health No.1010/MENKES/PER/XI/2008 on Drug Registration
- Regulation of the Minister of Health No.1799/MENKES/PER/XII/2010 on Pharmaceutical Industry

  GMP requirements: Pharmaceutical industry must comply with GMP, proved by valid certificate for 5 (five) years.
- Decree of the Head of NADFC No.3 of 2013 on Amendment of Decree of the Head of NADFC No. HK.03.1.23.10.11.08481 of 2011 on Drug Registration: regulate registration drug generic name and approvable letter.
- Decree of Head of NADFC No. HK.03.1.23.10.11.08481, 2011 on Criteria and Procedure of Drug Registration
- Decree of the Head of National Agency of Drug and Food Control No. HK.03.1.23.12.11.10217 of 2011 on Drugs required to do Equivalence Study
- Decree of the Head of National Agency of Drug and Food Control No. HK.03.1.23.12.11.10690 of 2011 on Implementation of Pharmacovigilance for Pharmaceutical Industries.
- MOH Decree No. 1799/2010 regarding Pharmaceutical Industry.

There are some guidelines that we use when we evaluate the dossier, especially for generic :

- 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

When? Before or at the arrival to Japan

How? Collected information will be summarized; then it will be sent to each participant. Participant will read carefully & understand it.

1. Organizational Chart

❖ ORGANIZATION OF NADFC:
  - Please Attach the organizational chart at national & Local levels about pharmaceutical administration in your country. (Attachment 1)
  - Please briefly describe each role and responsibility on pharmaceutical administration.

❖ Deputy I, Therapeutic Product, Narcotics, Psychotropic and addictive control.

IMPLEMENTATION OF DRUG

Pre-Market:

1. Setting, regulation and standardization;
2. Licensing and certification industry in the field of medicine and food based on the Good Manufacturing Practice
3. Registration and evaluation of products before they are allowed to circulate (Marketing Authorization Number);

Post-Market

4. Post marketing control, inspection of production facilities, distribution facilities, and service facilities, including sampling and laboratory testing, as well as law enforcement;
5. Pre-audit and post-audit of advertising and product promotion;
6. Research on the implementation of drug control policies and food; and
7. Communication, information and public education to increase awareness and knowledge of the safety, efficacy / benefit, and product quality.

Summary:

NADFC has 3 technical deputies divided base on commodity what we have to control pre and post market. Deputy 1 is related to drug and Biological product, Deputy 2 is related to traditional medicine, cosmetics, and complementary products. Then, deputy 3 is related to food.

NADFC has seven regulatory function of drug control including Licensing of premises, practices & persons, Inspection of manufactures, & distributors, Product assessment & registration, Monitoring quality of drugs and vaccines.

And I am in Deputy 1 especially in Directorate of Drug and Biological Product evaluation. Directorate of Drug and Biological Product evaluation has a main job to evaluate the product, drug and biological product, before they are marketed. To make a good quality decision which is the evaluation is based on scientific sound, within time target, predictable procedure and legally & sicentifically consistent, we have to do the good dossier practices including good, clear and defined process, conssistent application, evaluated by well trained people, and also based on good management review practices.

Before the product get approval, our directorate have to evaluate the registration dossier. Beside that, our directorate also do observations and site visits evaluation to pharmaceutical production companies for mapping the suitability of the quality of data applied in the dossier with the documentation in the production of medicines in facility.

Evaluating the registration dossier is based on risk based assement. For efficacy and safety aspects, we have to evaluate non clinical study and clinical study, including phase I, II, and III, but this is only for originator product and biological drug registration. In quality aspect, we should evaluate manufacturing process according to GMP, product spesification, stability study and also bioequivalence study for generic. Then in labelling/product information concern, Product information should correct and objective to ensure the rationality of drug using. Beside that, there's also a specific criteria aspects such as drug for national program needing local clinical trial.

Our directorate contains three subdirectorate that are New Drug Evaluation, Copy drug and Biological Product Evaluation, and Evaluation on Therapetic for special purpose. For generic drug evaluation is under authority of Sub Directorate of Copy Drug and Biological Product evaluation. Copy drug here is meant generic.

Beside that, for controlling in market, our institution will be helped by Drug and Food Control Regional Offices located in every province in Indonesia. Their main job is to do the post-market control.

❖ Organization of Directorate Of Drug And Biological Product Evaluation (Attachment 2).

2. Legislation on pharmaceutical Administration

Please briefly bulletined major laws/acts

National level

- **administered by**

Local Level

- **administered by**

PIC/s

Yes OR No, If yes joined when

In Indonesia, Pharmaceutical administration for National level is administered by National Agency of Drug and Food Control.

Major laws/acts on pharmaceutical administration:

Updated Regulation

- Regulation of the Minister of Health No.1010/MENKES/PER/XI/2008 on Drug Registration
- Regulation of the Minister of Health No.1799/MENKES/PER/XII/2010 on Pharmaceutical Industry
- Decree of the Head of National Agency of Drug and Food Control No. HK.03.1.23.10.11.08481 of 2011 on Criteria and Drug Registration Procedure
- Decree of the Head of National Agency of Drug and Food Control No. HK.03.1.23.12.11.10217 of 2011 on Drugs required to do Equivalence Study
- Decree of the Head of National Agency of Drug and Food Control No. HK.03.1.23.12.11.10690 of 2011 on Implementation of Pharmacovigilance for Pharmaceutical Industries.
- Updated regulation on drug registration:
  - To improve efficiency of the process in anticipating Global Harmonization trend
  - To accelerate drug evaluation process without compromising Safety, Efficacy & Quality → GRP (Good Review Practices)
  - To provide a transparent and efficient communication with stakeholders

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

3. Regulatory Services

- **Please describe pharmaceutical regulatory services of your country in response to each item provided below**
- **Please add anything (systems, regulations, etc) related to the following services & briefly describe who administers it.**
- **Please prepare to explain your answer in case that you are asked about pharmaceutical regulatory services of your country**

❖ Drug import/export

- Systems, regulations, etc

Administered by

- System and Regulations of drug import/export are regulated on Decree of Head of NADFC No. HK.03.1.23.10.11.08481, 2011 on Criteria and Procedure of Drug Registration.

- Registration of drug for export only is conducted by the applicant.
- Registration of drug for export only consists of:
  a. Domestically manufactured product intended for export only, and
  b. Imported drug for export only.
- Imported drug is drug to be made by overseas pharmaceutical industry in the form of finished products or bulk products in primary packaging which will be marketed in Indonesia.
- Imported drug can be:
  a. Imported bulk products, or
  b. Imported finished products.
- Imported drugs can be distributed inside the country and/or for outside of the country.

REQUIREMENT FOR IMPORTED DRUG

❖ **Applicant**

✓ Pharmaceutical Industries in Indonesia having written authorization from the manufacturer abroad.

❖ **Manufacturer**

✓ Have manufacturing Licence and meet GMP requirement as proven by : - Valid GMP Certificate

- Data of last inspection within the last 2 years

✓ Submit latest Site Master File (SMF) document, if :

- The manufacturer has not had any product with the same dosage form authorized to be marketed in Indonesia
- The manufacturer has product with the same dosage form authorized to be marketed in Indonesia, but there is a change of production facilities.

❖ **Site Inspection**

✓ If SMF evaluation results requires evidence of compliance to GMP, site inspection will be conducted.

❖ Pharmaceutical Manufacturing

Administered by

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

Good Manufacturing Practice is administered by NADFC, Deputy I, Directorate of Therapeutic Product and Consumer Good Production Control:

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

Relationship between Dynamic GMP and Registration Requirements (Attachment 3).

❖ Marketing Authorization
Systems, Regulations, etc

Administered by

Example: Good Quality Practice

Quality Requirement
Drug Master File (DMF) requirement for :

- NCE
- 1st Copy Drug
- Copy drug for life saving and serious illness (i.e. Cancer, cardiovasculer, antibiotic drug)
- On site evaluation at the facility of product manufacture (*in-situ*)
  - To support the quality of products
  - To ensure the validity of information written in documents of Quality as well as to check the GMP inspection

❖ Drug Distribution (including drug selection, procurement, sale)
Systems, regulations, etc

Administered by

Example: Good Distribution Practice

Indonesia had Technical Guidelines on Good Distribution Practices published in 2012 by NADFC.
Drug distribution in Indonesia is administered by NADFC, Deputy I, Directorate of Therapeutic Product and Consumer Goods Distribution Control.

❖ Medicine Safety (post-marketing)
Systems, regulations, etc

Administered by

Example: Good Pharmacovigilance Practice

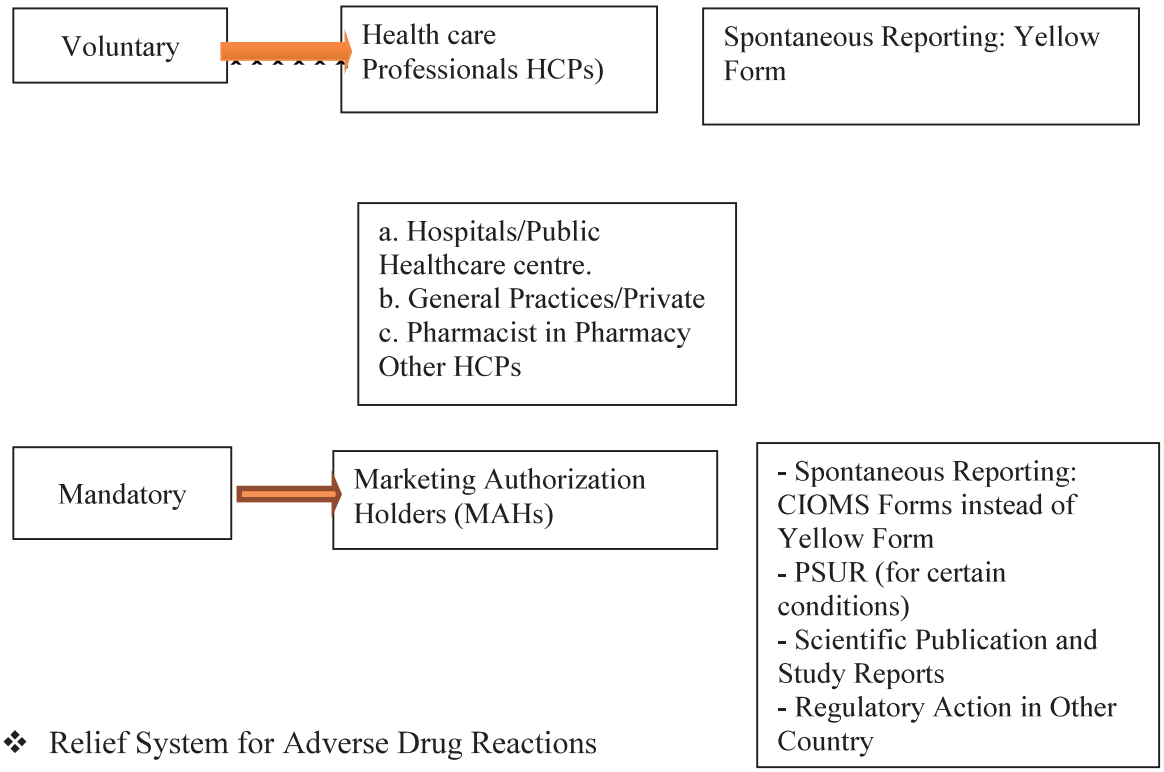
POST-MARKET CONTROL ACTIVITIES ON DRUG SAFETY: Pharmacovigilance Program
Legal framework:

- MoH Regulation No. 1010/Menkes/Per/XI/2008 on Drug Registration , Article No. 22
  Re – evaluation of marketed drug is done under following circumstances:

- Post-market surveillance reveals that the risk outweighs its benefit
- The effectiveness is not better than its placebo
- Not meet bioequivalence requirements
- Need to improve composition and reformulation

- MoH Regulation No. 1799/Menkes/Per/XII/2010 on Pharmaceutical Industry, Article No. 9
  Pharmaceutical Industry (Marketing Authorization Holder) must perform Pharmacovigilance
- Head of NADFC Regulation No. HK.03.1.23.12.11.10690 of 2011 on Implementation of Pharmacovigilance for Pharmaceutical Industry
  Technical Guidance of Pharmacovigilance for Pharmaceutical Industry.
  Key player in pharmacovigilance:
  1. Pre market: Clinical Trial-Marketing Authorization
  2. Post Market: Public health program, Health Care Professionals, Patient, Marketing Authorization Holder, Drug Regulatory Auhtority(DRA), WHO, other DRA

PHARMACOVIGILANCE SYSTEM IN INDONESIA



❖ Relief System for Adverse Drug Reactions
Systems, regulations, etc

Administered by

Pharmacovigilance is post market control: Safety Consistency, ADRs and AEFI Monitoring, Post Market Surveillance (Pharmacovigilance).
Standards Operating Procedures (SOPs) are established to follow up Adverse Drug Reaction (ADR) reports.

Regulation and Guidelines (if applicable) are established for :
- Monitoring safety of new pharmaceutical products.
- Monitoring safety of generic products
- Electronic reporting system (current system and future plan)
- Mechanism to disseminate scientific data related to ADR reports.
- Mechanism to suspend or withdraw marketing authorization of pharmaceutical products due to safety issues

4. Drug Pricing

Please describe about price control and drug price mechanism at public sector in your country.
MoH regulation No.069/Menkes/SK/II/2006: Pharmaceutical Industry (Marketing Authorization Holder) must list the highest retail price on the drug label.

5. Statistic data

a. Number of pharmacists: 18786 (2015)
b. Number of GMP Inspector (National & Local): 104 (2012)
c. Number of pharmaceutical manufacturers/manufacturing sites: 210 (2015)
d. Number of traditional medicine manufacturers/manufacturing sites: 386 (2015)
e. Number of pharmaceutical wholesalers: 2685 (2015)

PART III.

SSFFC (Substandard, Spurious, Falsely-labelled, Falsified, or Counterfeit drug)

1. Short questions

- Please answer the following questions and concisely explain each answer
  1: Laws/Acts that intend to avoid SSFFC.

  Counterfeit drugs are drugs that are produced by an unauthorized by the legislation in force or the production of drugs by labeling of the identity of the other drug that has had a marketing authorization.

  NADFC has been actively participating in International program regarding SSFFC such as:

  - Member states of mechanism SSFFC coordinated by WHO
  - STORM Project coordinated by INTERPOL (International Criminal Police Organization) : initially dealing with Malaria drug counterfeit, now expanded to all counterfeit drug
  - PANGEA project coordinated by INTERPOL dealing with control of counterfeit product marketed through on line
  - MOH Decree No. 1799/2010 regarding Pharmaceutical Industry: ***Pharmacovigillance***

    Pharmaceutical industry must report to NRA if they knew their product substandard and/or cannot fulfill safety, efficacy, quality requirement.

2. Organizations that inspect questioned products to detect the SSFFC

- National Agency of Drug and Food Control in cooperation with INTERPOL (International Criminal Police Organization).

3. How organizations/hospitals/airports/seaport/other authorities inspect SSFFC nationally, locally, and cooperatively.

- Please briefly describe it
- In addition to routine surveillance, NADFC also involved in the operation Pangea IV cooperating with international Interpol in September 2011.
- Violations related to the transaction or the distribution of counterfeit drugs is a criminal offense (pro justisia) that must be processed through the courts.
- Combating counterfeit drugs can not be done solely by NADFC, therefore, NADFC initiated the establishment of the Task Force on Combating Drug and Food Illegal on January 31, 2011 which aims to strengthen law enforcement and combat the circulation of counterfeit drugs / illegal and empowerment of communities in fortify themselves against counterfeit food and drug / illegal by involving law enforcement agencies and relevant institutions.

-

4. Detailed information
   - ❑ Brief history related to SSFFC problem in your country
   - ❑ Current Situations
   - Current problems that your country is trying to solve
   - Present countermeasures
   - Conceiveable ways to improve the current situation
   - And more
   - ➢ Indonesia has expressed desire to set up an intergovernmental negotiating body to draw up legally binding instrument at the international level designed to prevent the manufacture, export, import, or trade of counterfeit medical products on international markets and in international trade and regulate and oversee supply and distribution networks.
   - ➢ Indonesia has stressed that the improvement of access to affordable, safe and efficacious medicines is an important element in the effort to prevent medicines with compromised quality, safety and efficacy.
   - ➢ With regard to falsified medical products, Indonesia proposed the following non-exhaustive elements of a definition: a falsified medical product gives a false representation of its identity and/or source and/or record keeping for traceability; pretends to have been assessed and approved by the competent regulatory authority, pretending to be a genuine quality product; has an intention to deceive by a fraudulent activity; is falsified for profit motives, disregarding public health and safety; and that disputes concerning patents or trademarks must not be confused with falsification of medical products.

- Indonesia then considered the future role of WHO in the areas of substandard and SFFC medical products under three headings: Information and awareness creation, Norms and standards and Technical support to countries.

❑ Other

- If there are any specific cases to share lesson learnt on countering SSFFC in your country, please describe the issue and related information.

Criminal investigations

- Conducting inquiry and investigation toward any law infringement in therapeutic products, narcotic, psychotropic and addictive substances, traditional medicines, cosmetics, health supplement, food and beverages, and other related products.
- NADFC officers have been trained as investigator.
- Given special authority to conduct investigation in terms of and according to the Legal Basis
- Functionally coordinated and supervised by National Police's Investigator

Challenge and Opportunity

- Strengthening of GMP and GDP inspector competency
- Strengthening of Drug Evaluator competency
- Improving the NQCL capacity and capability especially in a new/sophisticated dosage form, biological product (stem cell)

MALAYSIA

Roles of Regulatory Systems and Pharmacists

Inception Report Format for Government Officials

Name: Khirul Falisa Mustafa
Country: Malaysia
Organization/Department/Division:
National Pharmaceutical Control Bureau, Ministry of Health Malaysia

This report consists of three parts: Part I, Part II, and Part III. The main purpose of this report is to collect information in regard to pharmaceutical regulatory services of your country and more to

Part I: INFORMATION SHARING

Why? → *To share the basic information related to pharmaceutical administration in each country.*
What? → *Information that overviews each-other situations in regard to pharmaceutical laws, regulations, and etc.*
When? → *Before or at the arrival to Japan*
How? → *Collected information will be summarized; then it will be sent to each participant. Participant will read carefully & understand it.*

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.

Organizational charts - please refer Sheet 2

1 **Ministry of Health Malaysia**

-Establishment of pharmaceutical services, i.e. Pharmaceutical Services Division (PSD) to deliver a more comprehensive pharmacy services to the Malaysia population

2 **Pharmaceutical Services Division (PSD)**

The Pharmacy Services Programme
-One of the programmes under the Ministry of Health Malaysia (MOH)
-Responsible in
i)ensuring that public gets access to safe, efficacious and quality pharmaceutical products
ii)protecting their interest via enforcement of relevant legislations
iii)ensuring rational use of mediciens by both healthcare providers and patients

The Pharmaceutical Services Division
-One of the main division under this programme
-Carries out responsibility through three main activities
i)Pharmacy Policy & Management
ii)Pharmacy Practice & Development
iii)Pharmacy Enforcement

3 **National Pharmaceutical Control Bureau (NPCB)**

-Pharmaceutical regulatory agency and also the Secretariat to the Drug Control Authority
-An agency under The Pharmacy Services Programme
-Responsible for regulating pharmaceutical products in the marketed country
-Established to implement quality control on pharmaceutical products
-Task
i)Ensure the quality, efficacy and safety of pharmaceuticals through the registration and licensing scheme
ii)Evaluation of scientific data and laboratory tests on all products before they are marketed
iii)Setting up a system to monitor products in the market
iv)Drug information service for medical profession and consumer
v)Handles courses and provides training to personnel from the ASEAN countries

② **Legislation on pharmaceutical administration**

—Please briefly bulletined major laws/acts

◆National Level

・Registration of Pharmacists Act 1951 and Regulations	administered by	Pharmaceutical Services Division, MOH
・Poison Act 1952 and Regulations	administered by	Pharmaceutical Services Division, MOH
・Sales of Drug Act 1952 and Regulations	administered by	Pharmaceutical Services Division, MOH
・Dangerous Drug act 1952 and Regulations	administered by	Pharmaceutical Services Division, MOH
・Medicines (Advertisement & Sale) Act 1956 and Regulations	administered by	Pharmaceutical Services Division, MOH
・Control of Drugs and Cosmetics Regulations 1984	administered by	Pharmaceutical Services Division, MOH

◆Local Level (same as National Level)

・ administered by

・ administered by

◆PIC/S

Yes OR No If yes, joined when since 1 January 2002

③ **Regulatory Services (activities are under the Control of Drugs and Cosmetics Regulation 1984 and current guidelines/directives/circulars)**

—Please describe pharmaceutical regulatory services of your country in response to each item provided below.

—Please add anything (systems, regulations, etc) related to the following services & briefly describe who administers it.

—Please prepare to explain your answer in case that you are asked about pharmaceutical regulatory services of your country.

◆ Drug Import/Export

・ Systems, Regulations, etc

i)	Any company that want to manufacture, import or wholesale any registered products need to have Manufacturer's Licence, Import Licence or Wholesale Licence	administered by	Licencing Unit, Centre for Compliance and Licensing
		administered by	

◆ Pharmaceutical Manufacturing

・ Systems, Regulations, etc

i)	Good Manufacturing Practice (GMP) - compliance to GMP is a pre-requisite for the application of a manufacturing license, as well as product registration/cosmetic notification	administered by	Centre for Compliance and Licensing
ii)	All manufacturers must comply to GMP standards according to PIC/S. Manufacturers not a member of the PIC/S or not certified by any PIC/S participating authority is not allowed to register a product	administered by	Centre for Registration of Product (evaluation of dossier), Centre for Compliance and Licensing (GMP inspection/verification of GMP inpection reports)
iii)	Good Laboratory Practice (GLP) - of test facilities conducting non-clinical safety testing of test items contained in pharmaceutical products, cosmetic products, veterinary products and food addictives, and claimed to be compliant with the OECD Principles of GLP, under the Malaysian GLP Compliance Programme	administered by	Centre for Investigational New Product (The Malaysian Compliance Monitoring Authority (CMA))

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

◆ Marketing Authorization

・ Systems, Regulations, etc

i)	Drugs must be registered and approved by The Drug Control Authority (DCA) for sale/use in Malaysia. Registered products will be given registration number and validity of 5 years from the date of registration	administered by	Centre for Registration of Product
ii)	Marketing authorization holder for products intended to be marketed in Malaysia must be a local agent registered with Registrar of Company (RoC) in Malaysia and is held responsible for all matters pertaining to the registration of the products	administered by	Centre for Registration of Product
iii)	On-line submission for product registration through QUEST system	administered by	Centre for Registration of Product (evaluation of dossier), Centre for Organisational Development (IT support)

※Example: Good Quality Practice

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

・ Systems, Regulations, etc

i)	Good Distribution Practice (GDP) - included in the scope of a GMP inspection	administered by	Centre for Compliance and Licensing

ii)	Drug Selection - The Ministry of Health Medicine (Drug) Formulary (MOH Formulary) known as Formulari Ubat Kementerian Kesihatan Malaysia (FUKKM) is the list of medicines allowed to be used in MOH facilities. The first MOH Formulary was published in year 1983 and served as a guide for the selection of medicine therapy. It is reviewed 2 to 3 times in a year and the updated list is uploaded into pharmacy website (www.pharmacy.gov.my). Selection of medicine is a process to list medicines registered with Drug Control Authority into the MOH Formulary. The MOH Formulary holds the objective of managing excessive medicines use by encouraging rational and quality use of medicines. This is in line with the aim of National Medicine Policy towards achieving rational use of safe, effective, cost effective and affordable medicines in MOH facilities. All medicines to be listed into the formulary need to be evaluated in terms of efficacy/effectiveness, safety and cost effectiveness before presenting to the MOH Drug List Review Panel.	administered by	Pharmacy Practice & Development and Pharmacy Policy & Management, Pharmaceutical Services Division
iii)	Drug Procurement - Procure drugs which is listed in MOH Drug Formulary Procurement is decentralised by each Hospital & Health District Office based on their drugs use trends/ needs Procurement method is determined by current annual usage Tendering process of drugs is administered centrally	administered by	Pharmacy Practice & Development and Pharmacy Policy & Management, Pharmaceutical Services Division
iv)	Drug Sale & Procurement - Based on Ministry of Finance circular and directive	administered by	Pharmacy Practice & Development and Pharmacy Policy & Management, Pharmaceutical Services Division

※Example: Good Distribution Practice

◆ Medicine Safety (post-marketing)

- Systems, Regulations, etc

i)	Post Market Surveillance Program for Registered Products	administered by	Surveillance and Product Complaint Section, Centre for Post Registration of Product
ii)	Handling of Product Complaint for Registered Products	administered by	Surveillance and Product Complaint Section, Centre for Post Registration of Product

※Example: Good Pharmacovigilance Practice

◆ Relief System for Adverse Drug Reactions

- Systems, Regulations, etc

i)	Malaysian Adverse Drug Reaction Advisory Committee	administered by	National Centre for Adverse Drug Reaction Monitoring

④ **Drug Pricing**

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

Pricing			
Agency that sets prices	Ministry of Domestic Trade, Cooperatives and Consumerism.		
Pricing regulation in the public sector?	Yes, Indirectly through public procurement processes.	Pricing regulation in the private	No
Pricing policies			
Free pricing?	In Private sector	Price negotiations?	For single source products in the public sector
External price referencing?	Yes for new pharmaceuticals purchased in public sector	Internal price referencing?	Practiced in public procurement
VAT on medicines	Public sector – Exempted Private sector- GST 6% on all medicines except for 4000 items listed in NEML		
Recent changes in pricing policies *Please describe* Work is in progress towards developing a legal framework to develop a medicines pricing policy in Malaysia. Price monitoring of In the private sector, medicines are supplied by private hospitals, dispensing doctors and retail pharmacies. Administratively, differential pricing between distributing channels is discouraged and a Guidelines on Good Pharmaceutical Trade Practice has been			

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	13282	(2015)
2: Number of GMP inspector (National & Local)	21	(2015)
3: Number of pharmaceutical manufacturers / manufacturing sites	76	(2015)
4: Number of traditional medicine manufacturers / manufacturing sites	163	(2015)
5: Number of pharmaceutical importers	247	(2015)
6: Number of pharmaceutical wholesalers	1009	(2015)

Figure 1 (National & Local Level)

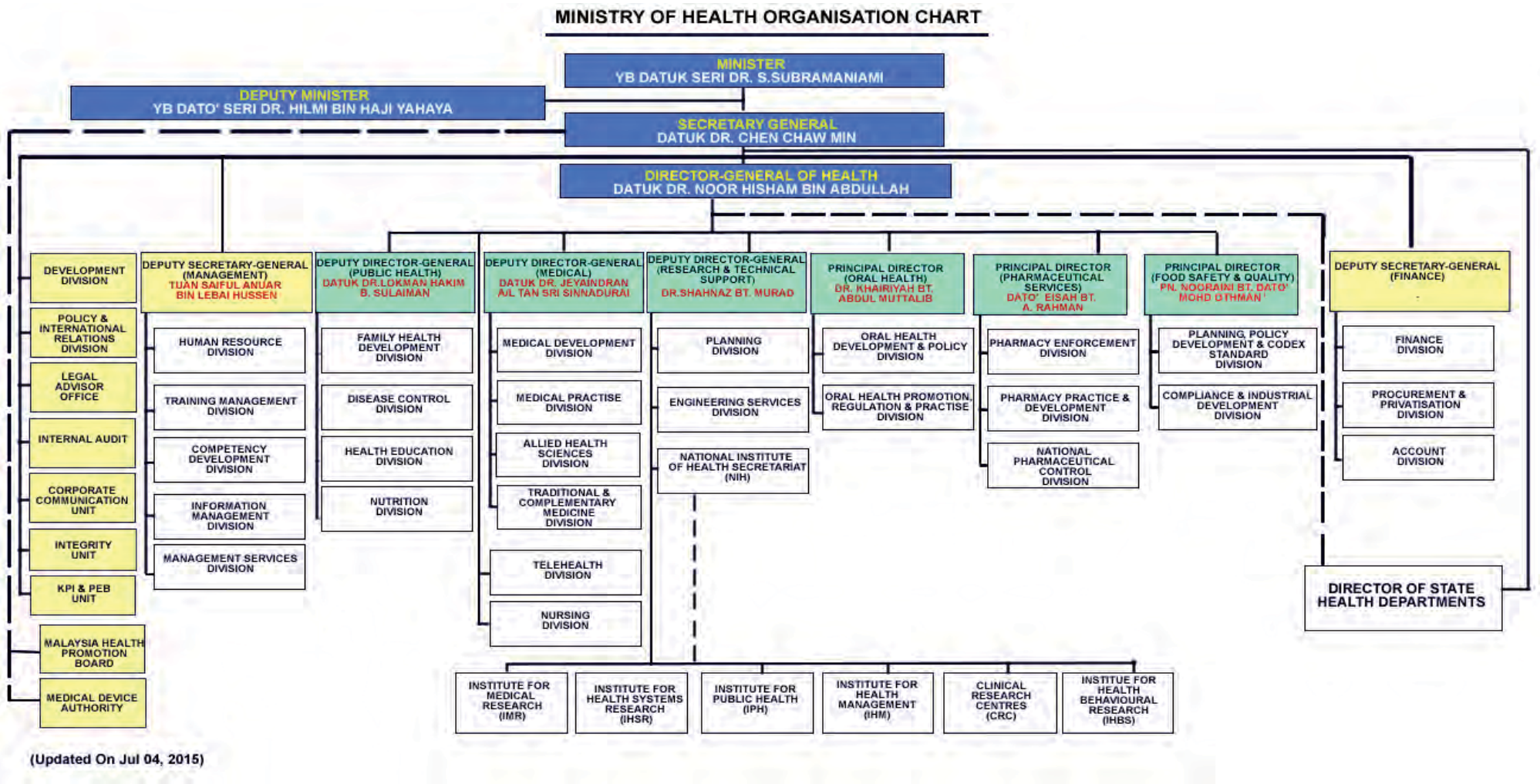


Figure 2 (Pharmaceutical Services)

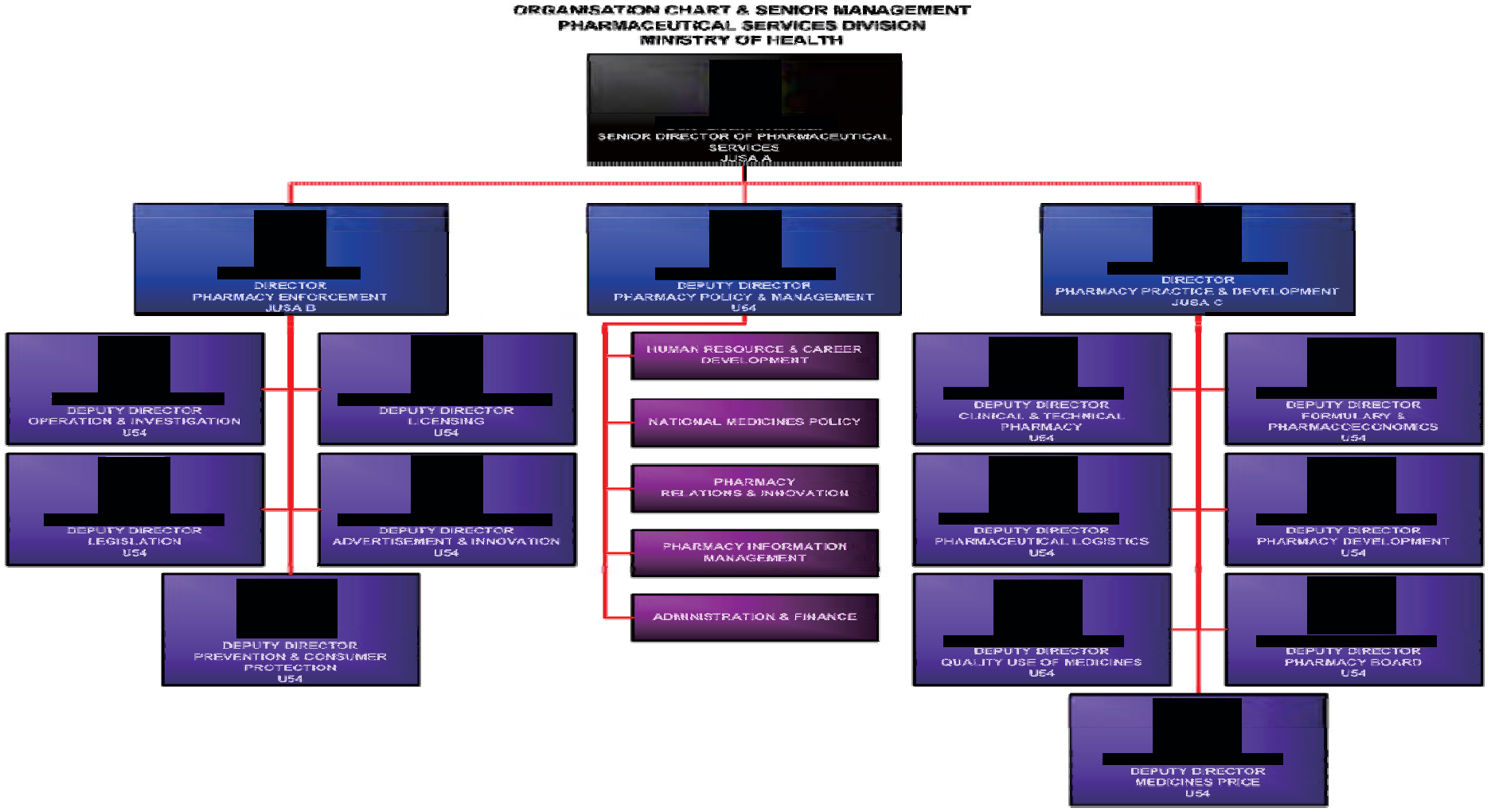
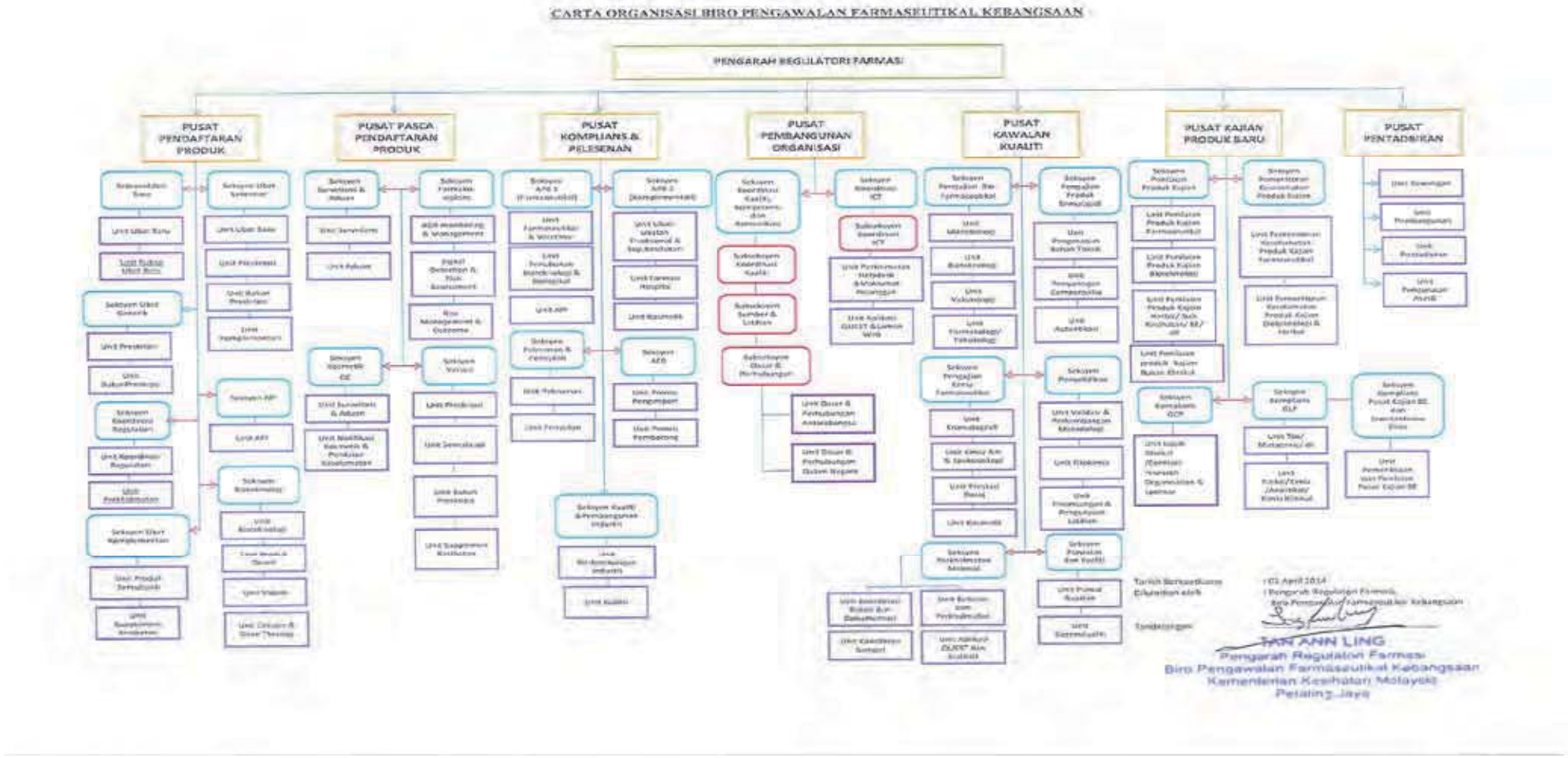


Figure 3 (National Pharmaceutical Control Bureau)



PAPUA NEW GUINEA

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

Country Presentation: Papua New Guinea

Graham Wavimbukie
Quality Control Unit
Pharmaceutical Services Branch
National Department of Health

Introduction

Pop: 7.5 mill

Language: 700 plus, Official, English and Pidgin

Introduction – (Map location)

Papua New Guinea
National Department of Health

Introduction - Organization

Introduction

Organization – National Department of Health
Medical Standards Division
Pharmaceutical Services Branch
Quality Control Unit

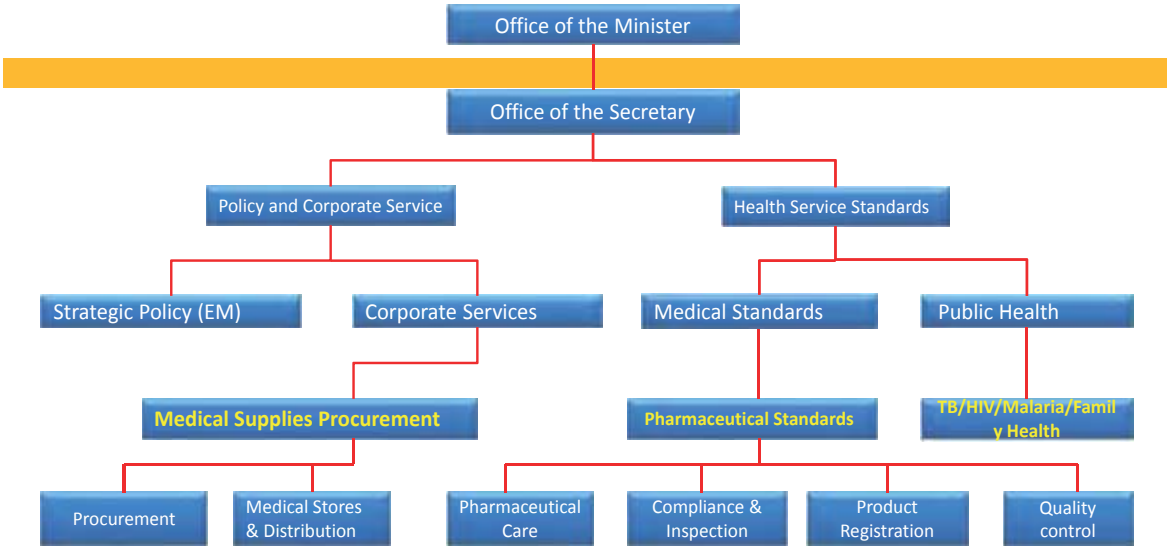
Branch – was created recently in 2011 after recommendation by AusAID in 2008
We are working to develop, improve and align drug regulatory systems

✓ Job tenure –
- Pharmacist by Profession
- Technical Advisor – Quality Control
- 4 years of service now, joined in 2011

✓ Regulatory Services engaged in – Quality Control of pharmaceuticals, but support across other Regulatory Areas where required as we build our systems.

Papua New Guinea
National Department of Health

Organizational Structure – Ministry of Health



Good Practices

Good Practices

- ✓ **Experiences/Examples**
  Good Storage Practices (GSP), Good Distribution Practices (GDP) and Good Pharmacy Practice (GPP) - WHO Standard

Achievements

- Creation and Designation of Pharmaceutical Regulatory Branch in 2010
- Join the WHO Upsalla for ADR reporting and monitoring 2013
- Revision of the Medicines Policy and passed by Gov;t 2014
- Appointment and gazettal for 24 Inspectors nationwide 2013

Solutions for past problems

- Sourcing of medicines and vaccines from WHO prequalified manufacturers
- Quality Testing in WHO accredited labs
- Increased inspections mostly spot and site inspections
-

Good Practices (2)

Ongoing projects to deal with current problems

- Improve drug registration process and guidelines for commencement of registration
- Construction of a Quality Control Laboratory
- Roll of out Hospital Based Therapeutic Committees
- Revision of Act and Regulations
- Revision of MOU with TGA Australia, and hopefully establish new with Malaysia

Bad practices

- ✓ Lack of Networking and international cooperation
- ✓ No GMP clearance for overseas manufacturers
- ✓ No Regulation of price for medicines
- ✓ Very little post market surveillance

Way forward

Learn and adopt good practices from other economies

Areas of Interest

Interests (3 areas from this course)

- ✓ Market Approval (generics)
- ✓ Countermeasures against Counterfeits and SSFFC medicines
- ✓ GMP

Inception Report Presentation

Reuben O. Kigil
Pharmacist & Pharmaceutical Inspector
Milne Bay Provincial Health Authority
Papua New Guinea

Outline

- Introduction
- Good Practice
- Bad Practice
- My Interests

Introduction

- Milne Bay Province of Papua New Guinea Data
  - Maritime province & the eastern tip of PNG
  - Pop.: 276, 000 (2011), Average age: 55-60yrs
  - Growth rate: 2.5% (4 child/woman)
  - Provincial Hospital: 01
  - District Hospitals: 02 (1 Pharm. Technician)
  - Health Centres: 37
  - Aid posts (open): 108
  - Prov. Dispenser: 01 (1 Pharm. Technician)

Intro cont'd

- Prov. Hospital facts
  - 177 beds
  - 4 main clinical dept.
  - 524 (726 – MBPHA)
  - 3 Pharmacists (1 Clinical and Manager, 1 Pharm. Inspector)
  - 1 Pharmacy Technician
  - 1 Procurement Officer
  - 1 Storeman
  - 4.3 metres sq. disp. room
  - 149 Outpatients/day

Intro cont’d

- Pharmacist
  - Dispense medicines to outpatients & inpatients,
  - Attend to ward orders based on imprest system,
  - Maintain stock inventory,
  - Submit orders to Area Medical Store for new stock,
  - Do quarterly trips to Area Medical Store to fast track orders,
  - Go on supervisory patrols to rural areas

Intro cont’d

- Pharmaceutical Inspector
  - Inspect shops and informal markets for illegal sales of medicines,
  - Inspect retail pharmacies annually for compliance to standards before renewal of license,
  - Inspect public health facilities for compliance to Good Storage Practices and standards,
  - Do public awareness's.

Intro cont’d

- Pharmacists main role in my country at present is management of medical supplies at different levels of all health facilities. It starts from procurement, storage, distribution to health facilities and eventually dispensing to patients. Quality of the medical supplies are checked (physical observations) at all levels.

Good Practices

- Achievements & Solutions to past problems
  - Imprest System - (2003)
  - Shelves and work benches installation - 2006
  - New patient waiting area - 2012
  - Average monthly consumption (AMC) - 2014
  - Inventory system (Stock cards to mSupply – 9/2015)
  - Prepacks for dispensing
  - Weekly visits to wards to check imprest cupboards
  - Quarterly trips to Area Medical Stores (x 5)

Good Practices cont'd

- Ongoing projects to deal with current problems. Maintain:
  - data entry into mSupply
  - prepacking for dispensing to outpatients
  - stock takes
  - quarterly trips to AMS
  - Submit AMC to National Dept. of Health

Good Practices cont'd

- Successful counter measures against problems
  - Maintaining data entry into mSupply

Bad Practices

- Stealing
  - On three separate occasions – x3 staffs sacked
- Warehouse is still in a mess
- Requests for pallets were not entertained
- Sending storeman alone to warehouse
- Shelving still a mess
- No TDM/MTC
- No Clinical Ward rounds
- Stock take is still on a ad hoc basis
- Frequent orders from HC to Hospital

My Interests

- Pharmaceutical regulatory system in Japan (Legislation, Pharmaceutical approval system, Good Manufacturing Practices(GMP), Health insurance system and drug price listing, Safety measures.
- Role of stakeholders to ensure quality-assured medicines (Activities by importers, manufacturing companies, wholesalers, hospitals and pharmacies).

- Anata no chui o arigato gozaimashita!
- Shitsumon ya komento wa?

SRI LANKA

Roles of regulatory systems and pharmacists on proper access to quality assured medicines (J15-04386)

Inception Report Presentation – Part II

Yadalgoda Muhandiramlage Priyantha KUMARA
State Pharmaceuticals Manufacturing Corporation – Sri Lanka
www.spmclanka.lk

What is SPMC – Sri Lanka

- State Pharmaceuticals Manufacturing Corporation is the sole state sector manufacturer of pharmaceuticals to the Sri Lankan nation.
- SPMC is established under Industrial Corporation Act number 49 in 1987
- Donation from Japanese government and JICA in 1987
- We have a product list about 69 drugs which fulfill a part of essential drugs in Sri Lanka.
- Our annual capacity now exceeds 2000 million tablets and capsules.
- In 2016 another expansion program stats with the aid of Japanese Government to increase the out put to 4000 million units.

Category A
Introduction of work

1. Manufacturing of products

Production department is responsible in manufacturing of tablets and capsules in SPMC. Therefore our key objective is to carry out all the processes up to the standards stated in the pharmacopoeias without any quality defect. To obtain the quality level we try our best to follow the Standard Operating Procedures, implement and follow GMP regulations.

2. Validation of manufacturing process

Our ultimate goal is to manufacture a quality product. With that aim the production department together with the formulation and quality control departments involve in validation of the manufacturing processes of tablets and capsules.

3. Maintaining production data and cleaning data as to comply with GMP.

- All the documents maintained for 5 years until the products exceeds its shelf life.
- If some marketing complain occurs in the market we should be able to trace the file.
- When NMRA(National Medicines Regulatory Authority) inspect the premises for re-registration we should be able to produce required data.

4. Conducting training and development of trainees and university students

- SPMC recruits new people for production and quality control departments from Advance level science stream. So we have to train them for the job at least one and half years. There they can aware about every department in SPMC like Production, Quality Control, Maintenance, Procurement, Marketing, Finance and Administration.

- Sri Lanka now conducting B.Sc (Pharmacy) and B.Pharm degrees in National Universities. So we are providing them the industrial visits and relevant training as needed. Other than that if they need any technical assistance for their projects we give our support.

Category B - Good practices

1. **Quality checking of raw materials at 4 intervals**
    - At the tender sampling –initial tender samples are checked
    - Pre-shipment sampling- samples from the exactly the same batches to be sent.
    - Full analysis Testing-one sample from each batch
    - Identification test-testing of each drum

Contd..

2. In-process quality checking
- Tablet weights are statistically controlled during manufacturing to ensure the dose of the tablets.
- Weights of tablets are monitored by narrowing down the pharmacopeia standards

3.Finished good quality checking
- Finished goods are checked before releasing the products to the market.

4. Adhere to GMP guidelines in Manufacturing.

5. Follow British Pharmacopoeia, United States Pharmacopoeia standards for manufacturing and quality control.

Category C - BAD PRACTICES

1. Procuring of raw materials by not selecting suppliers but through Government Tender Procedures.

   -Process validation is not convenient.

2. Selecting suppliers through questionnaires without visiting the suppliers.

   -Supplier reliability is questionable

3. Do not have mechanism to do GMP audit to know at what level we adhere to GMP.

4. No post marketing surveillance. So lack of data after marketing the product and do not have mechanism to do competitive analysis.

Category D
INTEREST TROPICS

1. GMP audits-

one of my primary interests is to learn how to carry out a GMP audit. As a manufacturing firm we are directly involved in implementing and following GMP regulations within the factory premises. If we have a fair knowledge about GMP auditing that would be an added advantage for us to correct our shortcomings. Also this would upgrade the level of standards in our organization.

2. Health insurance system proceed in japan-

-How the health insurance system proceed in Japan according to the government regulations.

3. How to carry out of clinical trials of the drugs and bio equivalence testing.

4. ADR reporting system and Product recall procedures-

- It is mandatory to establish a correct recall procedure.

5. Regulations in Herbal medicine in Japan-

-How the herbal drugs are regulated and the conditions for storing herbal products.

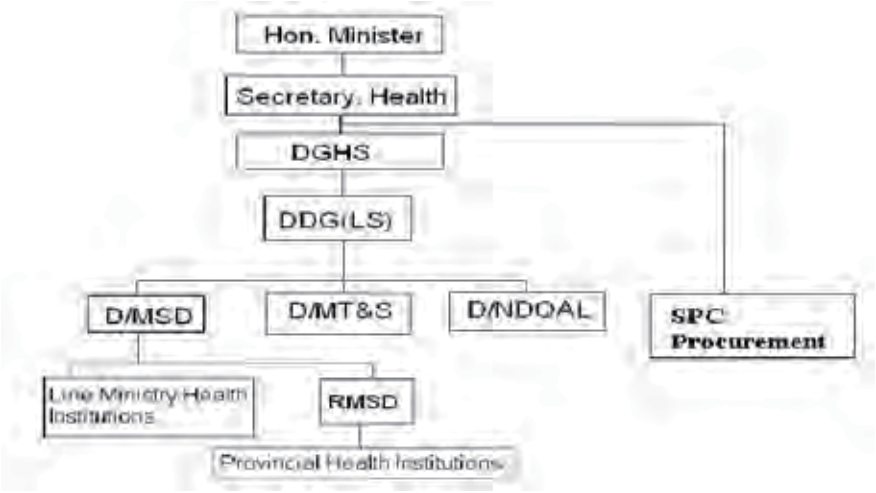
Roles of regulatory systems and pharmacists on ensuring proper access to quality assured medicines

Job Report as a part of Requirements of the Programme
By
Y.M.P.Kumara
Of
State Pharmaceutical Manufacturing Corporation of Sri Lanka

1. Over view of country and organization

Sri Lanka is an Island in South Asia surrounded by the Indian Ocean with a Population of 21,866,445 and 65610 sq Km land. Politically it is a country governs by parliament Democracy and headed by an Executive President selected by people 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 countrymen have 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.

- **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.

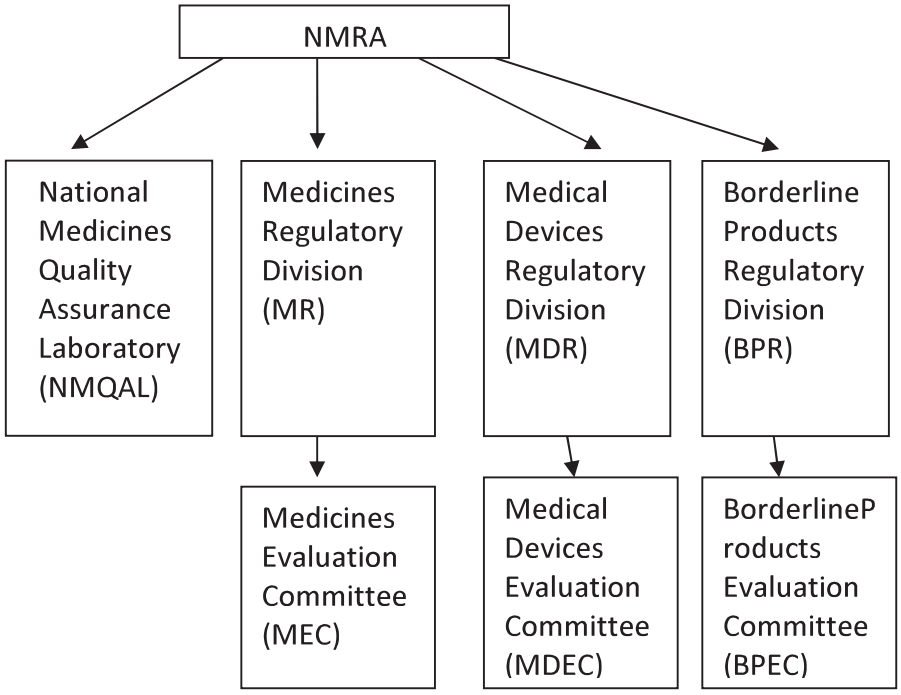
viii. Regulate the promotion and marketing of medicines, medical devices and borderline products.

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

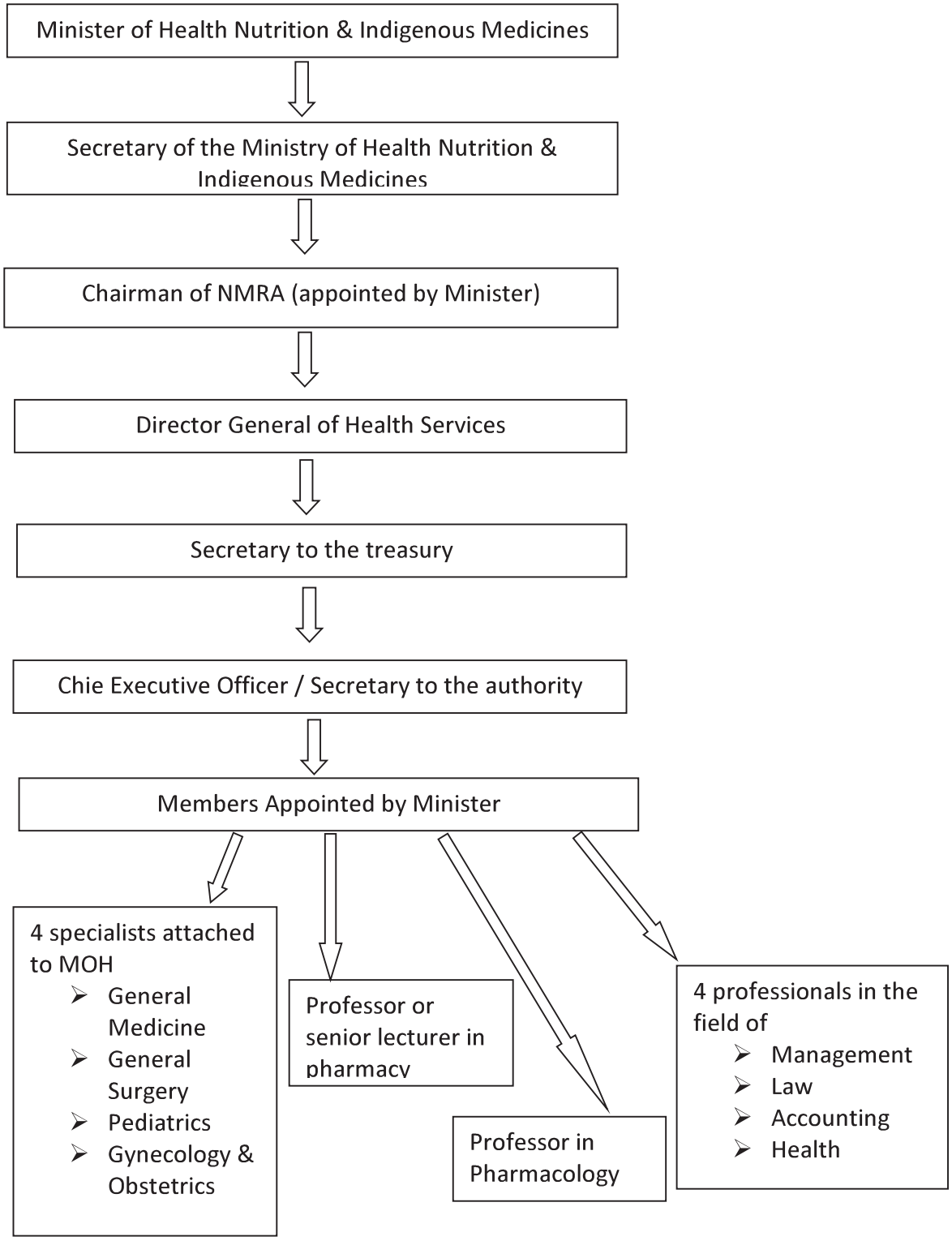
x. Conduct post marketing surveillance on quality, safety and adverse reaction of the medicines medical devices and borderline products.

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

2.1 Institutions established under NMRA act



2.2 Organizational chart of National Medicines Regulatory Authority



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 Manufacturing 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 a license for manufacturing from Medicines Regulatory Division (MR Division). The items to be manufactured should 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 a full registration. 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 drugs prevails within the island.

VI. Relief system /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 pharmaco vigilance unit located at the Department of Pharmacology, Faculty of Medicine, and University Of Colombo.

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 tender will govern the price. However apart from this the government also procures drugs directly from SPMC. Prices for these drugs are negotiated between the two government organizations. In the case of private sector there is no such regulation in prices. Same drug is available in different prices in the market.

5. Statistical Data

Category	Data	Year
a) Number of pharmacists	6311	2013
b) Number of inspectors	40	2013
c) Number of pharmaceutical d) Manufacturers	30	2013
e) Number of traditional medicine manufacturers	Statistical data not available	
f) Number of pharmaceutical importers	211	2013
g) Number of pharmaceutical whole sellers	57	2013

SUDAN

The National Medicines and Poisons Board

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

Sudan's Experience Of Medicines Regulation

Dr. Ahmed Yagoub Yahia Dafaalla

Inspector of pharmaceuticals manufacturer of Sudan's NRA

November 2015

Who is the National Medicines and Poisons Board (NMPB) ?

The BOARD is authorized body for the setting & development of regulation in Sudan, it also responsible of quality assurance measures to ensure the safety, effectiveness and quality of pharmaceutical products, medical devices and cosmetics, as needed, in order to protect and promote the health and wellbeing of the peoples.

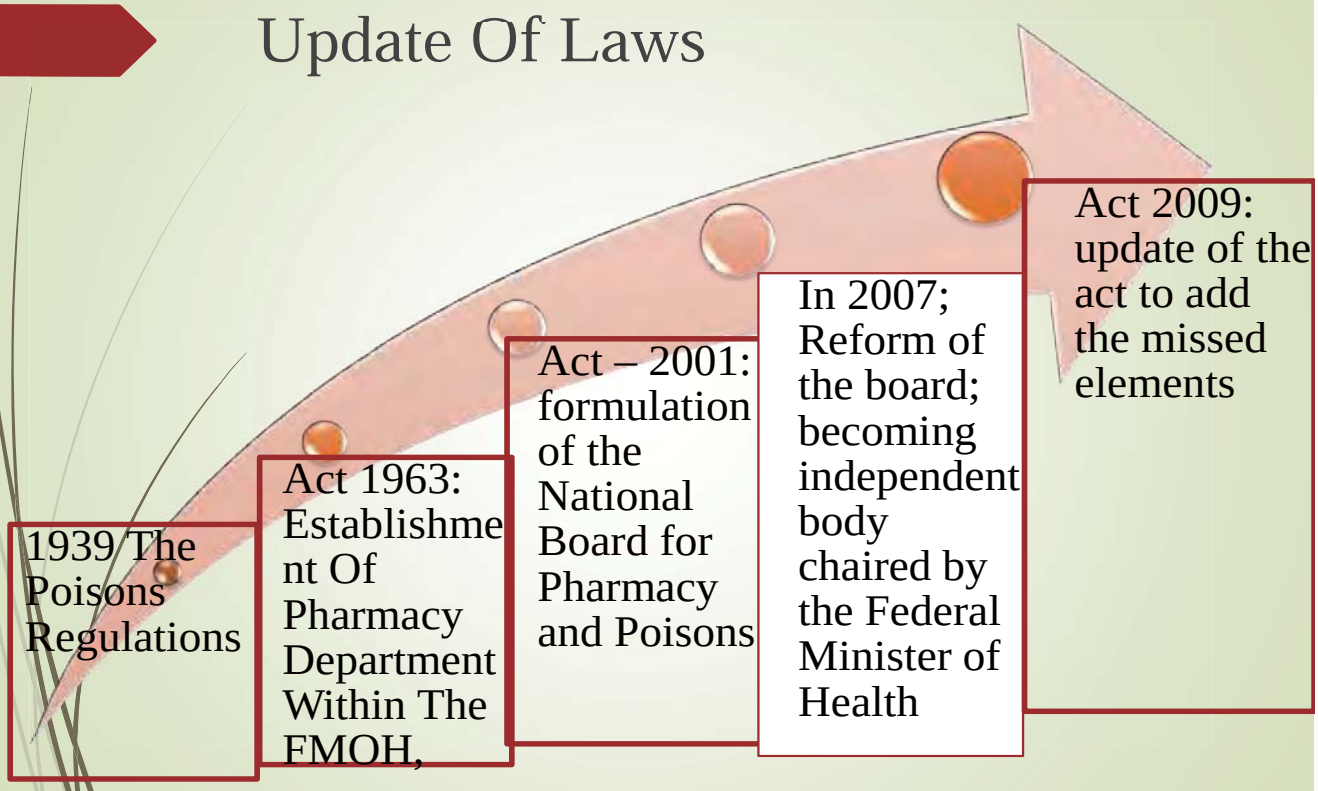
Vision

- The BOARD aspires to develop and take sound and effective regulation and quality assurance measures to ensure the safety, effectiveness and quality of pharmaceutical products, medical devices and cosmetics, as needed, in order to protect and promote the health and wellbeing of the Sudanese people and to attain the strategic goals set by the state;
- using scientific approaches based on the principles of good governance and values of justice, transparency and partnership.

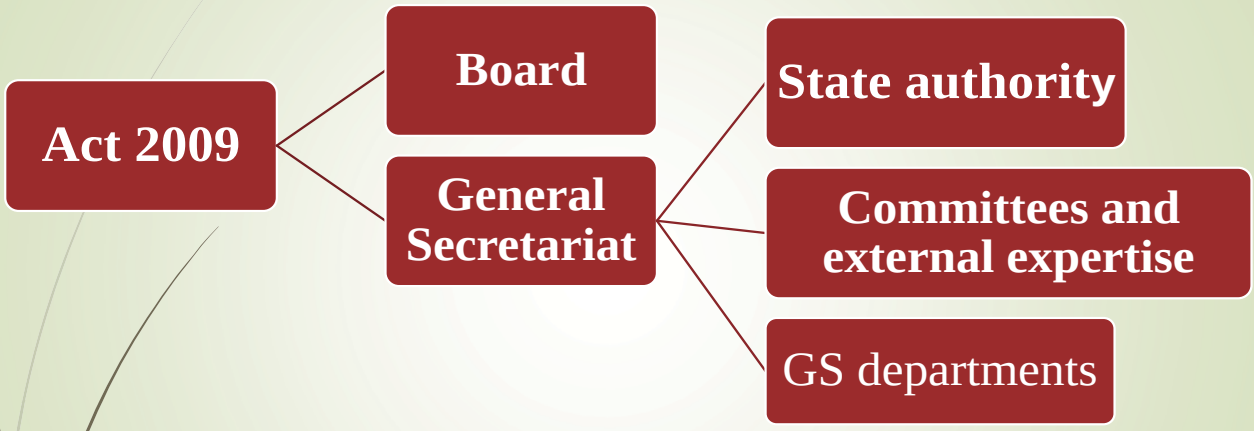
Mission

- The BOARD is committed to ensure the safety, efficacy and quality of pharmaceutical products, medical devices and cosmetics by instituting and maintaining a competent and effective national regulatory system, structures and resources capable of providing the necessary regulatory services and achieving the national objectives of the BOARD.

Update Of Laws



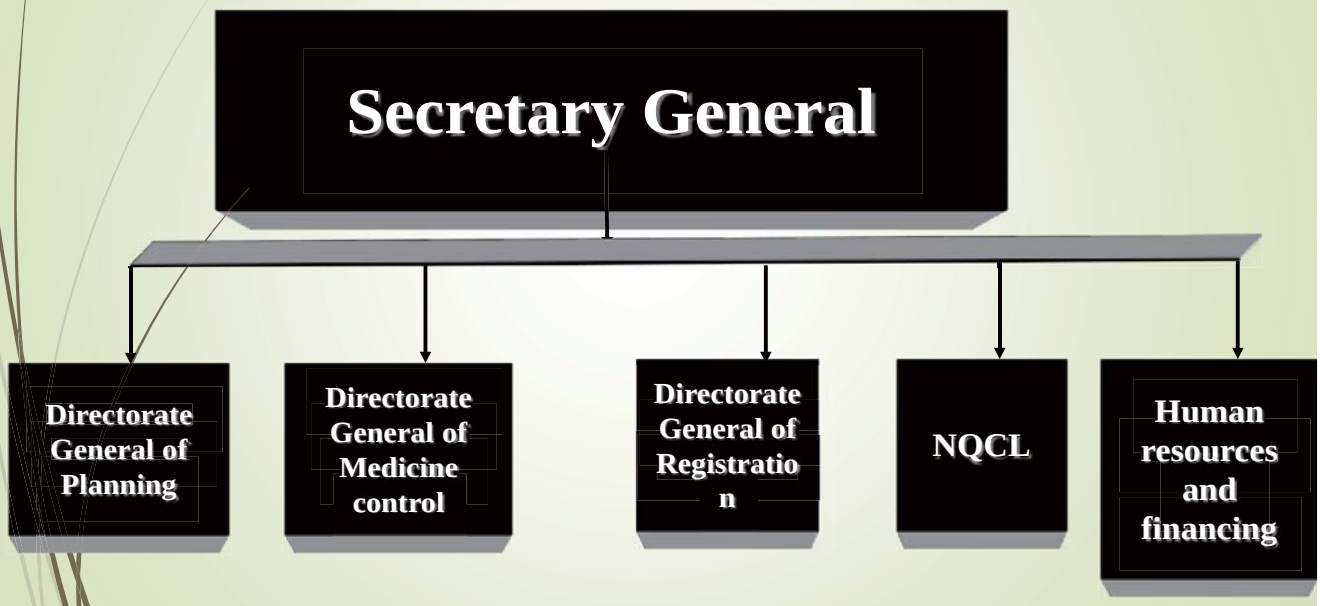
Legal Framework For Medicines Regulations



- Quality Management System
- Funding
- Governance
- HR: independent recruitment

6

Organizational Structure And Functional Secretariat



The Aim of the Secretariat General

- Quality assurance of medicines in the Sudanese market and prevention of entry of counterfeit, substandard and low quality medicines, by establishing a secretariat effectively and powerfully operate according to the appropriate laws.

The main objectives of the Secretariat General:

- Assurance of safety and quality of human and veterinary medicines.
- Setting standards for medical and diagnostics devices.
- Control and supervision of the special procedures for licensing pharmaceutical and medical devices plants.
- Exchange and dissemination of information with legal and scientific organizations both locally and internationally and preparation of medicine data base.

The BOARD is carrying out their duties through well trained technical staff & professional committees.

Technical Committees

- Registration committee of:
  - Human medicines.
  - Vet medicines.
  - Medical Devices.
  - Cosmetics.
  - Herbal Medicines.
- Licensing Committee.
- Appeal Committee.
- Ethical Committee.
- Legislation Committee.
- Costing & Pricing.

National Drug Quality Control Laboratory

- Conducting the required laboratory tests for samples of pharmaceutical preparations, starting materials, biological products and cosmetics. The analysis could be pre and/or post marketing.
- Participation in setting specifications and standards for drugs and medicinal preparation for public sector tenders.
- Participation in GMP (Good Manufacturing Practice) and GLP (Good Laboratory Practice) inspection for both local and foreign pharmaceutical firms.
- Participation in medicines and pharmaceutical preparation inspection at the borders and also in warehoused goods for general sale.
- Conducting studies and research to develop method of analysis and to establish comparative bioequivalence testing procedures.

Directorate General of Medicines Registration

I. Human Medicines Registration Directorate
II. Veterinary Medicines Registration Directorate
III. Medical Devices Assessment Directorate
IV. Cosmetics Registration Directorate

I. Human Medicines Registration Directorate

- The main job is assessment and evaluation of registration application of human medicine which may be; chemical, herbal, biotechnology, hormones and vaccines preparation.
- Also it works as a secretariat for Human Medicine Registration Committee.

II. Veterinary Medicines Registration Directorate

- It is responsible for the evaluation of registration applications of veterinary medicines including those preparations which are used to increasing animal weight by an anabolic effect or the production of animal products such as milk.
- Also it acts as the secretariat for Veterinary Medicine Registration Committee.

III. Medical Devices Directorate

- Responsible for the assurance of safety and efficacy of all medical devices from simple wound dressing to complex diagnostics machines.
- Works as a secretariat for Medical Devices Registration Committee.

IV. Cosmetics Registration Directorate

- Responsible for the assurance of quality and safety of cosmetics preparation
- It works as secretariat for Cosmetics Registration Committee.

Directorate General of Medicines Control

I. GMP Compliance Department
II. GDP Inspections Department
III. Importation Department
IV. PMS Department

Directorate General of Medicines Control

- Responsible for the quality assurance of imported medicines and it monitors quality and safety throughout storage and distribution. The main duties are:
- Prevention of the importation of unregistered medicines.
- To ensure that appropriate action is taken when receiving reports of low quality medicine.
- Investigation of manufacturing, importation, sale, supply of any suspicious illegal drugs, cosmetics or medical devices.

Directorate General of Medicines Control

- Post marketing surveillance.
- Monitoring adverse drug reactions
- Inspection of local & foreign facilities.
- Costing & Pricing of medicines.
- Control narcotics & Psycotropic medicines

Stakeholders

- Governmental Sector:
  - CMS.
  - Customs.
  - Police
  - etc.
- Non- Governmental Sector:
  - Importers.
  - Manufacturers.
  - Civil Societies/NGOs.
  - etc.

Achievements and best experiences in medicines regulation

- Implementation of electronic system for clearance of imported medicines, in collaboration with concerned authorities
- Formulation of settlement policy for local pharmaceutical manufacture, as part of the investment encouragement policy
- Organization of the first conference for medicines regulatory authorities in Sudan and neighboring countries, in collaboration with WHO during December 2014
- Cooperation for effective regulation of medicines

Promoting partnership towards effective harmonization of medicines regulations

- The Conference Recommends: to start projects with IGAD and other neighboring countries on cross-border supply chain security and combating Substandard/spurious/falsely-labelled/falsified/ counterfeit medical products (SSFFC) medical products by sharing reporting on (SSFFC) medical products

Challenges In Medicine Regulation

- Inadequate functionality of regulatory authorities at the states level and weak connection though LIMS System.
- Introduction of CTD and bioequivalence studies
- Vast open borders with 7 countries
- Achievement of collaboration and harmonization at regional and international levels

Challenges In Medicine Regulations

- Retention of highly skilled personnel
- Financial policies/systems
- Relation with private sector to enforce regulations
- Regulations of medical devices- new experience

Challenges In Medicine Regulations

- Increasing capacity of NQCL:
  - Equipments
  - Supplies
  - Rehabilitation
  - International Standards (Prequalification, etc)
- Increasing capacity of Medicines control.
  - PIC/S members
  - Prequalification of Inspectors
- Human resources
  - Training
  - Motivations
- Limited financial resources

Opportunities In Medicine Regulation

- High political commitment
- Technical independency - strong decisions
- Willingness for collaboration among partners including neighboring countries
- Promising pharmaceutical market in East Africa and IGAD countries
- Existing successful stories for capacity building (pre-qualified laboratories, CTD,…etc)

Way Forward

- We confirm that Sudan is looking forward to be effective partner and to do our best in order to implement the outcomes of this this training knowledge and experience.


ealth Organization
بالتعاون مع منظمة الصحة العالمية
cines Regulatory
hboring Countries
المؤتمر الأول
The First Conference
ll- Khartoum , Sudan
٨ ديسمبر ٢٠١٤م بقاعة الصداقة بالخرطوم
تحت شعار:
(فلنتعاون من أجل رقابة دوائية فاعلة)
برعاية السيد/ النائب الأول لرئيس الجمهورية
الفريق أول ركن/ بكري حسن صالح
السيد/ وزير الصحة الاتحادي- رئيس المجلس القومي للأدوية والسموم
ations of Medicines
st Vice President
ekri Hassan Salih
eral Minister of Health
and Poisons Board