Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

Country Reports

Japan International Corporation of Welfare Services (JICWELS)

Contents

Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

AFGHANISTAN

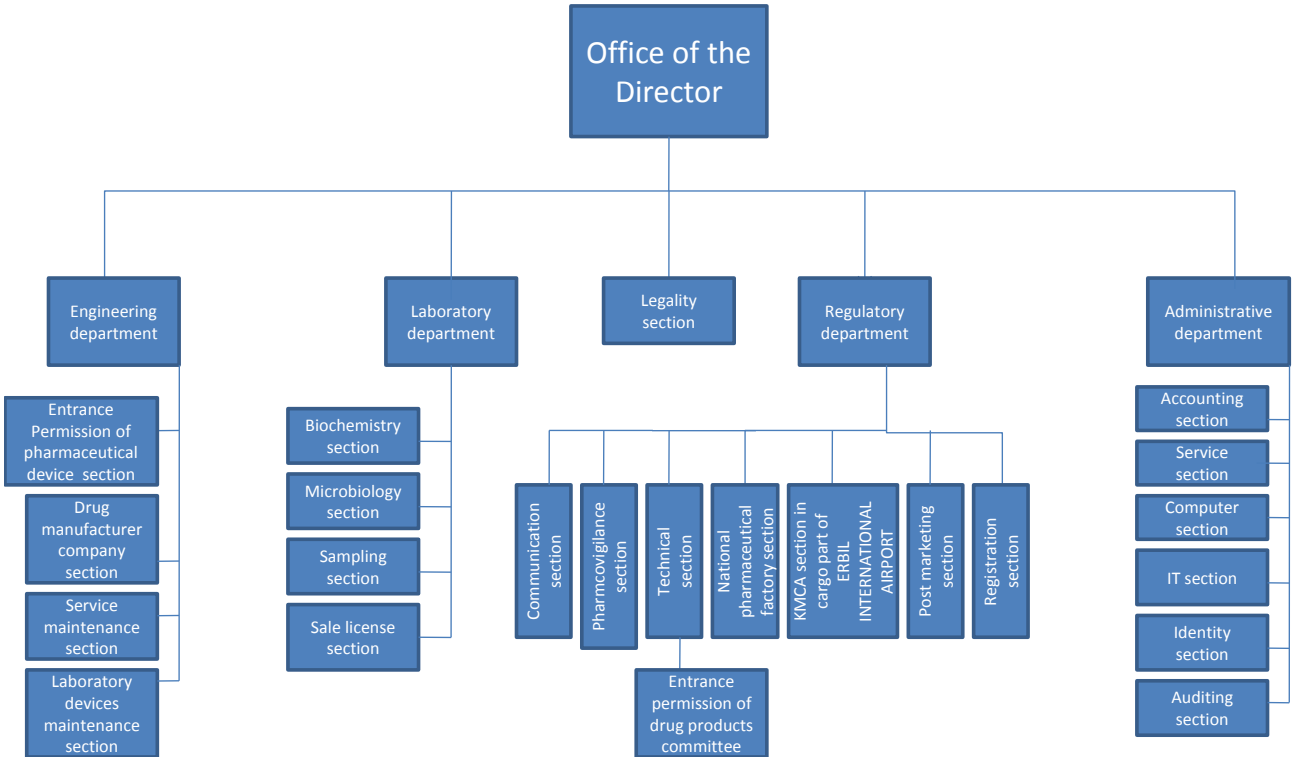
IRAQ (1)

Inception report

Regulatory Affairs Department Kurdistan
Medical Control Agency Ministry Of Health
Kurdistan Regional Government.

Part I

1- Organization chart
of
(Kurdistan Medical Control Agency)



2- Legislation on pharmaceutical administration

--National level:

- Law of Practicing the profession of pharmacy, in 1972 which is administered by Ministry of health of Iraq.

--Local level:

- Ministry of health instruction number 1 (drug regulations) in 2011.
- Ministry of health instruction number 2 (drug regulations ' revised') in 2013.

Both are administered by Kurdistan region ministry of health.

--PIC/S: not joined.

3-Regulatory services

--Drug import/export:

- Drug import starts with giving entrance allowance for each batch, which is administered by Entrance permission committee of regulatory affairs department.
- No drug exportation.

--Pharmaceutical manufacturing:

- Rules for establishing pharmaceutical manufacturer .
- Periodic site inspections according to GMP.

These are administered by regulatory affairs department.

. Random batch selection for analysis according to GLP, which is administered by Laboratory department.

--Marketing authorization:

- Drug Manufacturing company registration, with special instructions in form A1.
- Medical devices company registration, with special instruction in form B.
- Pharmaceutical products registration, with special instructions in form A2.

All these actions are administered by registration section of regulatory department.

--Drug distribution:

- Drug selection is no more related to KMCA, there is a committee in MOH regarding this procedure.
- Procurement is the duty of Directorate of health.
- Sale, sampling, routing analysis then sale permission, are administered by laboratory department of KMCA.

--Medicine safety :

- Parallel import monitoring.
- Counterfeit medicine monitoring.

These actions are administered by post marketing monitoring team.

. Customer complain record by pharmacovigilance section.

--Relief system for adverse drug reactions:

- Focal points in public hospitals.
- Patient complains follow up.

Administered by Pharmacovigilance section.

4-Drug pricing

- On October 2014 a committee of 7 members including KMCA pharmacists established in Ministry of health, revising the price structure to control the market.

5-Statistic data

1-Number of pharmacists in KMCA (25) in 2014, and all pharmacists in KRG is more than (600) pharmacists.

2- Number of GMP inspector (2) since (2011).

3- Number of pharmaceutical manufacturer (2) , one in Erbil city since (2008) & one in Sulaimaniya city since (2011).

4- Number of traditional medicine manufacturer, not available.

5- Number of pharmaceutical importers,(120) till (2014).

6 – Number of pharmaceutical wholesalers, (50) till (2014).

PART II

Category A: (Introduction of work)

- --KMCA /Regulatory affairs department
- --Deputy Manager
- --Head of regulatory affairs department

Category B
Good practice

- --Good manufacturing practices
- Good distribution practices
- Good storage practices
- --certificate of intendance for GMP inspection according to WHO requirements
- (Alkem laboratories….india….april 2011)
- Certificate or intendance for GMP Guidelines (WHO…march…2014)

- Other local trainings …
- --KMCA founded in 2006, I employed in 2008, started with the beginning of controlling medicines in the region (Safety, efficacy, quality, import control….etc)
- --Capacity building, training courses, implementing the rules that governing medicines in well developed countries(agencies) and evaluating which rules are applicable with our situation.
- --started controlling the marketing by post marketing surveillance
- Then giving import license based on registration of Baghdad
- Then opening our own registration unit, registering the pharmaceutical manufacturers
- Then giving import permit for every batch entering Kurdistan region.
- Then activating pharmacovigilance.
- Taking samples from each batch entering Kurdistan for analysis.
- Auditing pharmaceutical manufacturers according to our instructions for the purpose of registration.

Category c:
Bad practice

- --presence of medicines which entered Kurdistan without our permission
- --price control. Till now a day we are trying to put rules for controlling the margin of benefit for importers, whole sailors, pharmacies.(it is open market).
- --we made a contract with an external laboratory to made gap analysis then decide how to build capacities, the contract period was 2 years, during this period the analysis and registration was their duty, was a bad practice because they didn't finished all their duties on time, the contract finished on 12th November 2014.

Category D
Interests

- --visiting a pharmaceutical facility.
- --applying worldwide regulations for medicine control to be up to date.
- --e-CTD format for marketing authorizations.

Thank you

IRAQ (2)

Inception report

Registration section
Regulatory department Kurdistan Medical
Control Agency Kurdistan Region / Iraq

Part I

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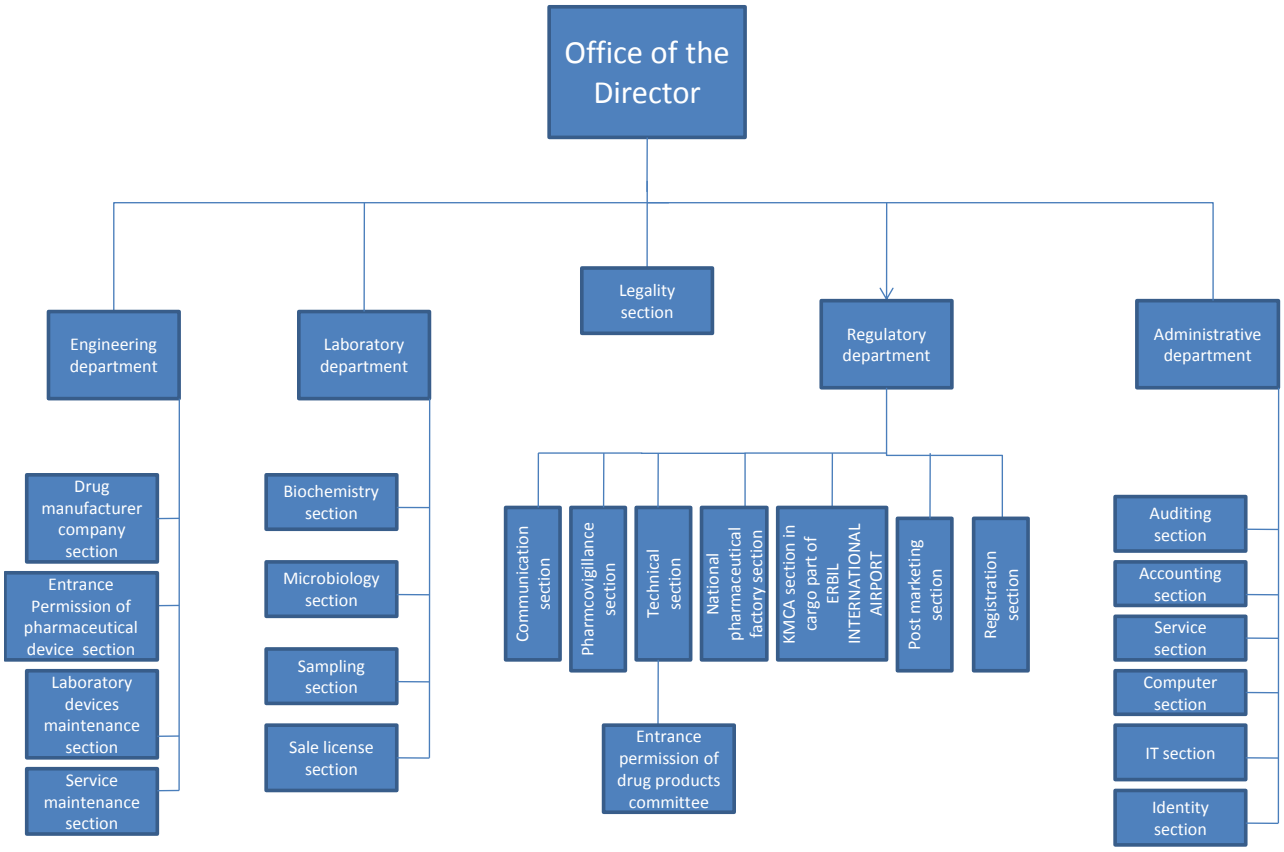
of
(Kurdistan Medical Control Agency)



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PART II

Category A: (Introduction of work)

- --KMCA /Regulatory affairs department
- Since April 2009.
- Expert pharmacist in registration section.

Category B
Good practice

Achievements:

. Prompt registration of manufacturers.

. Prompt Registration of medical devices companies.

. Prompt registration of pharmaceutical products.

. Auditing pharmaceutical facilities.

Solutions for past problems

. Revising our instructions about registration procedure of both manufacturers and pharmaceutical products.

. Good manufacturing practice implementation.

. Hiring more pharmacists and training them.

On-going projects to deal with current problems

- Insistence on non-entry of unregistered medicines.
- Re-informing the distributers with generalization letters about any new instructions regarding registration process.
- Primary registration of pharmaceutical products.

Successful countermeasures against problems

- No entering permission for un-registered drugs.
- No drug import license for un-registered drugs and drugs need re-registration.
- Controlling the market from counterfeit medicine by routine tour of post marketing team.
- Enforcement of sanctions and penalties to distributers.
- Imposing price structure.

Category c:
Bad practice

- Illegally entered drugs.
- No price control.
- Un-registered drugs.
- Counterfeit, substandard & falsely labeled drugs.
- Absence of qualified pharmacists .

Category D
Interests

- Visiting a pharmaceutical facility.
- Registration process of manufacturer and medicines.
- CTD format for marketing authorizations.

END OF THE REPORT

SPECIAL THANKS

MALAYSIA

GOOD GOVERNANCE OF MEDICINES FOR NATIONAL PHARMACEUTICAL REGULATORY AUTHORITIES
(JFY 2014)

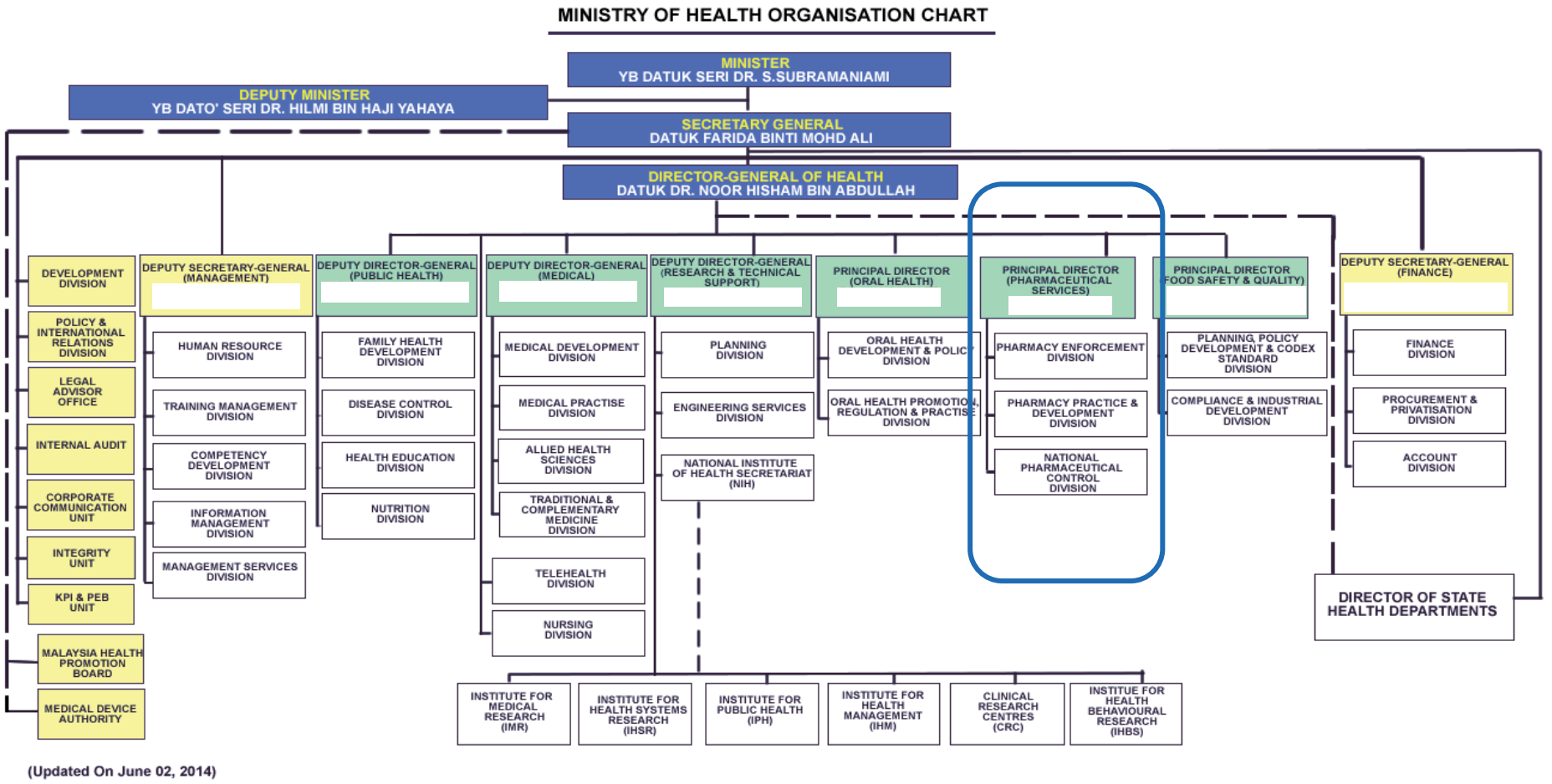
INCEPTION REPORT

Country	:	Malaysia
Organization	:	Pharmaceutical Services Division, Ministry of Health Malaysia

Part 1: INFORMATION SHARING

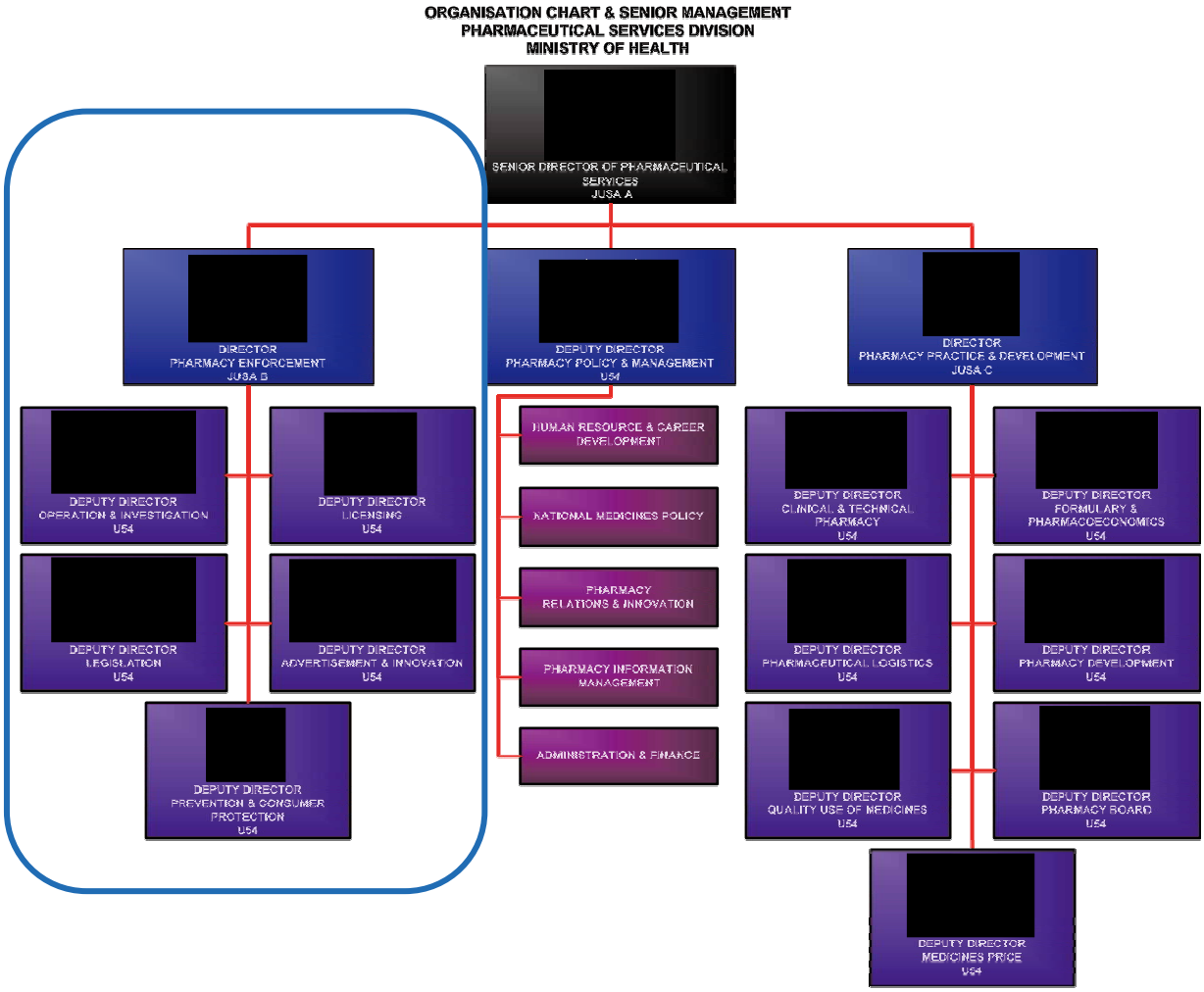
1) Organizational Chart

(a) Organization Chart of Ministry of Health Malaysia Appendix A

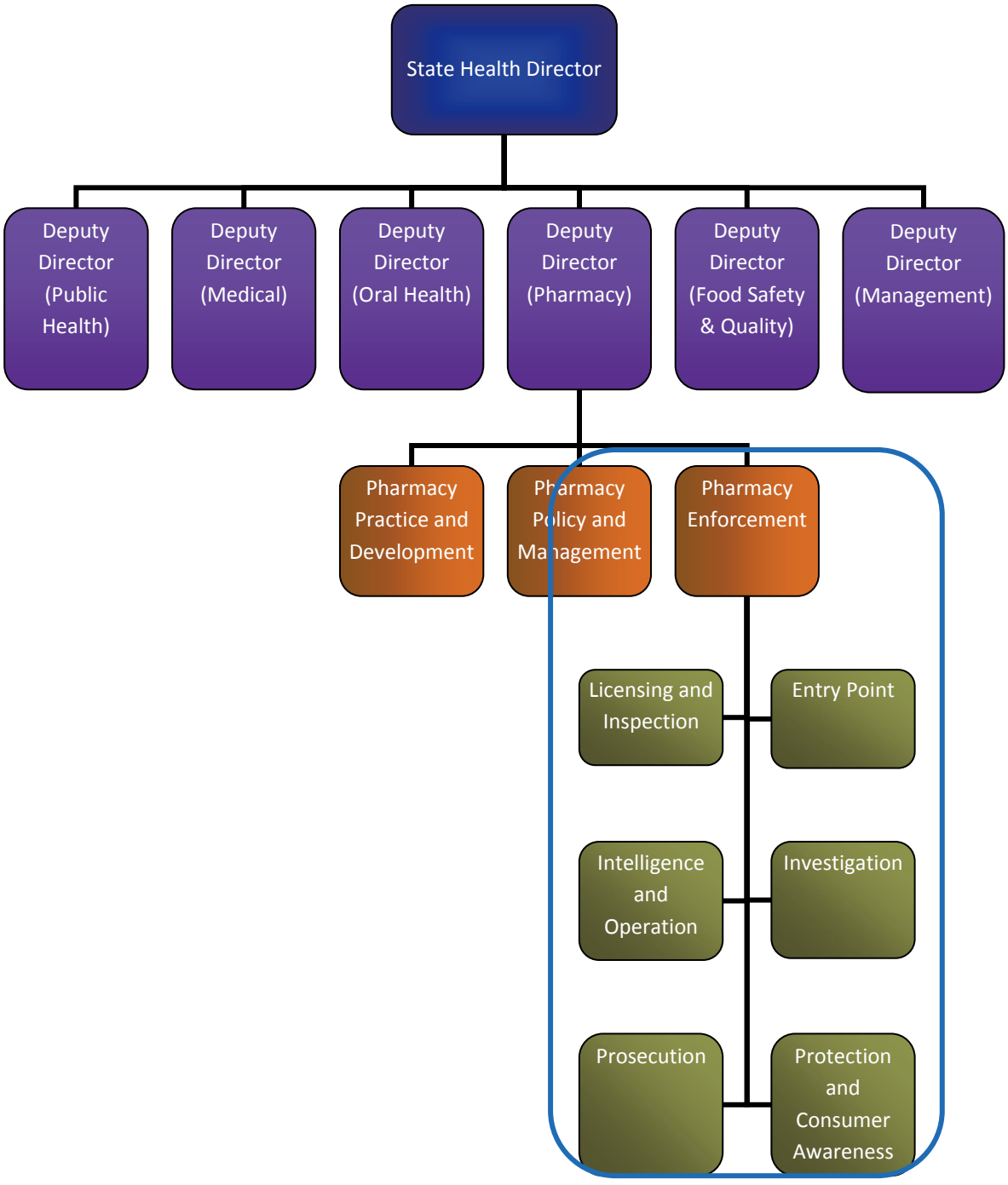


(b) Organization Chart of Pharmaceutical Services Division Appendix B

(i) **National Level**



(ii) **State Level** Appendix C



Role and responsibility on pharmaceutical administration:

The Pharmaceutical Services Division as one of the main divisions under the Pharmacy programme carries out its responsibility through three (3) main activities namely Pharmacy Policy & Management, Pharmacy Practice & Development, and Pharmacy Enforcement. **(Appendix A, B and C)**

(a) **Pharmacy Policy and Management** is responsible for ensuring that pharmacy services strategic plan and policies are implemented accordingly.

(b) **Pharmacy Practice and Development** is responsible for ensuring optimised drug therapies and provides comprehensive pharmaceutical care.

(c) **Pharmacy Enforcement** plays an important role to ensure that pharmaceutical, traditional, and cosmetic products that are available in the market are genuine in terms of registration and notification.

2) Legislation on pharmaceutical administration

There are five (5) Acts enforced by the Pharmacy Enforcement under the Pharmaceutical Services Division, Ministry of Health Malaysia namely:

(a) **Registration of Pharmacists Act 1951 (Act 371) and Regulations** - relating to the establishment of a Pharmacy Board and the registration of pharmacists.

(b) **Poisons Act 1952 (Act 366) and Regulations** - regulate the importation, possession, manufacture, compounding, storage, transport, sale and use of poisons.

(c) **Sale of Drugs Act 1952 (Act 368) and Regulations -** relating to the sale of drugs.

(d) **Medicines (Advertisement and Sale) Act 1956 (Act 290) and Regulations** - prohibiting certain advertisements relating to medical matters and to regulate the sale of substances recommended as a medicine.

(e) **Dangerous Drugs Act 1952 (Act 234) and Regulations** - regulating the import, export, manufacture, sale, and use of opium and of certain other dangerous drugs and substances.

❖ These acts are administered at both national and local level by the Pharmacy Enforcement Division.

- PIC/S – National Pharmaceutical Control Bureau is a member of PIC/S and had joined since 2002.

3) Regulatory Services

The National Pharmaceutical Control Bureau (NPCB) carries out the regulatory control of pharmaceutical. The function of NPCB is to ensure safety, efficacy and quality of drugs; safety and quality of traditional medicines and cosmetics marketed locally.

There are seven centers under NPCB:

No.	Center
1.	Centre For Administration
2.	Center For Product Registration
3.	Center For Post Registration
4.	Center For Compliance And Licensing
5.	Centre For Quality Control
6.	Centre For Organizational Development
7.	Centre Investigational New Product

- Drug Import/Export

  Drug import/export is mainly regulated under the Sale of Drugs Act 1952 (Act 368) and Regulations and the Poisons Act 1952 (Act 366) and Regulations. All importers need to obtain an import licence from the Director of Pharmaceutical Service in order to import the drugs.

  As a member of The Convention on Psychotropic Substances of 1971 and Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988, each exportation of narcotic drugs will be approved to a country who issued the import permit and importation of precursors will be notified to the country of importing via pre-export notification.

- Pharmaceutical Manufacturing –GMP

  A manufacturer's licence will be issue to a company to manufacture the registered products in the premises specified in the licence and to sell by

wholesale or supply the products. The manufacturer must comply with the Good Manufacturing practice as specified in the license conditions. According to the Control of Drugs and Cosmetics Regulations 1984, complaince to Good Manufacturing Practice is a pre-quisite for the application of a manufacturing license as well as product registration/ cosmetic notification . Good Manufacturing Practice (GMP) is a standard that should be followed by manufacturers to ensure that the product manufactured is safe, efficacious and of quality.

The inspection of Good Clinical Practice (GCP) maybe carried out through routine inspection or maybe triggered by issues arising during the assessment of the dossier or by other information such as previous inspection experience. The DCA has set up a guidelines for the inspection to be carried out.

The Control of Drugs and Cosmetics Regulations 1984 (CDCR) requires that the standard of manufacture and quality control of medicinal products manufactured outside Malaysia be taken into consideration before the products are registered with the authority namely Drug Control Authority (DCA). NPCB as the secretariat to the DCA is responsible to ensure all manufacturers of registered products in Malaysia are able to provide acceptable evidence that the manufacturing premises conform to current GMP requirements. Hence, foreign manufacturers are also subjected to GMP conformity assessments through acceptable GMP evidence or GMP inspection

The Principles of GLP should be applied to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetics products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some circumstances, may be living organisms. The purpose of testing these items is to obtain data on their properties and/or their safety with respect to human health and/or the environment. Non-clinical health and environmental safety studies covered by the Principles of GLP include work conducted in laboratory, greenhouses, and in the field.

- Marketing Authorization

A wholesale licence will be issue to a company to sell by wholesale or supply the registered products from the address of the business premises specified in the license. Meanwhile, a pharmacist will be issue a Type A Poison Licence under the Poisons Act in order for them to supply drugs from their premises.

The responsibilities of a Marketing Authorization Holder in terms of pharmacovigilance activities are:

i) Establishment of an ADR monitoring system

ii) Submission of spontaneous ADR reports to National Centre for Adverse Drug Reaction Monitoring

iii) Submission of reports from published scientific literature & post-registration studies

iv) Evaluation of benefit-risk profile of registered products

v) Compliance with circulars and directives issued by DCA Drug Distribution (including drug selection, procurement, sale)-GDP

Drugs distributor must comply with the Good Distribution Practice. GDP is defined as important steps that should be considered in the storage, transportation and distribution of registered products / notified cosmetics, including associated materials in order to preserve its characteristics and quality until it reaches the consumer .

- Medicine Safety (post-marketing)

Active product monitoring via the Post Market Surveillance (PMS) program is conducted by the authority to ensure that only safe products are being marketed. The activities consist the following:

i) Screening of product formulation and information

ii) Audit on the Product Information File (PIF) for compliance with the regulations

iii) Sample collection, testing and monitoring of label compliance

iv) Audit of premises to ensure compliance with Guidelines Investigation of complaints

v) Initiation of warning and information sharing system between ASEAN countries

vi) Monitoring of adverse reactions reported by Healthcare Professionals or consumers.

vii) Monitoring of product advertisement

- Relief System for Adverse Drug Reaction

Every Adverse Drug Reaction must be report to the NPCB. The manufacturer, importer and wholesaler are required to have a procedure for product recall to remove or withdraw a particular material and/or product and/or cosmetic from all links of distribution due to critical quality defects discovered or serious adverse drug reactions reported which might cause health risks to users. The degree of recall is classified according to the severity of quality defects and adverse reactions of the products and/or cosmetics.

Degree I Materials and/or products and/or cosmetics with major health risks that might caused serious injuries or death. Should be under an embargo within 24 hours

Degree II Materials and/or products and/or cosmetics with minor health risks or are substandard. Should be under an embargo within 72 hours.

Degree III Materials and/or products and/or cosmetics with other reasons for recall. Should be under an embargo within 30 days or as specified.

The level of recall depends on the nature of problem, extent of the material or product or cosmetic's distribution and degree of hazard involved.

Level A To all consumers (end users). When there is imminent danger, the public are warned by a media release which is meant to urgently alert the public by radio, television and the press.

Level B To all points of sales (e.g Hospitals, Pharmacies, Clinics, Specialist Centres). Recall notices will be sent to all points of sales. At the same time, representatives from the company will be sent to these points of sale to retrieve the stocks.

Level C To all sub-distributors (wholesaler and stockist). The wholesalers and stockists will be contacted by the company representatives so that arrangement can be made to retrieve all stocks concerned from the wholesalers and stockist.

4) Drug Pricing

Pharmaceutical Pricing Mechanism for Universal Health Coverage

As drugs price is a contentious issue the government is of the opinion that it should be handled very carefully. The Pharmaceutical Services Division (PSD) has set up a Price Monitoring Unit to conduct price monitoring for the country. Expert was brought to the country to train pharmacists on how to conduct price monitoring.

The price monitoring activities will ensure that as the price of drugs become transparent to prescribers and users, and this will encourage self-regulation by the distributors. At the same time, the authorities are also looking into other mechanisms of drug control.

The Medicine Price Database is being developed. Currently, the medicines price data, comprising of categories as below, are continuously compiled and updated.

i.	Fee Act (Full Paying Patient)	vi	National Essential Drug Price List (Public)
ii	Private Retail Price	vii	National Essential Drug Price List (Private)

iii	Public Wholesale Price	viii	Traditional Wholesale Price
iv	Private Wholesale Price (Controlled Medicines)	ix	Recommended Retail Price (RRP)
v	Private Wholesale Price (OTC)	x	Government Procurement (GP) Price

Newly listed medicines in the Ministry of Health (MOH) Drug Formulary are subjected to price monitoring. To further strengthen this monitoring procedure, firms requested for their medicines to be listed in the MOH Drug Formulary are required to submit their quotation of selling price to MOH facility if the aforementioned medicines have been successfully listed in the MOH Drug Formulary. The medicine price sold to MOH facilities should not exceed the said quotation for at least one a year. After that, any price increments will be monitored by the Medicines Price Determination Unit. The review is done once a year continuously by obtaining feedback from MOH hospitals. In the event where the medicines price is more than the predetermined price, the related firm is obliged to provide explanation regarding this issue and take corrective actions such as credit notes provision or reimbursement in the form of medicines

5) Statistic Data

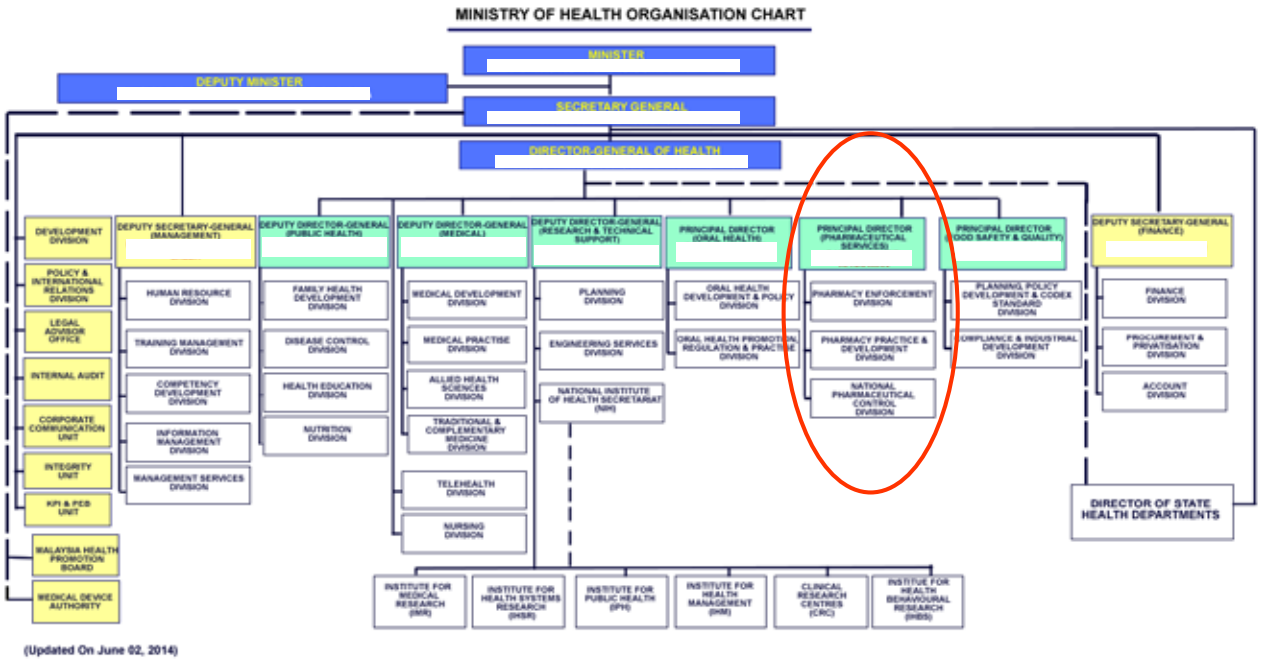
No.	Subject	Data	Year
(a)	Number of Pharmacists	11810	September 2014
(b)	Number of GMP Inspectors (National and Local)	21	September 2014
(c)	Number of Pharmaceutical Manufacturers/ Manufacturing Sites	84	September 2014
(d)	Number of Traditional Medicines Manufacturers/ Manufacturing Sites	161	September 2014
(e)	Number of Pharmaceutical Importers	231	September 2014
(f)	Number of Pharmaceutical Wholesalers	1001	September 2014

GOOD GOVERNANCE OF MEDICINES FOR PHARMACEUTICAL REGULATION AUTHORITIES (JFY2014)

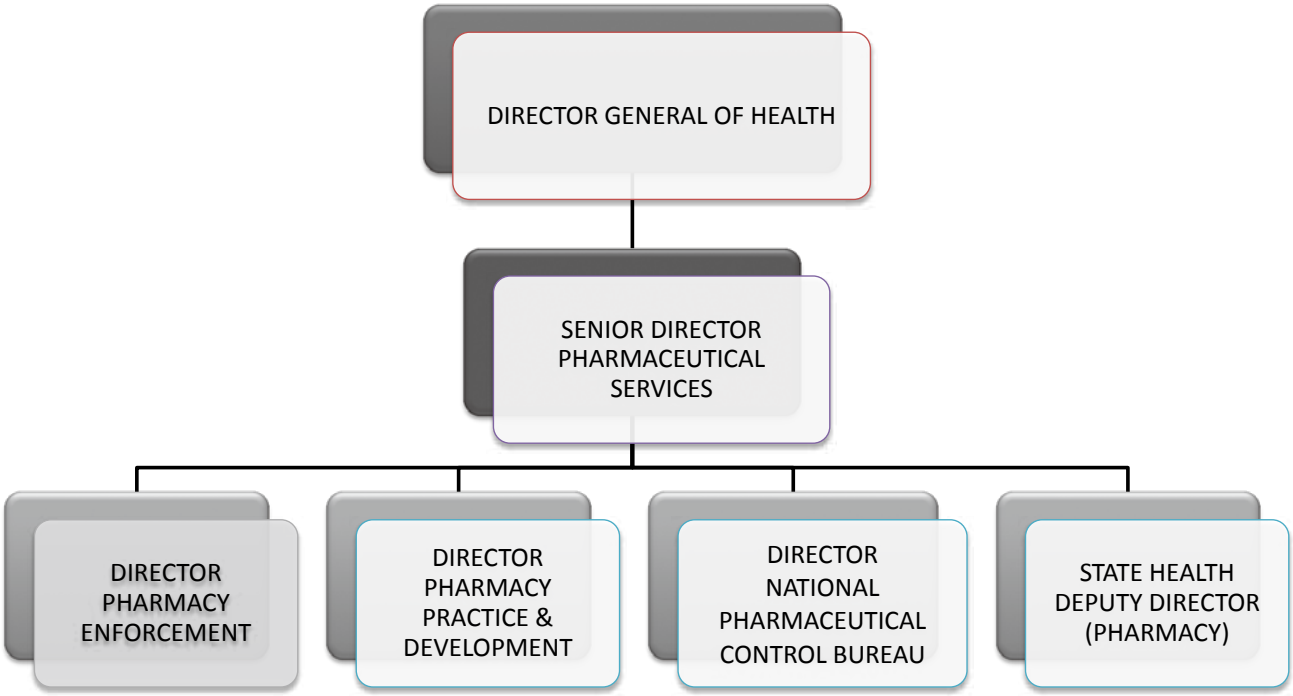
INCEPTION REPORT PRESENTATION

Pharmaceutical Services
Division Ministry of Health
MALAYSIA

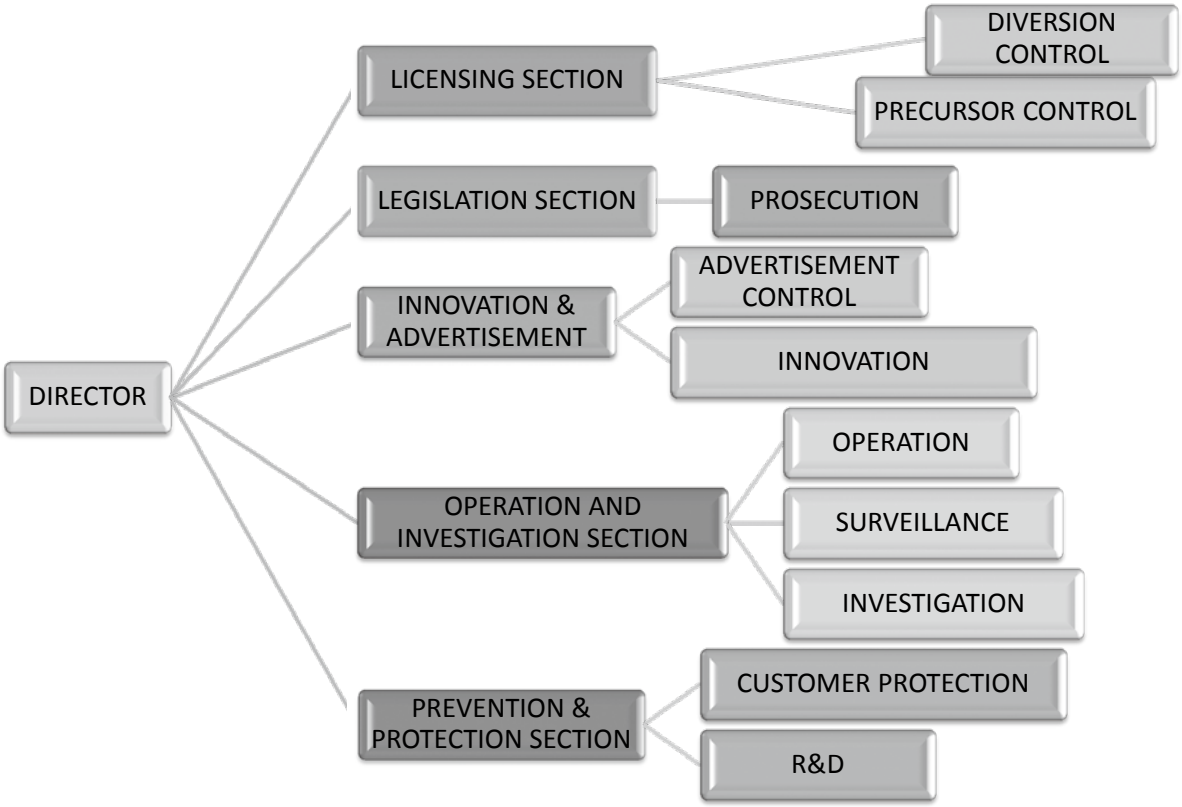
ORGANISATION CHART MINISTRY OF HEALTH MALAYSIA



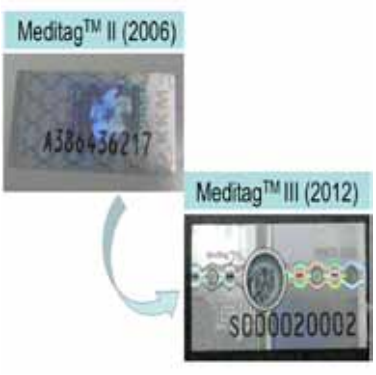
PHARMACEUTICAL ADMINISTRATION



ENFORCEMENT DIVISION



Recent achievement:



- New features of the Hologram Logo to indentified registered product
- Establishment of Enforcement Forensic Laboratory
- Establishment of Digital Forensic Pharmacy Unit to handle challenges in IT
- Shorten process period for advertisement approval (from 7 days to 5 days)

Recent achievement:

- Increase awareness of medicines advertising control
- Increase cooperation amongst enforcement agencies
- Establishment of Good Governance Of Medicines Training Module
- The New Pharmacy Bill to replace the current 5 Acts

Global Anti-counterfeiting Awards 2013, Paris, 28 May 2013

- The Ministry of Health Malaysia has taken several initiatives in protecting the public from dangerous and counterfeit medicines. These exceptional efforts have been accorded international recognition with the presentation of the "Global Anti-Counterfeiting Award 2013" in the public sector category by the Global Anti-Counterfeiting Group Network (GACG), an international anti-counterfeit organization based in London, UK. The award was presented in conjunction with the World Anti-Counterfeiting Day organized by Union des Fabricans in Paris, France on the 28th of May 2013. The award was received by Dato' Eisah bt. A. Rahman, Senior Director of Pharmaceutical Services Division on behalf of the Ministry of Health Malaysia.
- This 15th annual GACG award ceremony has positioned the Pharmacy Enforcement Division, MOH Malaysia at par with world renowned law enforcement agency like the INTERPOL, which also received the similar award in the international public body category. The Ministry of Health Malaysia will continue our commitment in protecting the public by combating counterfeit medicines in the marketplace.

PROBLEMS AND CHALLENGES

- Diversion of pharmaceuticals in the production of narcotic drugs
- Unregistered and counterfeit drugs are still rampant in the market
- Food adulterated with poison
- Interphase products- FDI, MDD
- Unethical medicine advertising
- Uncontrolled internet advertising and sales

Topics of interest

- ✓ Approach on public education to increase consumer awareness about the risk of using unregistered and adulterated products in the market.
- ✓ Implementation of Self-regulatory Guideline to Regulate Sale of Pharmaceutical Products via Internet
- ✓ Measures to Address Adulteration in Pharmaceutical Products and Food Supplements

MYANMAR

DEPARTMENT OF FOOD AND DRUG ADMINISTRATION , MYANMAR

GOOD GOVERNANCE OF MEDICINES FOR NATIONAL PHARMACEUTICAL REGULATORY AUTHORITIES (JFY 2014)

INCEPTION REPORT

Country's Profile

Location

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

Geography

The country is divided administratively into

- Naypyidaw Union Territory,
- 7 Regions
  (Yangon, Mandalay, Sagaing, Magway, Bago,Ayeyawaddy &Tahnintharyee) and
- 7 States
  (Kachin, Kayar, Kayin, Chin, Mon, Rakhaing & Shan)

It consists of (70) Districts, (330) Townships, (84) Sub-townships, (398) Towns, (3063) Wards, (13,618) Village tracts and (64,134) Villages.

Demography

The population of Myanmar in 2014 is about 51 .42 millions. About 70.4% of the population resides in the rural areas whereas the remaining are urban dwellers.

Religion

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

Inception Report

1.Organization

1.1. Ministry of Health

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

The Ministry of Health is headed by the Union Minister who is assisted by two Union Deputy Ministers. The Ministry has seven functioning departments, each under a Director General. They are

- Department of Health Planning
- Department of Health
- Department of Medical Sciences
- Department of Medical Research (Lower Myanmar)
- Department of Medical Research (Upper Myanmar)
- Department of Traditional Medicine
- Department of Food and Drug Administration

The Ministry of Health laid down the following objectives

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

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

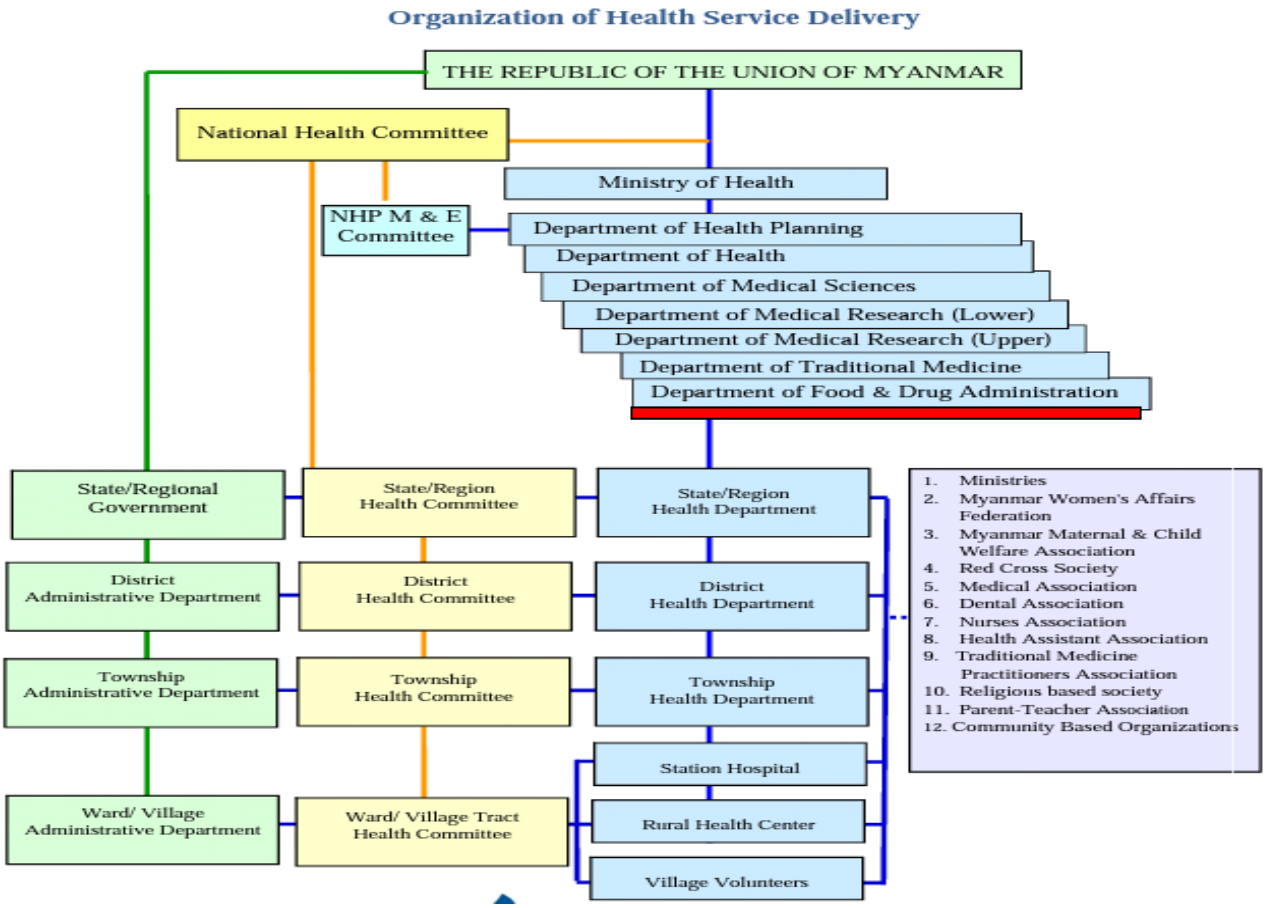
1. Widespread disseminations of health information and education to reach the rural areas.
2. Enhancing disease prevention activities
3. Providing effective treatment of prevailing diseases.

1.2. Department of Food and Drug Administration

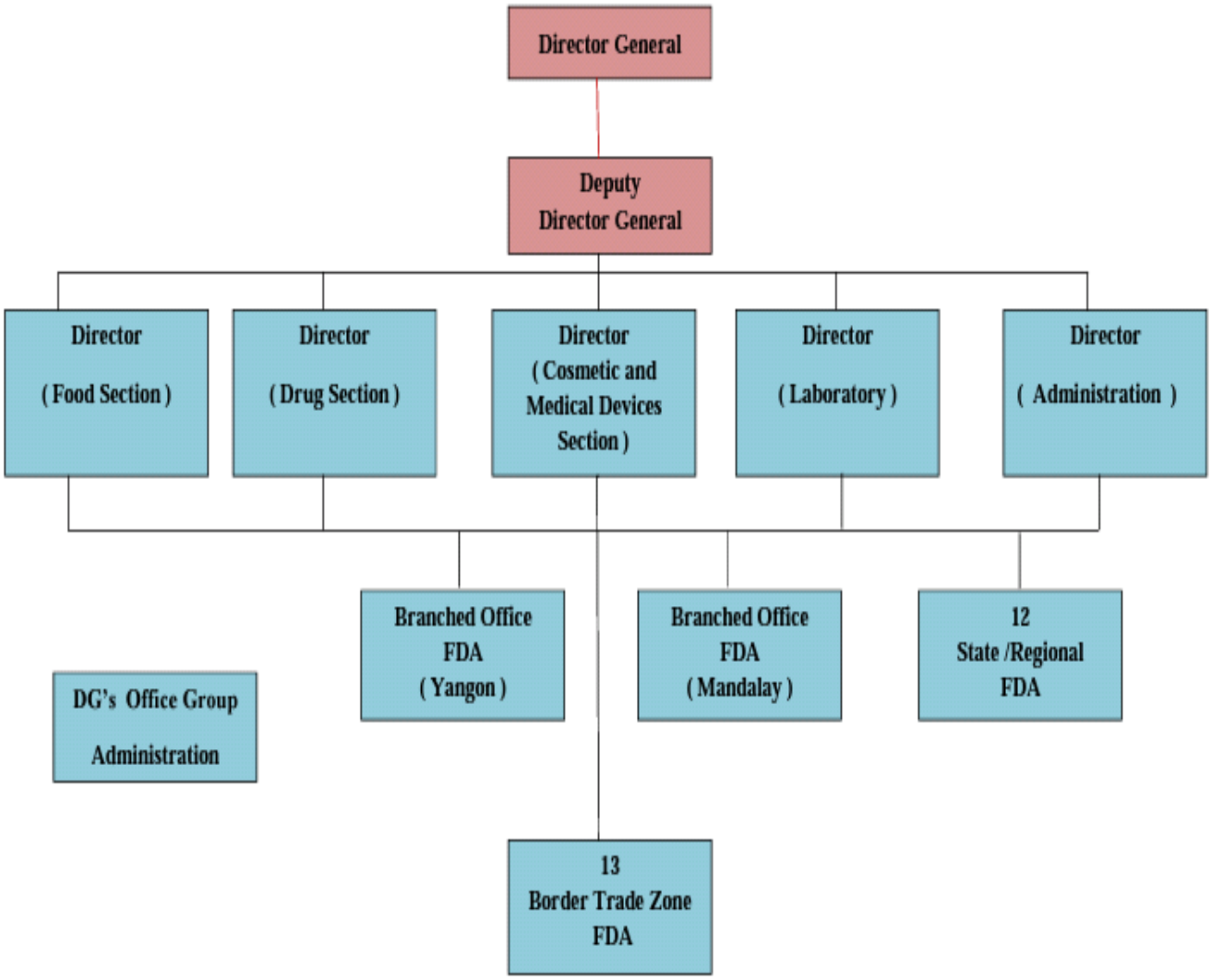
The Food and Administration (FDA) established since 1995, takes care of the safety and quality of Food, Drug, Medical Devices and Cosmetics. Food and drug control activities expanded with establishment of branches in Nay Pyi Taw, Yangon and Mandalay. The FDA division has been upgraded to a separate Department in April 2013.

FDA is responsible for issuing Health Recommendation for local food manufacturing businesses, import and export recommendation, import and export health certification.

Drug Control activities have been conducting for marketing authorization for new products, variations of existing authorization, quality control laboratory testing, adverse effect reaction monitoring, Good Manufacturing Practice inspection and Licensing of manufacturers, wholesalers and enforcement activities, drug promotion and advertisement. FDA issues notification and import recommendation of medical devices and notification of cosmetics.



Department of Food and Drug Administration – Organization chart



2.Legislation of Pharmaceutical Administration

2.1. National level

(a)	Public health law (1972)	It is concerned with protection of people's health by controlling the quality and cleanliness of food , drugs , environmental sanitation, epidemic diseases and regulation of private clinics.
(b)	National Drug Law (1992) (April, 2014 Amendment)	Enacted to ensure access by the people safe and efficacious drugs. Describe requirement for licensing in relation to manufacturing, storage, distribution and sale of drugs. It also includes provisions on formation and authorization of Myanmar Food and Drug Board of Authority.
(c)	Narcotic Drugs and Psychotropic Substances Law (1993)	Related to control of drug abuse and describe measures to be taken against those breaking the law. Enacted to prevent danger of narcotic and psychotropic substances and to implement the provisions of United Nations Convection Against Illicit Traffic in Narcotic Drug and Psychotropic Substances.
(d)	Traditional Drug Law (1996)	Concerned with labeling, licensing and advertisement of traditional drugs to promote traditional medicine and drugs. It also aims to enable public to concern genuine quality, safe and efficacious drugs. The law also deals with registration and control of traditional drugs and formation of Board of Authority and its functions.
(e)	National Food Law (1997,2014)	Enacted to enable the public to consume food of genuine quality, free from danger, to prevent public from consuming food that may causes danger or are injurious to health, to supervise production of controlled food systematically and to control and regulate the production, import, export, storage, distribution and sale of food systematically. The law also describes formation of Board of Authority and its functions and duties.

2.2 PIC/S

NO

3.Regulatory Services

FDA is responsible for issuing Heath Recommendation for local food manufacturing, businesses, import and export recommendation, import and export health certification. FDA has issued Health Recommendation for drinking water factories (621) and food production establishments (342) which comply with Good Manufacturing Practice (GMP) and small traditional food production facilities (65) which comply with Good Hygienic Practice (GHP) so far.

In 2012, post market survey was done for non permitted coloring in chili powder, lentil, colored drinks, fish paste, chili sauce and meat sausage etc. (1806) samples were tested and (195) samples were found to be dyed with non permitted color and destroyed accordingly.

Drug Control Activities have been conducting for marketing authorization for new products, variation of existing authorization, quality control laboratory testing, adverse drug reaction monitoring, Good Manufacturing Practice inspection and licensing of manufacturers, wholesalers, enforcement activities, drug promotion and advertisements. Sustainable financing is essential to promote effective drug regulation. FDA issues notification and import recommendation of medical devices and notification of cosmetics. During 2013, under the guidance of Drug Advisory Committee and Central Food & Drug Supervisory Committee, Food & Drug Administration issued 2506 Drug Registration Certificates (DRC), 77 Drug Importation Approval Certificates (DIAC) and also rejected 167 drugs for registration from the aspect of quality, safety and efficacy. The number of Pre/ Post Market Drug Samples was 2240 and these samples had been tested in Drug Quality Control Laboratory in 2013. FDA also issued 711 cosmetic notification certificates. Under guidance of Ministry of Health, FDA regularly notifies the public as well as State/ Regional Food and Drug Supervisory Committees about alert news of counterfeit and illegal medicines.

Food and Drug Administration takes necessary measures to ensure that only drugs that are registered are imported. Food and Drug Administration is closely cooperated with Custom Department, Directorate of Trade and Myanmar Police Force.

4.Statistic Data

1.	No: of Pharmacists	>2000 pharmacists (2014)
2.	No: of GMP Inspectors	10-20
3.	No: of Pharmaceutical Manufactures	7
	Manufacturing sites	Yangon, Pyin Oo Lwin, Kyaut Sae, Sagaing
4.	No: of Traditional Medicine Manufactures	About 100
	Manufacturing sites	Capital cities
5.	No: of Pharmaceutical Importer	186
6.	No: of Pharmaceutical Wholesalers	700

INCEPTION REPORT
(MYANMAR)

Department of Food & Drug Administration

1

Country Profile

Location

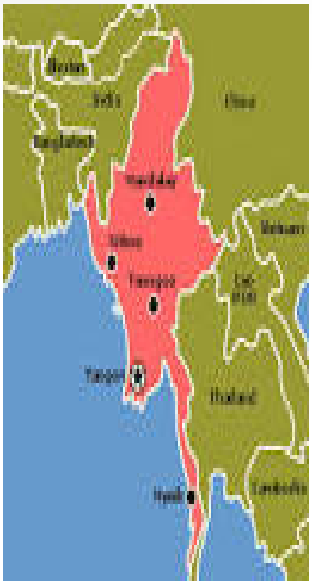
- The Republic of Union of Myanmar is the westernmost country in South East Asia,
- located on the Bay of Bengal and Andaman Sea.

Country Profile

Location

It is bordered by

- the Lao
- Thailand,
- Republic of China
- Republic of India and
- Republic of Bangladesh.



Country Profile

- **Geography**

The country is divided administratively into

- **Naypyidaw Union Territory,**
- **7 Regions**

  (Yangon, Mandalay, Sagaing, Magway, Pago,Ayeyawaddy &Tahnintharyee)
- **7 States**

  (Kachin, Kayar, Kayin, Chin, Mon, Rakhaning & Shan)

Country Profile

- **Demography**

The population of Myanmar in 2014 is about 51 .42 millions. About 70.4% of the population resides in the rural areas whereas the remaining are urban dwellers.

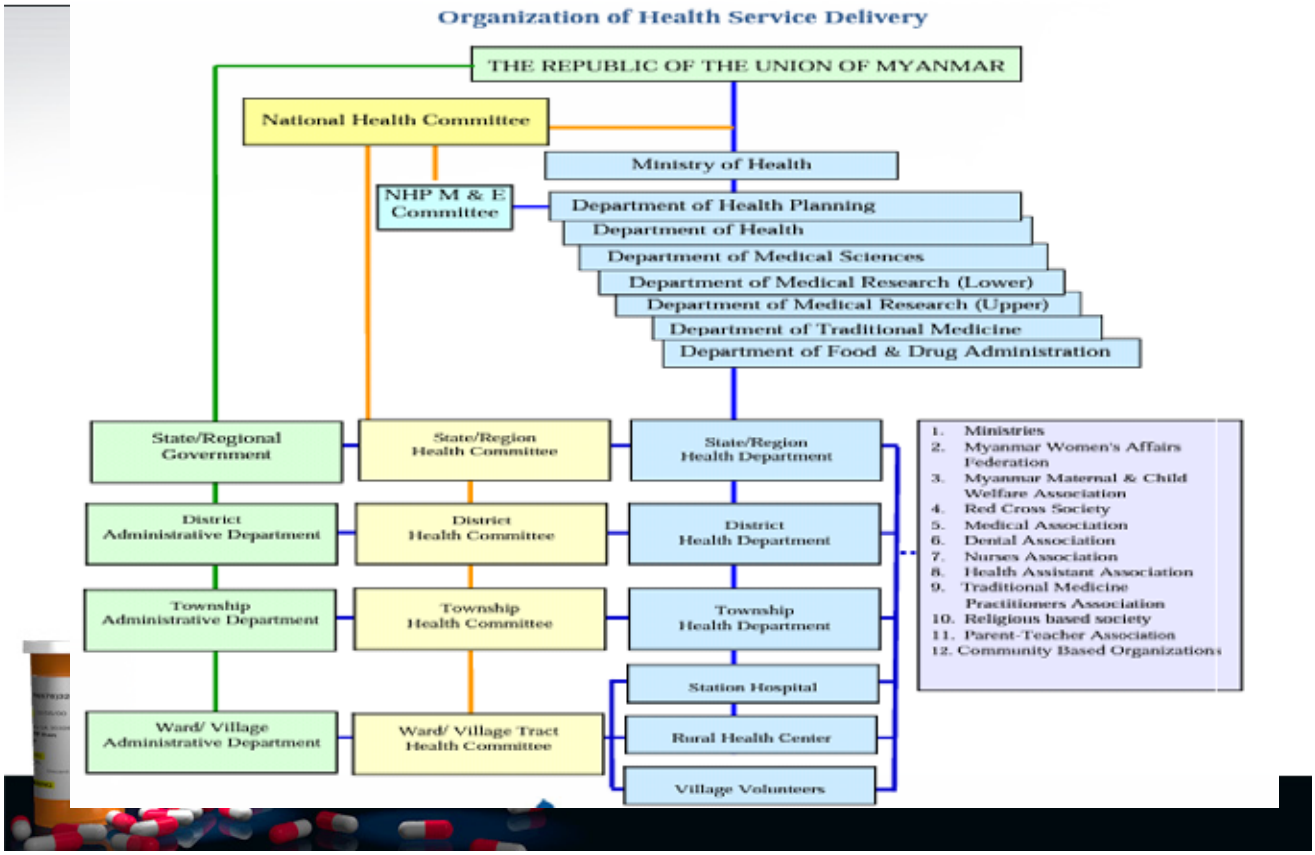
- **Religion**

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

Inception Report

- **Ministry of Health**
  - Department of Health Planning
  - Department of Health
  - Department of Medical Sciences
  - Department of Medical Research (Lower Myanmar)
  - Department of Medical Research (Upper Myanmar)
  - Department of Traditional Medicine
  - **Department of Food and Drug Administration**

Ministry of Health – Organization Chart



Legislation of Pharmaceutical Administration

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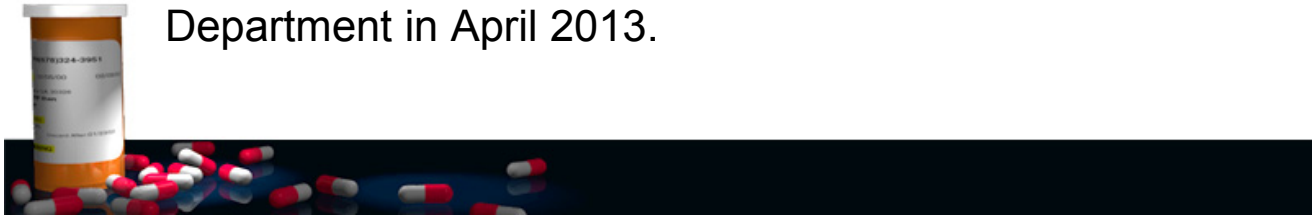
No.	Law	Year
1.	Public Health Law	1972
2.	National Drug Law Amendment	1992 (April 2014)
3.	Narcotic Drugs and Psychotropic Substances Law	1993
4.	Traditional Drug Law	1996
5.	National Food Law	1997

Statistic Data

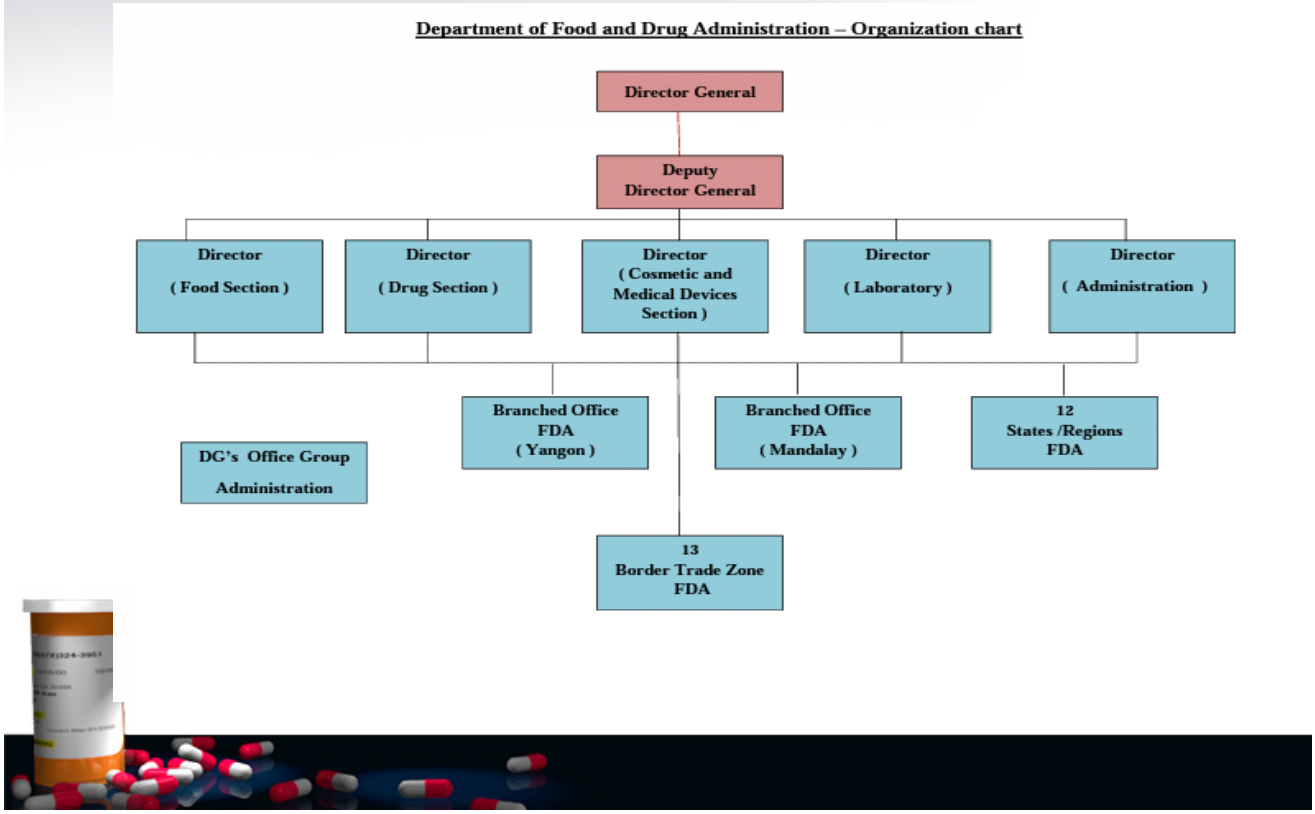
1.	**No: of Pharmacists**	**M.Pharm 76** **B.Pharm 2908**
2.	No: of GMP Inspectors	10-20
3.	No: of Pharmaceutical Manufactures Manufacturing sites	7 Yangon, Pyin Oo Lwin, Kyaut Sae, Sagaing
4.	No: of Traditional Medicine Manufactures Manufacturing sites	About 100 Capital cities
5.	No: of Pharmaceutical Importer	186
6.	No: of Pharmaceutical Wholesalers	700

Department of Food and Drug Administation

- established since 1995, takes care of the safety and quality of Food, Drug, Medical Devices and Cosmetics.
- Food and drug control activities expanded with establishment of branches in Nay Pyi Taw, Yangon and Mandalay.
- The FDA division has been upgraded to a separate Department in April 2013.



Department of Food and Drug Administation Organization Chart



Bad Experiences

- Developing country

- Inadequate man power
- High demand for a lot of training
- Lack of knowledge in public – difficult in educating the public
- Accusations on our department

Good Experience

- Market Survey and Notify the public

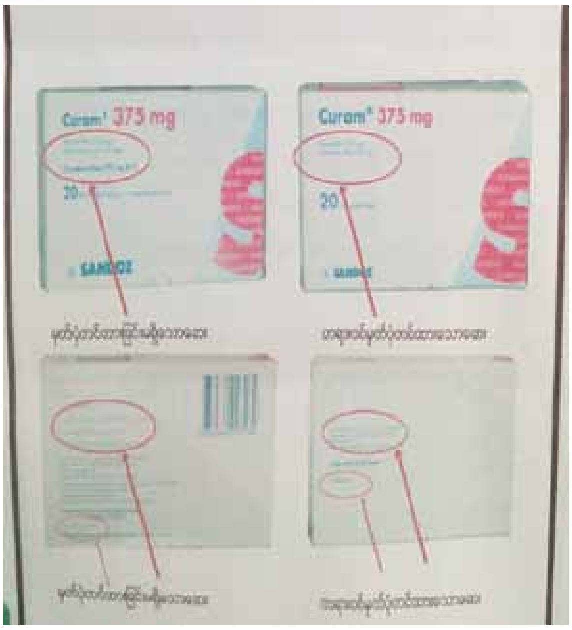
အလှကုန်ပစ္စည်းနှင့်ပတ်သက်သည့် သတိပေးချက်

စဉ်	အလှကုန်ပစ္စည်းအမည်	ထုတ်လုပ်သည့် ကုမ္ပဏီ/နိုင်ငံ	တားမြစ်ဆေးဝါးပစ္စည်းပါဝင်မှု
၁။	Mellano-Cream No.1	Ornets(Thailand) Co.,Ltd. Thailand	Mercury
၂။	Mellano-Night Cream No.2	Ornets (Thailand) Co., Ltd. Thailand	Hydroquinone
၃။	Mellano-Facial Nourishing Cream No.3	Ornets (Thailand) Co., Ltd. Thailand	Betamethasone 17-Valerate
၄။	Polla Platinum-Crystal White Nourishing Face Cream	Made in Thailand	Mercury
၅။	Polla Gold - Super White Perfects Cream	Made in Thailand	Betamethasone 17-Valerate
၆။	Polla - Anti-Melasma Cream (New Night Cream)	Made in Thailand	Hydroquinone
၇။	Nineteen Nano 19-Whitening Nano Night Repair Cream	Made in Thailand	Hydroquinone
၈။	Baschi-Day Cream (Whitening Cream)	Jiao Nuo Cosmetics Co.,Ltd. Thailand	Mercury
၉။	Baschi - Night Cream (Whitening Cream)	Jiao Nuo Cosmetics Co.,Ltd. Thailand	Retinoic Acid

ကျန်းမာရေးဝန်ကြီးဌာန

Good Experience

- Countermeasure against Fake Drugs



Good Experience

- Control of Quality ,Safety and Efficacy of Drugs, Cosmetic and Food

Good Experience

- Management of Expired Products

Good Experience

- Training (Drug inspector, Drug retailer-selling rule and regulation)

Our Interest

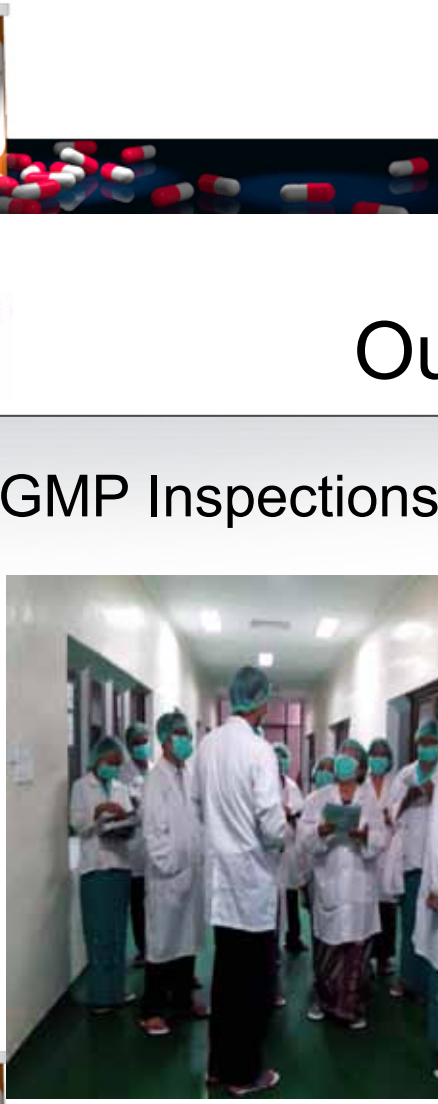
- Pharmaceutical Analysis

Our Interest

GMP Inspections

Our Interest

GMP Inspections



SRI LANKA
(1)

Good Governance of Medicines for National Pharmaceutical Regulatory Authorities (JFY 2014)

Job Report as a part of Requirements of the Programme

Of

State Pharmaceutical Manufacturing Corporation of Sri Lanka

Part 01

Over view of country and organization

Sri Lanka is an Island in South Asia surrounded by the Indian Ocean with a Population of 21 675 648 and 65610 sq Km land. Politically it is country govern 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. Organizational chart at National/State and Local level on pharmaceutical administration

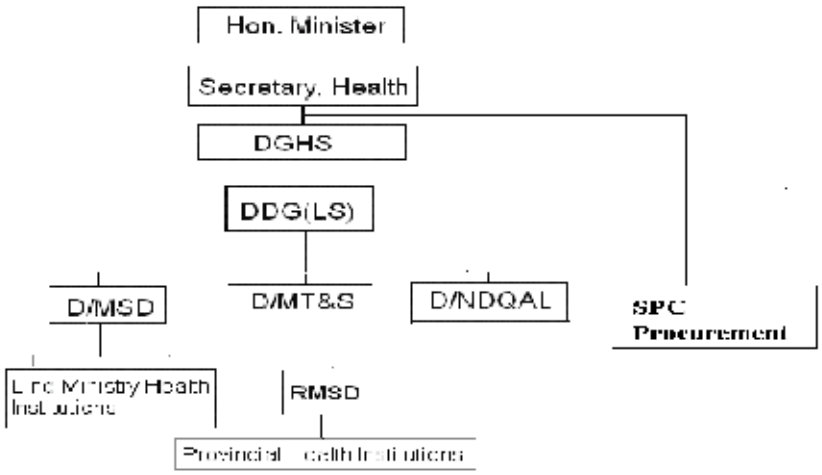


Figure 1 Organization Chart of drug management

- **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 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 Drug Quality Assurance Laboratory (D/NDQAL)-**The primary function of the NDQAL 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 health 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.

Manufacturing, Importing, Selling and Distributing of Pharmaceuticals in Sri Lanka is govern by the Cosmetic Devices and Drugs Act No. 27 of 1980 (CDDA Act) (with subsequent amendments) and regulations made under provisions of this Act.

Cosmetic Devices and Drugs Authority Act has provisions on regulating

1. Registration of Pharmaceuticals
2. Monitoring and approving changes to those products already approved.
3. Monitoring and Implementing good Manufacturing practices.
4. Licensing and monitoring of importation, manufacturing, sales advertisements and distribution surveillance of quality of drugs available in the market.
5. Reviewing and approving of advertisements.
6. Approving and Monitoring of clinical trials.
7. Recalling Pharmaceuticals from the market on safety grounds and all other relevant areas.
8. Approving, registering. Monitoring and regulating Pharmacists, wholesale and retail outlets, distributors and stockiest.

Cosmetics Devises and Drugs Authority (CDDA) established under provisions of the Act mentioned above is the implementing authority of provisions of the Act.

3. Regulatory Service

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

(i) Inflow of substandard pharmaceuticals to the country has an impact on national health care system, proper therapeutic administration and fair play in the market

(ii) 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.

(iii) 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.

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 Drug Regulatory Authority. The items to be manufactured should obtain separate license for such manufacturing from the Drug Regulatory Authority. 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 Drug Regulatory Authority.

III. Marketing Authorization

Marketing authorization is either taken by the manufacturer to market the products manufactured or by importers from Drug Regulatory Authorities. All these functions are monitored and authorized by the Drug Regulatory Authority under the Cosmetic Devices and Drugs Act.

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 own 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 Drug Quality Assurance Laboratory (NDQUAL). 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

Public sector in Sri Lanka is 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 governmental 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

PART 11

SPMC

SPMC-State Pharmaceuticals Manufacturing Corporation is the sole state sector manufacturer of pharmaceuticals to the Sri Lankan nation.

- Donation from Japanese government and JICA
- We have a product list about 66 drugs and annually about 48 products are manufactured.
- Out capacity now exceeds 2000 million tablets and capsules annually.

INTRODUCTION OF WORK

Manufacturing and quality control of products

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

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.

MAINTAINING STABILITY DATA FOR REGULATORY PURPOSES

- Store samples from each product as well as stability records to produce data to the Drug Regulation Authority .
- Testing of stability samples are carried out within the time frame given by the Drug Regulation Authority.

GOOD PRACTICES

- **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

GOOD PRACTICES

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

BAD PRACTICES

- Procuring of raw materials by not selecting suppliers but through Government Tender Procedures.
  - Process validation is not convenient.
- Selecting suppliers through questionnaires without visiting the suppliers.
  - Supplier reliability is questionable
- No post marketing –surveillance
  - lack of data after marketing the product

INTEREST TOPICS

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 in 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.

Health insurance system proceed in japan-

- How the health insurance system proceed in Japan according to the government regulations.
- Carry out of clinical trials of the drugs and bio equivalence testing

Product recall procedures-

as manufacturers sometimes we have to recall our products. It is mandatory to establish a correct recall procedure. Therefore, I would like to know the correct procedures of recalls and how we should handle a quality failure of a product.

Regulations in Herbal medicine in Japan-

- How the herbal drugs are manufacture and how to control the storing conditions for herbal products.
- Clinical trials of herbal products.

SRI LANKA (2)

GOOD GOVERNANCE OF MEDICINES FOR NATIONAL PHARMACEUTICAL REGULATORY AUTHORITIES(JFY 2014)

COURSE NO: J 1404123

INCEPTION REPORT -PART 1

by

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

1. AN OVERVIEW OF PHARMACEUTICAL LAWS ,REGULATIONS IN SRI LANKA

1.1 INTRODUCTION

The Government of the Democratic Socialist republic of Sri Lanka, with a population of 21,675,648, provides free healthcare services to the nation and a fair portion of the budgetary allocation for the health sector is invested in procurement of medicines.
Medicines are a vital and expensive component in the provision of health services hence ensuring an adequate supply of safe and effective drugs of acceptable quality is an integral part of the health policy in Sri Lanka.
Appropriate legislation and regulations are provided to implement such a policy.

Provision of Essential Medicines is one of the elements in the primary Healthcare Package.

Even though the Government is committed to the provision of drugs free to the nation all officials in the health system who engage in procuring, distributing, storing , prescribing and dispensing whether at national, provincial, regional or institutional level are responsible for the supply of medicines that meet the required parameters with regards to the quality of medicines.

1.2 Organizational Chart of State Drug Management

Figure 1 depicts the Organizational Chart for State Drug Management

Roles and Responsibilities

a) **Hon. Minister of Health**
Policy making such as introducing necessary amendments to the Cosmetics Devices & Drugs Act No. 27 of 1980 which govern the regulation and administration of medicines in Sri Lanka.

b) **Secretary, Ministry of Health**
Implementing the Regulations and Policies

Chief Accounting officer of the Ministry of Health

c) **Director General of Health Services – DGHS**

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.

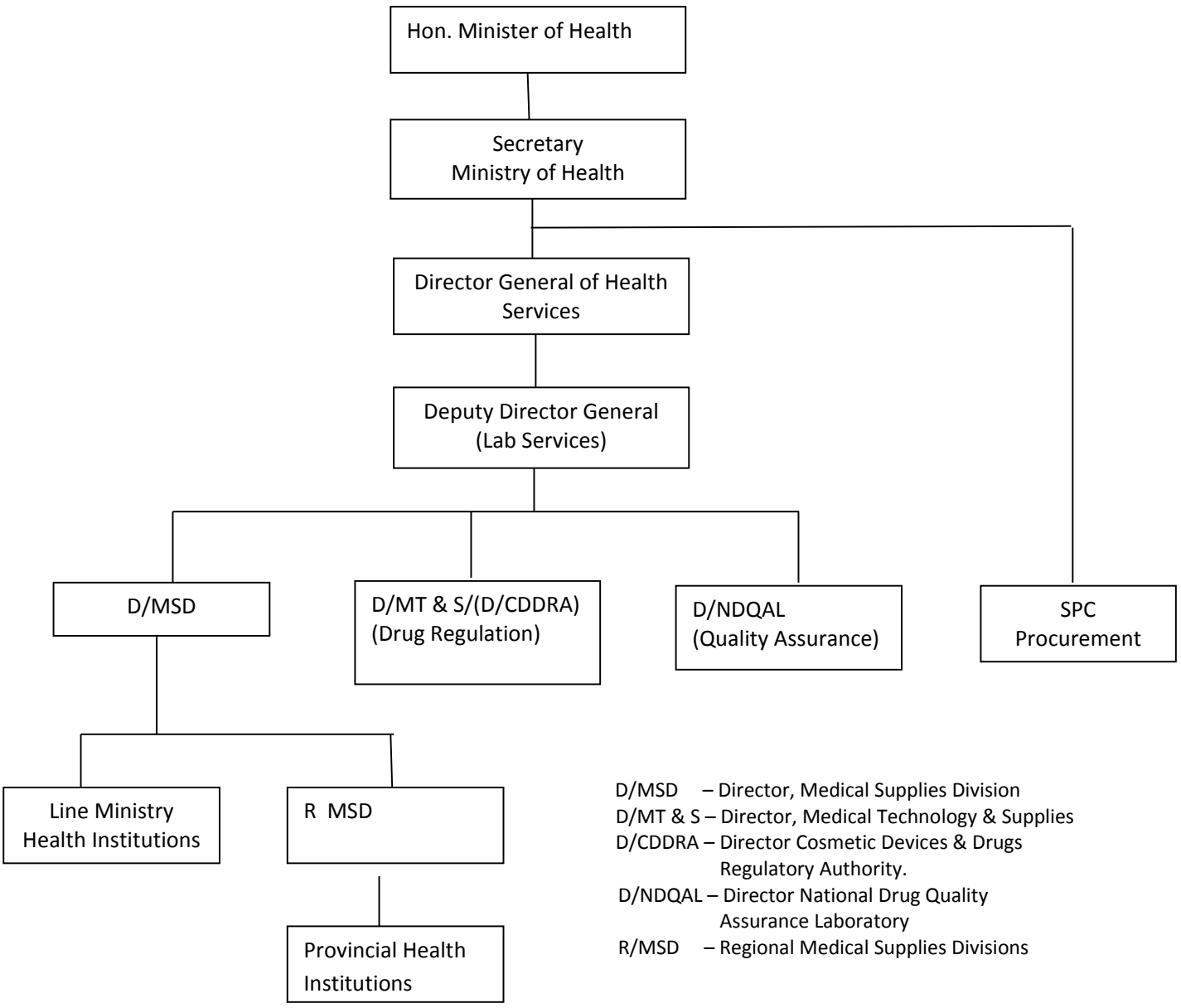


Fig. 1 **Organization Chart of State Drug Management**

d) **Medical Supplies Division - MSD**

The MSD of the Ministry of Health 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.

e) **Director Medical Technology & Supplies -D/MT & S**

Head of the Drug Regulatory Authority, 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 and S.

f) **Director National Drug Quality Assurance Laboratory – D/NDQAL**

The primary function of the NDQAL 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.

g) **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 purchase and supplied to the MSD of the Department of Health Services from where they are distributed to government health institutions.

h) **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

2.1 Cosmetics Devices & Drugs Act (CDDA Act)

Cosmetics Devices & Drugs Act No. 27 of 1980 (as amended by Act No. 38 of 1984, No. 25 of 1987 & No. 12 of 1993) provides the Legislative framework to control the use of cosmetics, medical devices & medicinal drugs in the country.

The regulations under the CDDA Act were published in Gazette Extraordinary No. 378/3 of 02.12.1985 and further amendments had been made from time to time.

This Act controls

a. Registration
b. Manufacture
c. Importation
d. Transportation
e. Sale (Retail & Wholesale)
f. Labelling
g. Advertising
h. Distribution of Drug Samples
i. Testing
j. Disposal of out dated or spoilt drugs

The main provisions of the CDDA Act with regard to Drugs

i. Only drugs which are registered with Cosmetic Devices & Drugs Regulatory Authority (CDDRA) can be manufactured, imported, offered for sale or used in the country.
ii. Licences are required for importation, manufacture, wholesale trade/retail trade and transportation of drugs
iii. All drugs registered with the CDDRA should confirm to specified standards.
iv. Labelling on the packs and advertisements regarding drugs should conform to the relevant regulations

The Cosmetics, Devices & Drugs Regulatory Authority (CDDRA) is the institution in which the Ministry of Health has vested the authority to ensure that the Pharmaceuticals and Medical Devices and Cosmetics available to the public meet the required standard / quality and are within the existing legislative framework with respect to the Production, Marketing and Dispensing of these items.

2.2 **Poisons, Opium & Dangerous Drugs**

Poisons, Opium and dangerous drugs ordinance (Chapter 218) as amended by Act No. 13 of 1984 regulation

a) Importation
b) Storage
c) Distribution
d) Use of poisons, opium and dangerous drugs.

3. REGULATORY SERVICES

3.1 Drug Import/Export

Drug import to Sri Lanka can be divided in to two categories such as imports to public sector and private sector. For the public sector drugs are imported mainly through State Pharmaceuticals Corporation by adhering to International Competitive Bidding procedure. They procure all Pharmaceuticals Surgical Devices for the Medical Supplies Divisions, which is the main unit responsible in distributing drugs and related items to the State sector hospitals.

The following conditions are laid down in the Bidding Document /Procurement Guidelines for the purchase/Importation of Pharmaceuticals by SPC.

- CDDA Registration
- Pre Qualification
- Technical Evaluation
- Inspections/Testing of samples

International Competitive Bids are called from Pre-qualified sources.

A) Registration with CDDA

I. All pharmaceuticals imported to Sri Lanka should be registered with the Cosmetics Devices & Drugs Authority of Sri Lanka.

ii. SPC shall request the prospective bidders to attach a notarially certified copy of the original registration certificate and any registration certificate where applicable to the bidding document which should be valid until at least six months after the last consignment of the pharmaceutical to be procured are due to be received in Sri Lanka.

iii. The requirement may be waived off in exceptional circumstances which is referred to as Emergency & Urgent procurement upon the issue of a 'No Objection Letter" (NOL) by CDDA.

Documents to be submitted to issue a No Objection Letter

1. Generic name and Trade name
2. Information on the dosage form
3. Product information leaflet
4. Storage and stability information
5. Certificate of Analysis

6. Information on the manufacturer such as

   I. Address, contact details, etc.
   II. GMP certification
   III. COPP
   IV. List of countries where the drug is registered
   V. Sample of the drug

B) **Pre Qualification of Suppliers for Multi-Source Products**

i. Pre-qualification is carried out for Multi-Source products only for the purposes of evaluating supplier/manufacturer capacity and reputation before bids are solicited for specific products, and is product specific and linked to specific manufacturing units.

ii. Pre-qualified Suppliers/Manufacturers

The list of pre-qualified suppliers/manufacturers for each product is revised at least once in every three years.

Continuous efforts are made by SPC to seek out potential suppliers/manufacturers in order to maintain competitive pressure on established suppliers/manufacturers that had been pre-qualified previously.

The pre-qualification process is based on documentation only.

C) Technical Evaluation

Technical Evaluation is carried out by an expert committee appointed for each and every procurement.

D) Inspection/Testing of Samples

i**. Tender/Bid Samples**

Tender Samples are tested of new suppliers to SPC.

ii. **Pre-shipment Samples**

Pre-shipment samples are tested depending on the nature of the product and the reliability of the supplier reliable of new supplier to SPC.

iii. P**ost Delivery Samples**

In instances where pre shipment samples testing could not be permitted due to urgency of the requirement posted delivery samples are tested of new suppliers to SPC.

3.2 Pharmaceutical Manufacturing

Both public and private sectors are involved in pharmaceutical manufacturing in Sri Lanka. A manufacturer must obtain a license for manufacturing from the Drug Regulatory Authority. A separate license for manufacturing each item should be obtained from the Drug Regulatory Authority. This license can be provisional which is valid for one year, and can be a full registration (5 years). Good Manufacturing Practices for manufacturing processes are monitored and given by DRUG Regulatory Authority.

3.3 Marketing Authorization

Marketing authorization is either taken by the manufacturer to market the products manufactured or by importers from Drug Regulatory Authorities. All these functions are monitored and authorized by the Drug Regulatory Authority under Cosmetic Devices and Drugs Act.

3.4 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 (RMSD). SPC is responsible for procuring medicines, surgical items and devices for government sector hospitals. Private hospitals procure their requirements directly from available drug manufacturers or suppliers. Apart from this there is government own pharmacies known as “Osu Sala out lets” managed by State Pharmaceuticals Corporation (SPC). SPC is responsible in supplying medicines and other additional pharmaceutical products for all the pharmacies (Osu Sala out lets) located island wide and to its distributors and Franchise Osu Sala out lets.

3.5 Medicine Safety/Post Marketing Surveillance

In Sri Lanka there is no such organized system for post marketing surveillance. But the National Drug Quality Assurance Laboratory (NDQAL) check the quality of Drugs Manufacture in Sir Lanka and Imported to Sir Lanka randomly or on a complain . NDQAL monitor the safety and efficacy of drugs in circulation within the island.

3.6 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.

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

(i) Inflow of substandard pharmaceuticals to the country has an impact on national healthcare system, proper therapeutic administration and fair play in the market.

(ii) 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.

(iii) Lack of facilities for scientific testing/researches on acceptability of products for registration, quality related issues, post market surveillance.

(iv) Lack of proper storage facilities in Regional Drug Stores and Drug Stores of Government Hospitals.

4. DRUG PRICING

Public sector in Sri Lanka is 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 governmental 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

Current situation and experiences of good and bad practices

State Pharmaceuticals Corporation of

Sri Lanka

Contents

- Primary Functions of SPC and functions of procurement and imports Division of SPC
- Regulatory services pertaining to SPC
- Recent achievements in regulatory services
- Experiences about bad practices
- Topics of interest

Primary Functions of SPC and functions of procurement and imports Division of SPC

Vision:

To become the prime partner in developing a Healthier Nation.

Mission:

To be the leading healthcare organization serving the general public of Sri Lanka by providing safe, effective and high-quality medical products and health services at affordable prices, while promoting the usage of generic drugs.

Primary Functions of SPC and functions of Procurement and Imports Division of SPC

1. Procurement of Pharmaceuticals, Surgical Devices, laboratory items for all government hospitals.

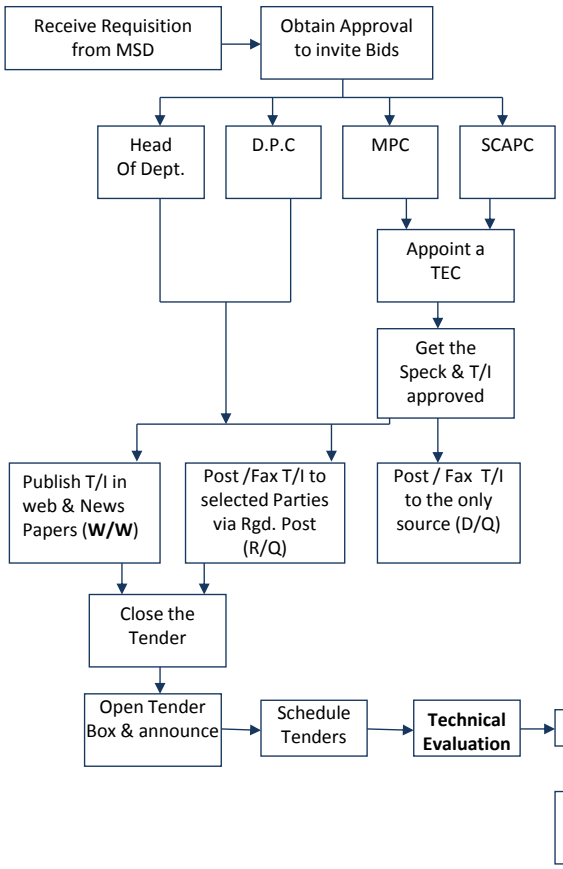
2. Retail selling of pharmaceuticals and surgical items through private retail network (31 SPC Pharmacies – *Osu Sala outlets*), Franchise dealers (101) and wholesale distributors (52).

Primary Functions of SPC and functions of procurement and imports Division of SPC **Contd..**

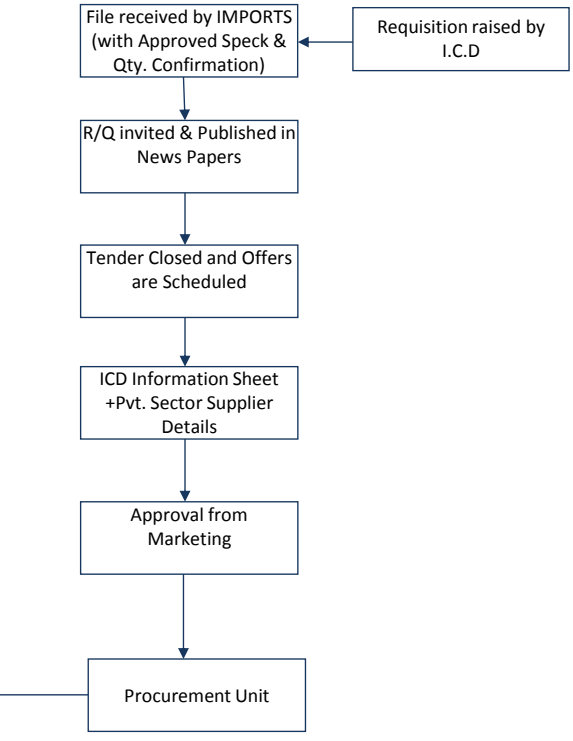
Procurement and Imports Division

- Making recommendations for policy formulation, preparation of plans pertaining to procurement of Pharmaceuticals and surgical items
- Sole Procurement Agent of Pharmaceuticals and Surgical Items to the State sector
- Procurement of pharmaceuticals to the Open Market for SPC pharmacies (Osu Sala outlets) and SPC distributors island wide
- Preparation of bidding documents with conditions to bid including regulatory procedures for the inflow of safe effective and quality assured medicinal products.

Flow chart depicting State Sector Procurement



Flow chart depicting Open Market Procurement



Drug Regulation in Sri Lanka

- Cosmetics Devices and Drugs Act No 27 of 1980 with subsequent amendments provides the legislative framework to control the use of cosmetics, medical devices and medicinal drugs in the country.
- The regulations under the CDD Act were published in gazette extraordinary no 378/3 of 02/12/1985 and further amendments were made from time to time.

- CDD Act controls
  - Registration
  - Manufacture
  - Importation
  - Transportation
  - Sale (Retail and whole sale)
  - Labelling
  - Advertising
  - Distribution of Drug Samples
  - Testing
  - And Disposal of outdated and spoiled drugs.

Main provisions of the CDD Act with regards to drugs.

- Only drugs which are registered with the authority can be manufactured, imported, offered for sale or used in the country
- Licenses are required for importation, manufacture, whole sale trade / retail trade and transpiration of drugs.
- All drugs registered with CDDA should conform to specified standards.
- Labelling on the packs and advertisements regarding drugs should conform to the relevant regulations.

A technical Advisory committee (TAC) has been setup under this act to advise the Hon. Minister of Health on matters pertaining to the implementation of the Act.

Regulatory services pertaining to SPC

- Pre-Qualification of suppliers of multisource products for invitation of bids.

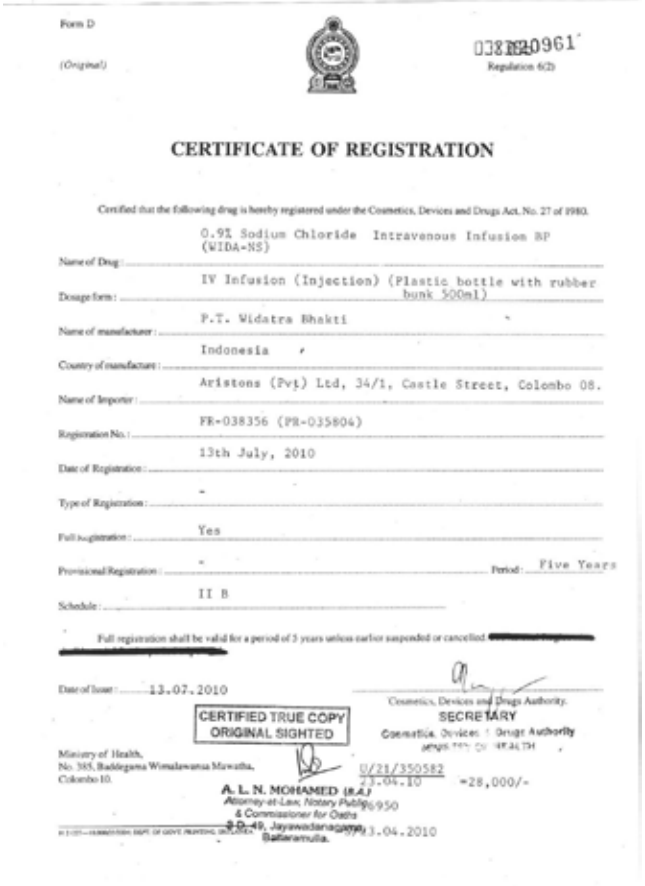
- Bidding Documents impose Conditions to regulate the supply of quality assured drugs.

- At the time of submission of bids, the following documents are requested.

Documents to be attached to the bid

- **A Copy of CDDA Registration Certificate** – (Notary certified)
- **Registration with Dept of Registrar of Companies.**
- **Letter of Authorization** (if any party other than manufacturer is the bidder / tenderer)
- **Power of Attorney if any other party other than the bidder (eg local agent) has signed the bidding form.**
- **Certificate of Pharmaceutical Product (CPP)**
- **Sample submission acknowledgement obtained from Administration Division of SPC**
- **Form to be filled by Local Manufacturers who claim Domestic Preference** (Annex V of Global Bid Document)
- **An Affidavit to certify the genuineness of all documents s**

A Copy of CDDA Registration Certificate – (Notary certified)



Form D

(Original)

Regulation 6(2)

CERTIFICATE OF REGISTRATION

Certified that the following drug is hereby registered under the Cosmetics, Devices and Drugs Act, No. 27 of 1980.

Name of Drug: 0.9% Sodium Chloride Intravenous Infusion BP (WIDA-NS)

Dosage form: IV Infusion (Injection) (Plastic bottle with rubber bunk 500ml)

Name of manufacturer: P.T. Widatra Bhakti

Country of manufacture: Indonesia

Name of Importer: Aristons (Pvt) Ltd, 34/1, Castle Street, Colombo 08.

Registration No.: FR-038356 (PR-035804)

Date of Registration: 13th July, 2010

Type of Registration: -

Full Registration: Yes

Provisional Registration: - Period: Five Years

Schedule: II B

Full registration shall be valid for a period of 5 years unless earlier suspended or cancelled [redacted]

Date of Issue: 13.07.2010

Cosmetics, Devices and Drugs Authority.

SECRETARY

Cosmetics, Devices and Drugs Authority

CERTIFIED TRUE COPY
ORIGINAL SIGHTED

Ministry of Health,
No. 385, Baddegama Wimalawansa Mawatha,
Colombo 10.

D/21/350582
13.04.10

=28,000/-

A. L. N. MOHAMED (B.A.)
Attorney-at-Law, Notary Public 6950
& Commissioner for Oaths
P.O. 49, Jayawardanapura,
Battaramulla.

13.04.2010

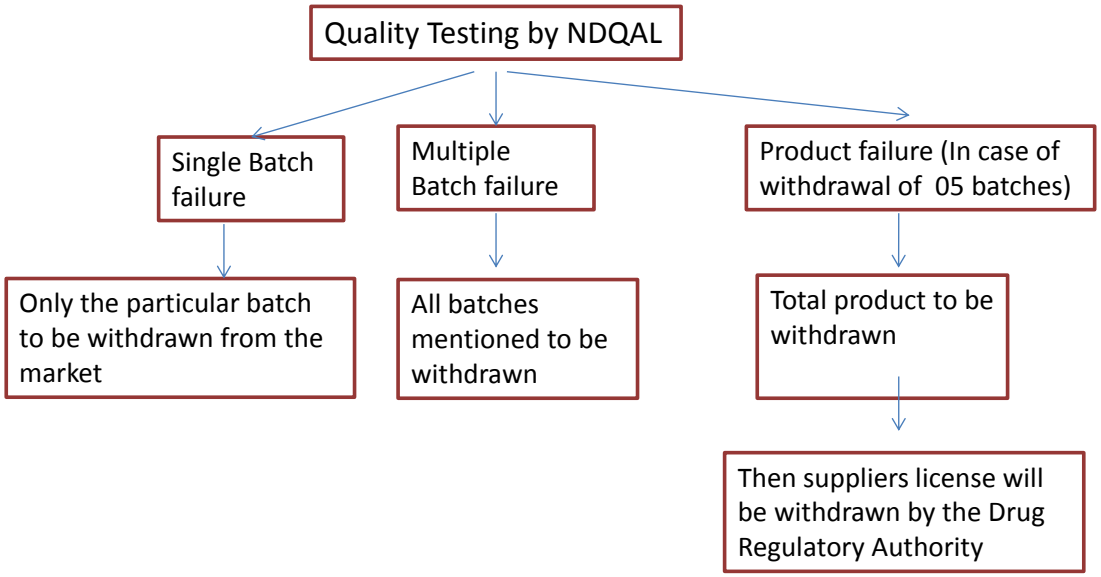
Technical Evaluation of Bids

- Tender Samples are tested of new suppliers / suppliers with previous batch withhold / withdrawals.
- A technical Evaluation Committee appointed comprising of Technical Expertise evaluate the bids and select the lowest responsive bidder and makes its recommendation to the Procurement Committee to make an award.

Pre-Shipment /Post Delivery Sample testing

- Based on the nature of the product, products from first time suppliers and depending on the availability, TECs / Procurement Committees decide on the testing of pre-shipment samples.
- SPC Quality Assurance Laboratory carries out testing samples for SPC Open Market Supplies.
- National Drug Quality Assurance Laboratory (NDQAL) testing for State Sector supplies

Quality Failures detected by NDQAL

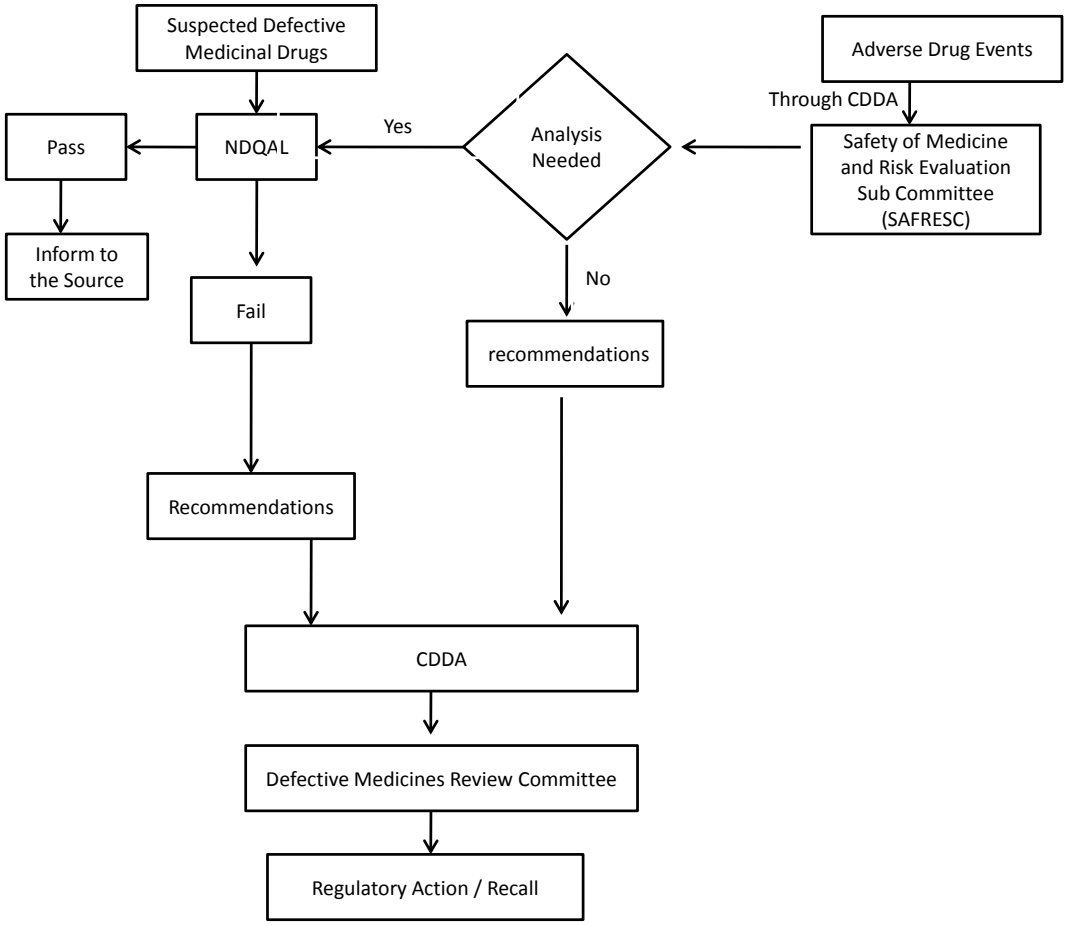


Drug Regulation

- The Health Ministry of Sri Lanka has taken steps to increase the number of Pharmacists and Inspectors at Cosmetic Devices and Drugs Authority (CDDA)
- The data base of the Drug Regulatory Authority has been updated with the assistance of WHO
- The fourth amendment to the CDDA Act has been enacted
- Drug Evaluation Sub Committee DESC evaluate and strengthen Drug Registration at CDDA

Recent Achievements in Regulatory Services

- Compiling the 05th Revision of National List of Essential Medicines 2013-2014
- Pre-Qualification of suppliers of multisource products by SPC and inviting bids from pre-qualified sources.
- Preparation of Guidelines on Re-call procedure for medicinal drugs.
- Preparation of Draft bill of the National Drug Policy making the Drug Regulatory Authority a more independent body.



Experiences about Bad Practices

- Even with comprehensive regulations Eg. CDD Act and Bidding Conditions, still the problem of inflow of substandard drugs persist.
- No. of complains received for year 2013 with regards to pharmaceuticals is 205
- During the year 2013, all products of 02 Indian drug manufacturers were withdrawn and SPC had to face an urgent procurement situation.
- Some of the examples of bad practices SPC experienced during the year 2013
  - Adrenaline injection supplied by M/S Poonam Pharmaceuticals India contained 02 vials without labels which later revealed to be Atropine injection. This was a severe mishap.

Experiences about Bad Practices Contd.

  - 03 batches out of a consignment of Rabies Vaccine (for human use) were less in potency when the summary protocol was inspected by the Medical Supplies Division (MSD)
  - 123 Cartons of Rabies Vaccine were exposed to normal temperature conditions (Whereas the temperature should be maintained at 2 °C - 8 °C) at Air Port due to the negligence of the Air Cargo Handling Staff .

Current Problems

- CDDA registration granted mainly on documentation. Hence, paves the way for the submission of forge documents by errant suppliers.
- Even though the regulations prevail, due to various issues no regular inspections are carried out by CDDA.
- No routine GMP inspections are carried out by CDDA.
- No routine post market surveillance due to lack of facilities at NDQAL.
- Non availability of proper storage conditions in drugs stores of Hospitals Etc.,
- Non availability of proper transport facilities required for drug transport.
- Bad Handling of cargo at the Airport leading to cold chain breakage

Current problems Contd.

- Pre-Qualification by SPC carried out only on documentation.
- Pre-Qualification applied only for multisource products.
- No regular system of testing due to inadequate laboratory facilities.
- In Sri Lanka, the Local Manufacturers base is very poor. Therefore, imported drugs constitute more than 75% of the current requirement and quality failures amounts to 82 suppliers from a supplier base of (Imports) 236. 34.7% for the year 2013.

Recent Achievements in the Health Sector with regards to Quality Assurance of medicines.

Consideration to be given to the creation and legislation of a new statutory body in the health infrastructure, the "National Medicinal Drug Regulatory Authority (NMDRA)“

Progress

- Achieved 100% political commitment
- A new Drug Act / policy have been formulated
- The Cabinet of Ministers approval was granted for same.
- Currently in the process of getting the public opinion on the Draft Bill
- It will be finalized with stakeholder suggestions and will be submitted to the parliament for the formal legislation
- Under this act the proposed NMDRA will be established.
- It will be an independent body

Parties Responsible – Sec/MOH, Legal Draftsman

Topics of interest

- Counter measures against the supply of quality failed sub standard drugs.
- Best Practices in drug regulation adopted in other countries.
- Monitoring and surveillance procedures of other countries

TANZANIA

Good Governance of Medicines for
National Pharmaceutical Regulatory Authorities （JFY 2014）

Format for Inception Report

Country: TANZANIA
Organization/Department/Division: MoHSW/PSU

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. Participants 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.

※Please see the attached sample A as a reference.

The quality, safety and efficacy of pharmaceutical products (medicines, medical devices and related products) are regulated by Tanzania Food and Drugs Authority (TFDA), a goverment regulatory body under the Ministry of Health and Social Welfare (MOHSW). The Director General of TFDA is responsible for daily operations of the organization. S/he reports to the Permanent Secretary of the MOHSW and the Chairperson of the Ministerial Advisory Board (MAB) which advices the responsbile Minister for policy and strategic issues of TFDA.

2) Legislation on pharmaceutical administration

–Please briefly bulletined major laws/acts

◆National Level

Oversight of regulatory issues	administered by	TFDA
Medicines policy issues	administered by	Pharmaceutical Services Unit (PSU) in the Ministry of Health and Social Welfare (MoHSW)

◆Local Level

Inspections at regional levels	administered by	Regional Health Management Teams (RHMTs)
Inspections at Council levels	administered by	Council Health Management Teams (CHMTs)

◆PIC/S

___ No

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

There is a designated department under the National Drug Regulatory Body which is looking after import and export control of medicines and related products. There are Medicines Import and Export Control Guidelines and specific Standard Operating Procedures (SOPs) which are used at Headquarters as well as Zone offices and Ports of Entry (POE). respective Regulations under the Tanzania Food, Drugs and Cosmetics Act, cap 219 are in the final stages of been approved, as to strengthern legal framework in the control systems. Inpectors have been allocated in all POEs whereby they use stationed Minilab kits for preliminary screening of imported and/or exported medicines before approval. All applications are received and processed, the necesary fees paid and approval grated through established Management Information System (MIS). through implemtation of Quality Management System (QMS), TFDA is also compliant to

administered by TFDA

administered by TFDA

◆ Pharmaceutical Manufacturing

・Systems, Regulations, etc

GMP Guidelines as well as Inspection Manual have been developed and are under use

administered by TFDA

There is a designated GMP desk and responsible desk officer/custodian who reports to the Manager, Medicines Inspection and Enforcement at TFDA. Inspectors checklists and SOPs are used purposefully to ensure compliance to minimum GMP and GLP requirements during pharmaceutical manufacturing sites inspection including the sites' QC labs.

administered by TFDA

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

◆ Marketing Authorization

・Systems, Regulations, etc

Medicine information/dossiers are evaluated by well trained and experienced evaluators. Respective samples are analysed in the WHO pre-qualified TFDA Medicine Laboratory to ascetain their quality, safety and efficacious standards before marketing authorization. There are Application Guidelines for Evaluation and Registration of human medicines which guide the evaluators during asssesment of dossiers. Moreover, the laboratory reports (of analysed medicine samples) form part of decicion criteria for marketing authorization by comparing with Evaluation report and respective manufacturing site GMP status. All applications are received and processed, the necesary fees paid and approval grated through established Management Information System (MIS). QMS implemetation is also observed.

administered by TFDA

TFDA

administered by

※Example: Good Quality Practice

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

・Systems, Regulations, etc

Its administered by National Medicines Procurement Agency named Medical Stores Department (MSD) which is again under the Ministry of Health and Social Welfare. TFDA has established Medicine Good Disribution Practice (GDP) Guidelines which are to be adhered to by MSD and other private firms resposible for medicines distribution and supply management. Responsible Regulations for Premises Registration, Import & Export Control of medicines are in final/good stages of development.

administered by MSD

Essential Medicines List and Standard Treatment Guidelines is administered by the Pharmaceutical Services Unit in the Ministry of Health

※Example: Good Distribution Practice

◆ Medicine Safety (post-marketing)

・Systems, Regulations, etc

There is developed 3 years PMS programme whereby selected medicines are being followed up to the market and samples taken to TFDA Laboratory for checking their quality, safety and efficasions standards before proposing way forward to Management team.

administered by

administered by TFDA

※Example: Good Pharmacovigilance Practice

◆ Relief System for Adverse Drug Reactions

・Systems, Regulations, etc

A passive way using YELLOW, prepaid forms to collect ADRs has proved low reporting rate by HCWs (around 60 ADRs/year). A designated Cohort Event Monitoring (CEM) which is an active strategy has been introduced to complement the passive initiative whereby around 9,700 cohorts were reported in the first year of implemetation (2008/09).

administered by TFDA

4) Drug Pricing

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

Pharmaceutical Services Unit conducts price survey frequently in collaboration with WHO. National Health Insurance Fund also sets prices

5) Statistic Data

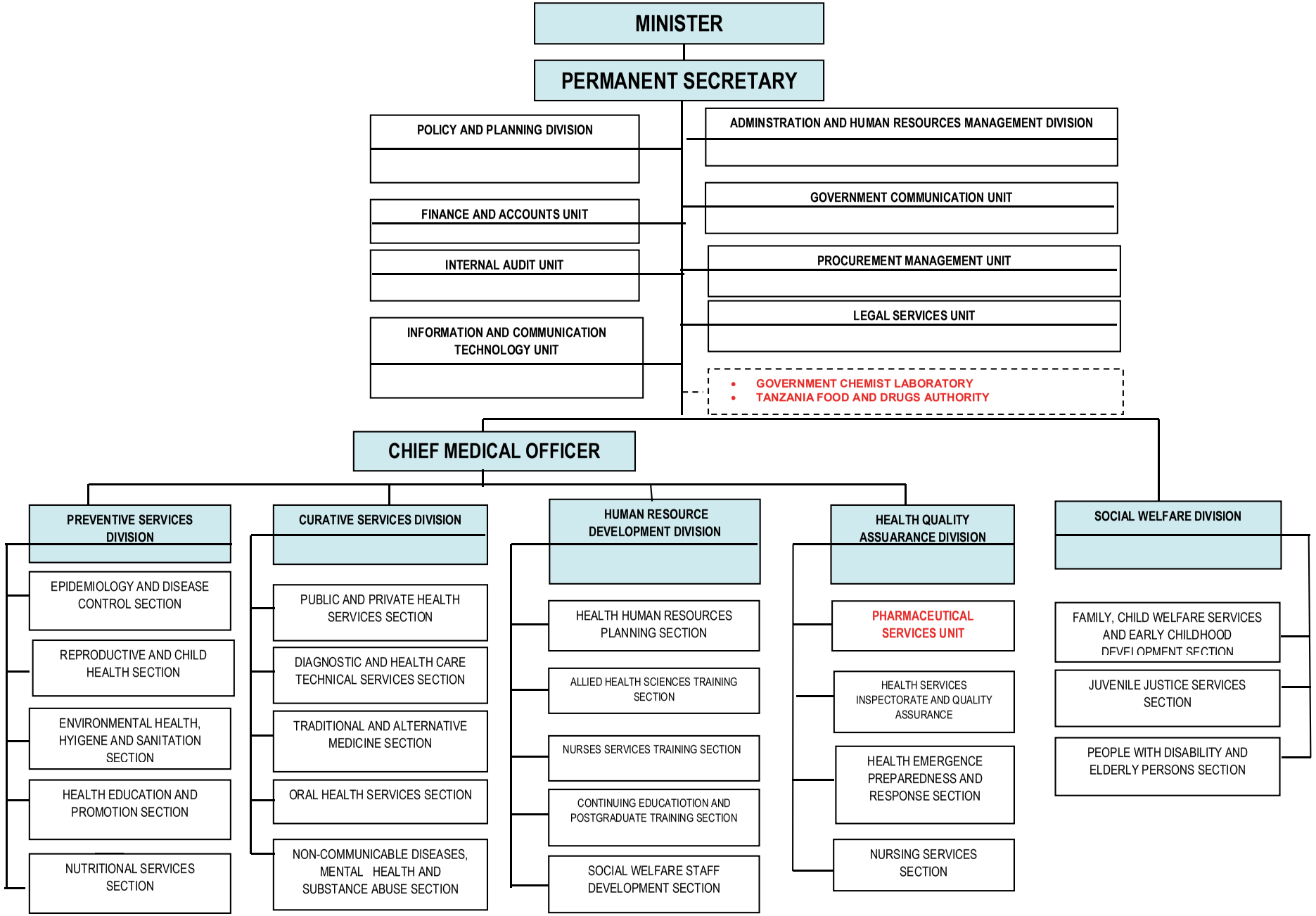
–Please answer the following questions (if the number is not applicable, please give an answer to the best of your knowledge).

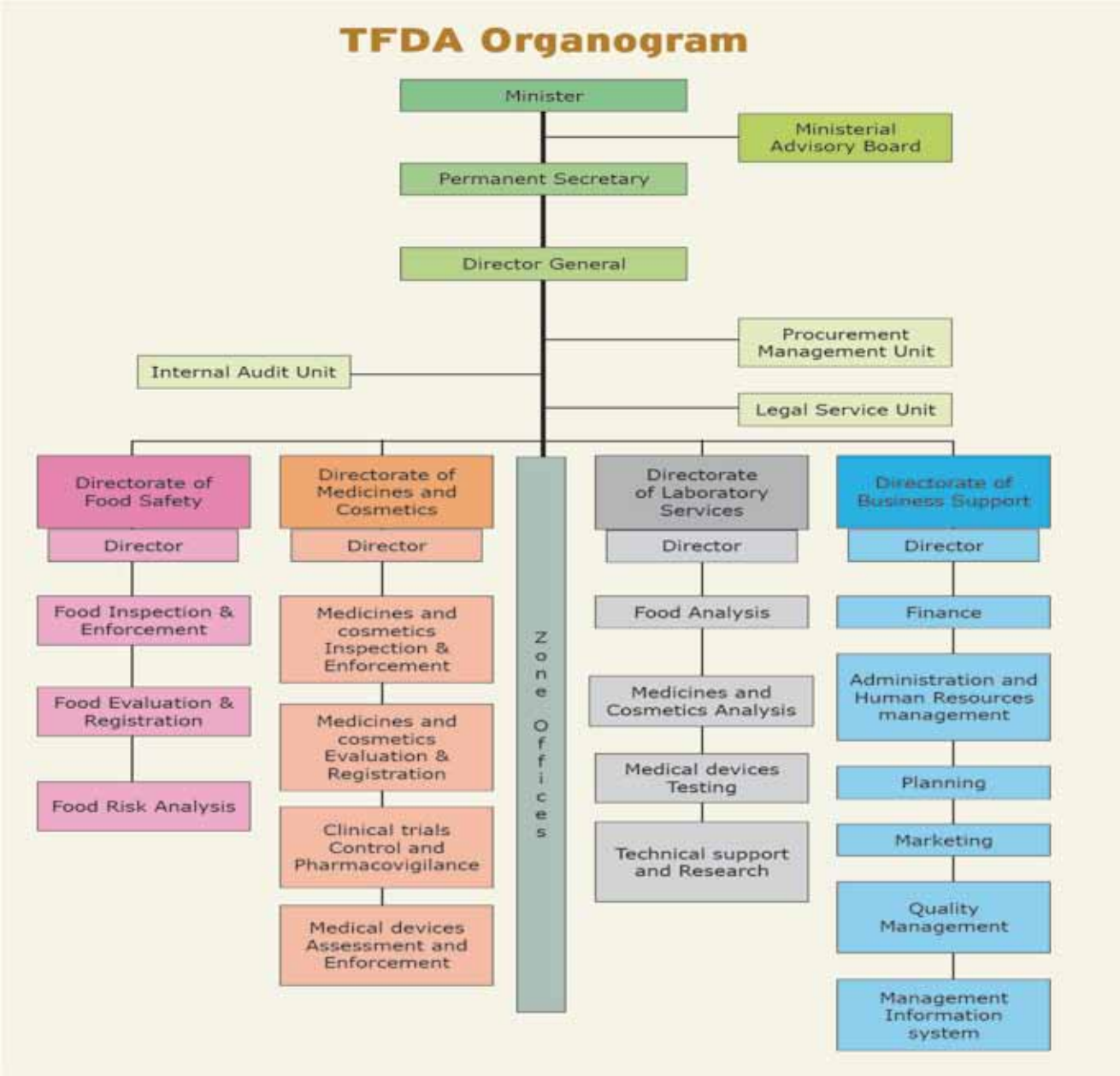
–Put the year of the presented data as well if it's available

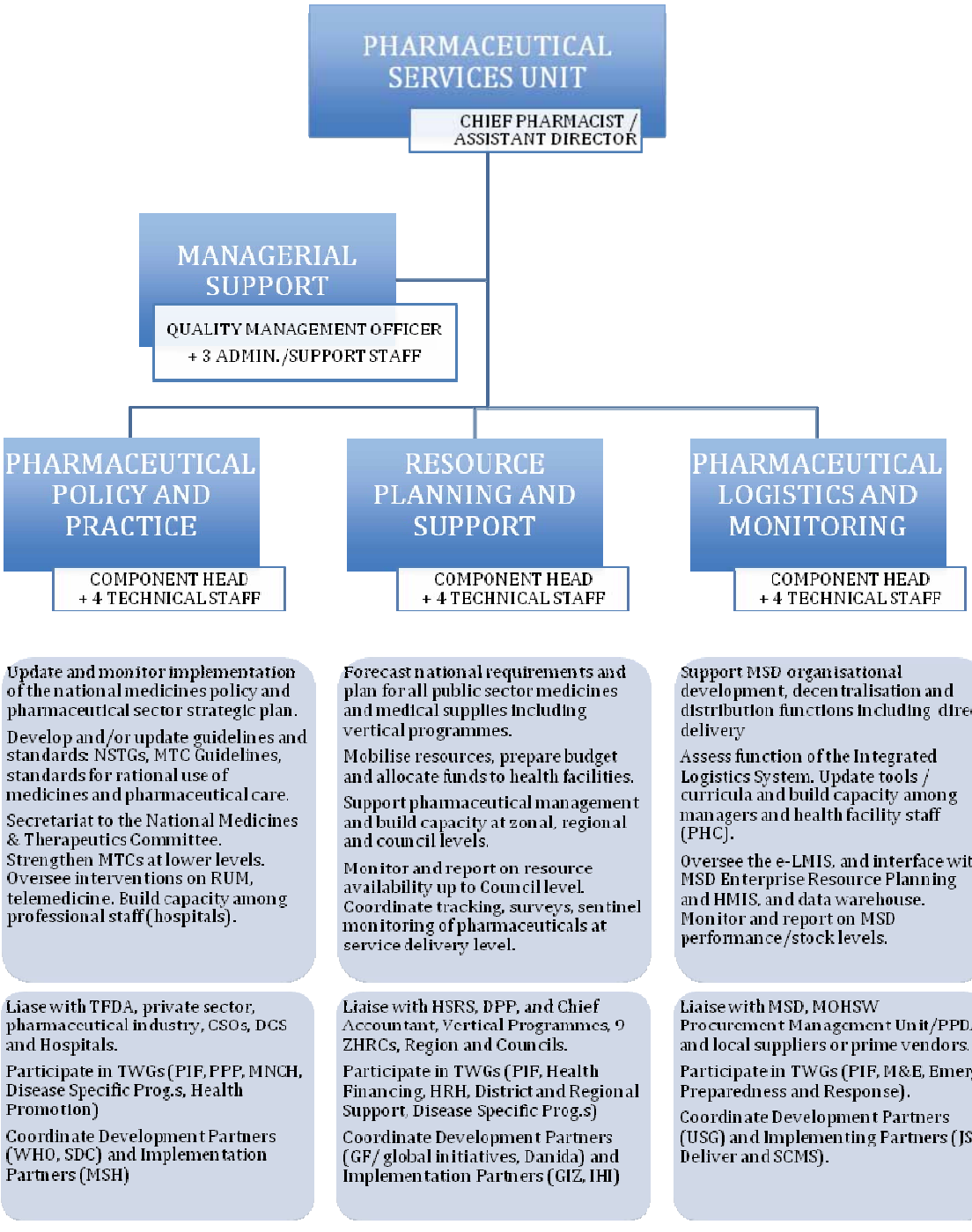
1: Number of pharmacists	1080	**-2014**	by considering that all TFDA Pharmacists are GMP inspectors
2: Number of GMP inspector (National & Lo	46	-2014	
3: Number of pharmaceutical manufacturers / manufacturing sites	11	-2014	
4: Number of traditional medicine manufacturers / manufacturing sites	1	-2014	
5: Number of pharmaceutical importers	80 + 24	-2014	80 are those paying 2% FOB whereas remaing 24 are exempted ones including FBOs, International NGOs such as CHAI, hospitals like KCMC, and Raw materials importation etc
6: Number of pharmaceutical wholesalers	273	-2014	After enactement of the Pharmacy Act, 2011 all wholesalers who are not importers are regulated by the PC whereas TFDA remain with Importers of

THE ORGANISATION STRUCTURE OF THE MINISTRY OF HEALTH AND SOCIAL WELFARE-TANZANIA.

(Approved by the President on 3rd June, 2011)




TFDA Organogram
Minister
Ministerial Advisory Board
Permanent Secretary
Director General
Procurement Management Unit
Internal Audit Unit
Legal Service Unit
Directorate of Food Safety
Director
Food Inspection & Enforcement
Food Evaluation & Registration
Food Risk Analysis
Directorate of Medicines and Cosmetics
Director
Medicines and cosmetics Inspection & Enforcement
Medicines and cosmetics Evaluation & Registration
Clinical trials Control and Pharmacovigilance
Medical devices Assessment and Enforcement
Zone Offices
Directorate of Laboratory Services
Director
Food Analysis
Medicines and Cosmetics Analysis
Medical devices Testing
Technical support and Research
Directorate of Business Support
Director
Finance
Administration and Human Resources management
Planning
Marketing
Quality Management
Management Information system


PHARMACEUTICAL SERVICES UNIT
CHIEF PHARMACIST / ASSISTANT DIRECTOR
MANAGERIAL SUPPORT
QUALITY MANAGEMENT OFFICER + 3 ADMIN./SUPPORT STAFF
PHARMACEUTICAL POLICY AND PRACTICE
COMPONENT HEAD + 4 TECHNICAL STAFF
RESOURCE PLANNING AND SUPPORT
COMPONENT HEAD + 4 TECHNICAL STAFF
PHARMACEUTICAL LOGISTICS AND MONITORING
COMPONENT HEAD + 4 TECHNICAL STAFF
Update and monitor implementation of the national medicines policy and pharmaceutical sector strategic plan.
Develop and/or update guidelines and standards: NSTGs, MTC Guidelines, standards for rational use of medicines and pharmaceutical care.
Secretariat to the National Medicines & Therapeutics Committee.
Strengthen MTCs at lower levels.
Oversee interventions on RUM, telemedicine. Build capacity among professional staff (hospitals).
Forecast national requirements and plan for all public sector medicines and medical supplies including vertical programmes.
Mobilise resources, prepare budget and allocate funds to health facilities.
Support pharmaceutical management and build capacity at zonal, regional and council levels.
Monitor and report on resource availability up to Council level.
Coordinate tracking, surveys, sentinel monitoring of pharmaceuticals at service delivery level.
Support MSD organisational development, decentralisation and distribution functions including direct delivery
Assess function of the Integrated Logistics System. Update tools / curricula and build capacity among managers and health facility staff (PHC).
Oversee the e-LMIS, and interface with MSD Enterprise Resource Planning and HMIS, and data warehouse.
Monitor and report on MSD performance/stock levels.
Liase with TFDA, private sector, pharmaceutical industry, CSOs, DGS and Hospitals.
Participate in TWGs (PIF, PPP, MNCH, Disease Specific Prog.s, Health Promotion)
Coordinate Development Partners (WHO, SDC) and Implementation Partners (MSH)
Liaise with HSRS, DPP, and Chief Accountant, Vertical Programmes, 9 ZHRCs, Region and Councils.
Participate in TWGs (PIF, Health Financing, HRH, District and Regional Support, Disease Specific Prog.s)
Coordinate Development Partners (GF/ global initiatives, Danida) and Implementation Partners (GIZ, IHI)
Liaise with MSD, MOHSW Procurement Management Unit/PPDA and local suppliers or prime vendors.
Participate in TWGs (PIF, M&E, Emerg. Preparedness and Response).
Coordinate Development Partners (USG) and Implementing Partners (JSI Deliver and SCMS).

PHARMACEUTICAL MANAGEMENT IN TANZANIA

MINISTRY OF HEALTH

AND SOCIAL WELFARE, TANZANIA

PRESENTATION LAYOUT

- Introduction
- Local production of pharmaceuticals in Tanzania
- Pharmaceutical Policies and Guidelines
- Key Players in the Provision of Pharmaceutical Services
- Medicine Supply System in Public Health Facilities
- Challenges in the Pharmaceutical Sector
- Initiatives to Improve Availability of Medicines
- Conclusion

INTRODUCTION

- I'm heading PSU since November 2012, major duties are:
- Provide stewardship of the pharmaceutical sector in the country
- Formulate and review medicines policies, regulations & guidelines.
- Forecast national requirements and plan for medicines and health supplies.
- Promote the development of domestic pharmaceutical manufacturing.
- Develop, oversee and support the pharmaceutical management, logistics systems.
- Develop and review mechanism to control and monitor prices of essential medicines.

Local Production of Medicines

- About 80% of medicines are imported from outside
- There are about 10 local producers of medicines and one producer of Traditional Medicines.
- GMP compliance is still a challenge to most local industries
- Promotion of local producers is currently a high agenda of the Ministry of Health
- A ten years Strategy to Promote Local Industries has been developed

PHARMACEUTICAL POLICIES AND GUIDELINES

- To ensure citizens have access to affordable quality, safe and efficacious medicines, the government has developed pharmaceutical policies, strategies and guidelines.
- Medicines Policy ensures that all stakeholders know their roles, rights and obligations in relation to management of medicines and related supplies, particularly provision and availability

PHARMACEUTICAL POLICIES AND GUIDELINES

- Cabinet approved the first National Medicines Policy in 1991
- The achievement of the 1991 Policy includes establishment of
  - ✓ Pharmaceutical Services Unit (PSU-MoHSW)
  - ✓ Medical Store Department (MSD) under MSD Act 13 of 1993
  - ✓ Tanzania Food and Drug Authority TFDA, under the Food and Drug Act No 1 of 2003
  - ✓ Pharmacy Council under the Pharmacy Act, No. 7 of 2002

Note: The revised Policy is waiting Cabinet approval

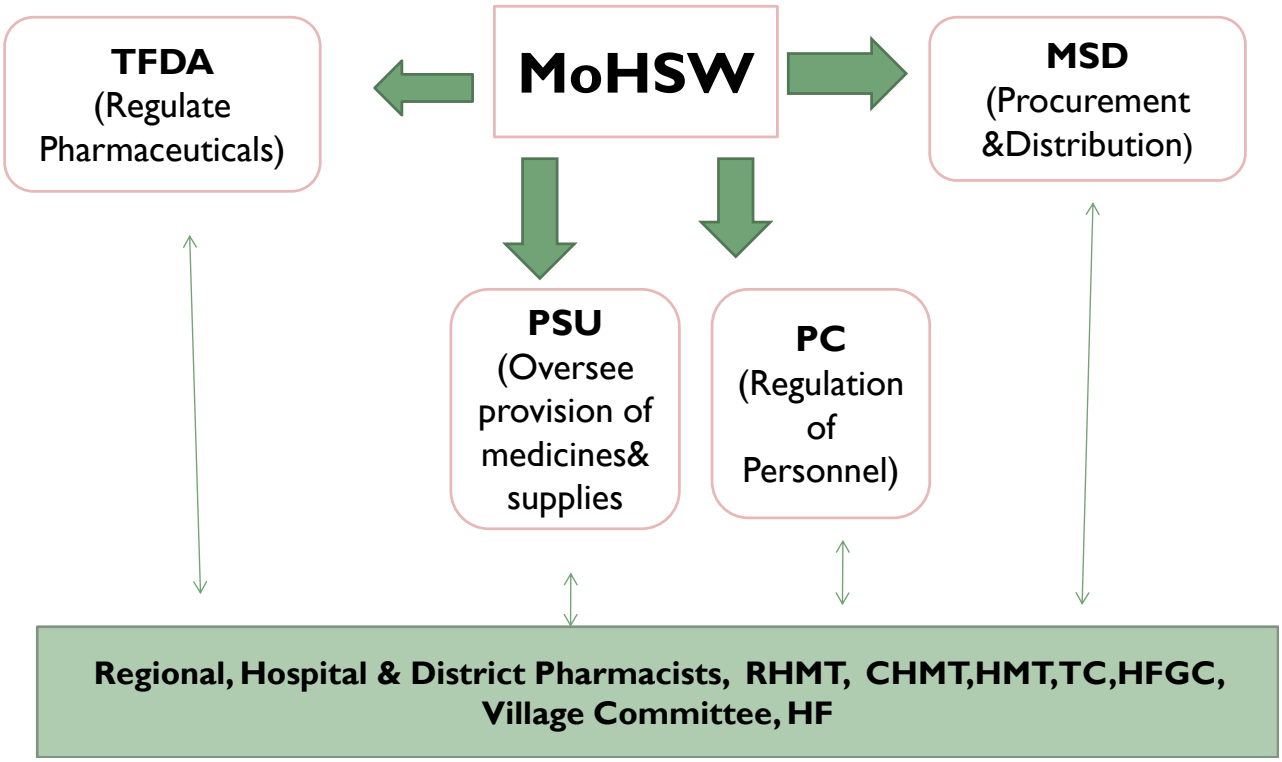
PHARMACEUTICAL POLICIES AND GUIDELINES

- Standard Treatment Guidelines make decisions about appropriate treatment for specific clinical conditions
- The essential drug concept stresses the selection of medicines to meet the real public needs

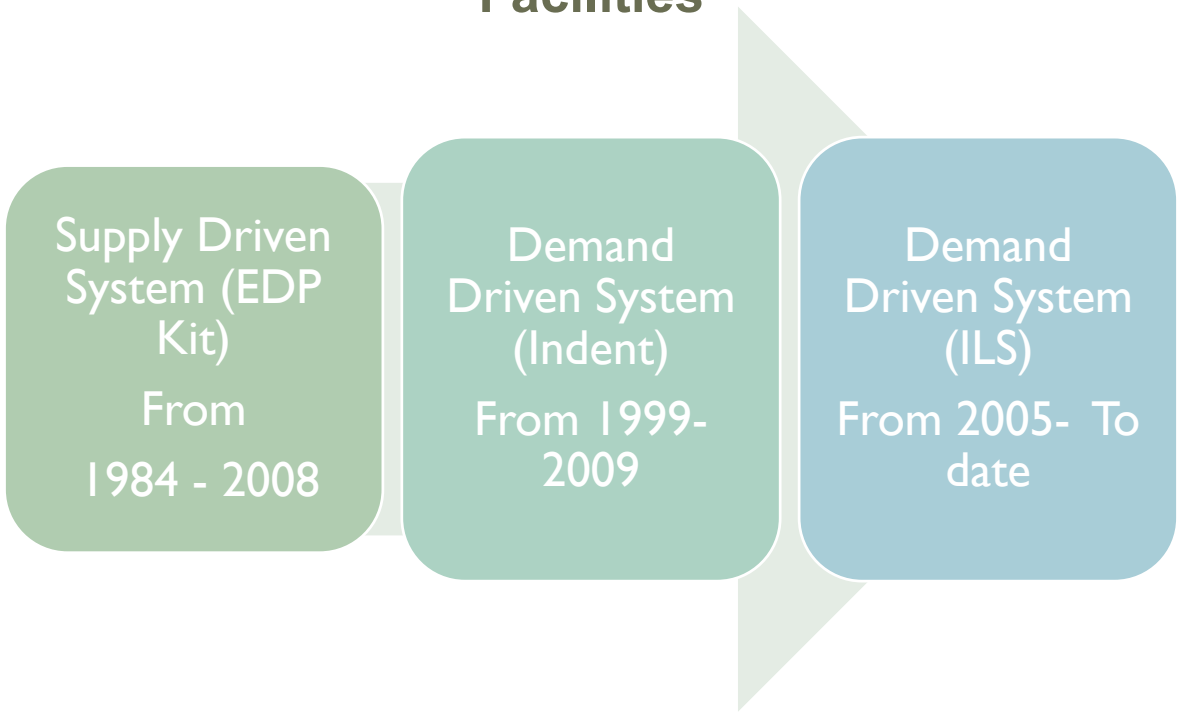
National STGs and NEMLIT in Tanzania

- ✓ First edition in 1991
- ✓ Second edition in 2003
- ✓ Third edition in 2007
- ✓ Fourth edition 2013

KEY PLAYERS IN THE PHARMACEUTICAL SECTOR



Medicine Supply System in Public Health Facilities



Challenges in Medicines Management

- Regardless of the Government efforts to ensure availability of essential medicines, public health facilities still face shortage of these crucial commodities.
- The government budget is limited
- There is a disproportion between the funds available for the purchase of medicines compared to the real requirement
- Irrational use of medicines
- Human resources for the pharmaceutical sector is a crisis
- Access of quality data for decision making
- Pile up of expired medicines

Initiatives to Improve Availability of Medicines

- **Direct Deliver to Health Facilities**
  - ✓ Health facilities have been experiencing stock outs of essential medicines and medical supplies attributed by delayed delivery, non-delivery of right quantities, and delivery of expired products
  - ✓ Currently, MSD is delivering medicines and related supplies direct to all public health facilities in the country

Initiatives to Improve ….

- **New Medicine Allocation Formulae**
  - The PSU allocates the funds 'vertically' between several levels of hospitals, health centres and dispensaries
  - The vertical resource allocation formula results in a share of about 50% for PHC, 40% for hospital levels and 10% other hospital supplies

eLMIS

- (eLMIS) was developed through a partnership between the Ministry of Health and Social Welfare (MOHSW) in Tanzania and the Ministry of Health (MOH) in Zambia.

- eLMIS is a web-based application which computerizes existing paper-based logistics management information systems (eLMIS) and is in line with National e- Health strategy that was launched in 2013.
- Currently the system is live operating in 162 district councils and some reports are now being received at MSD

eLMIS vision

An effective and sustainable electronic logistics management information system (eLMIS) should be user friendly and facilitate adequate quality and quantities of health commodities* that are always available at the point of service to meet patient demand. *The eLMIS must provide integrated access to:*

- *Accurate, timely and routine consumption data*
- *Real-time logistics management capabilities covering point of origin to point of consumption*
- *Demand forecasting, capacity planning & modeling based on consumption*

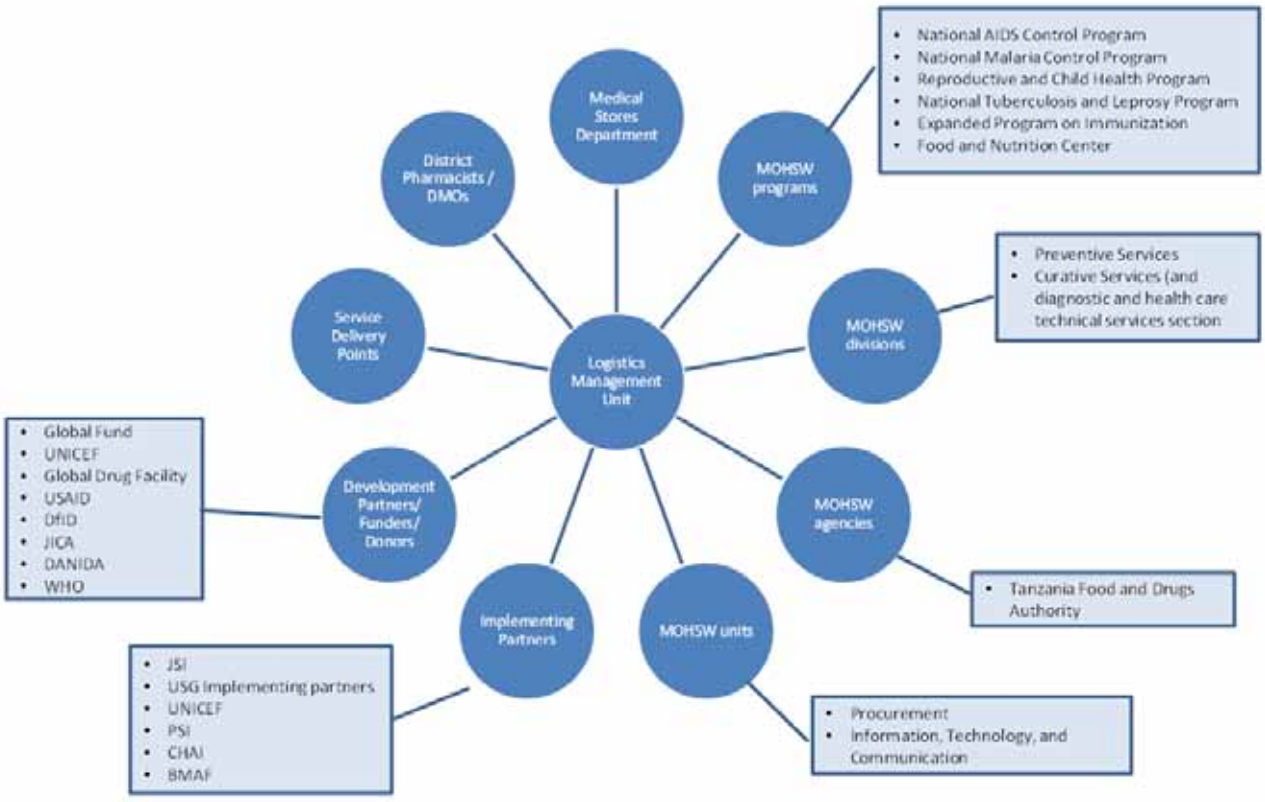
(vaccines, medicines, medical & diagnostic supplies, etc.)*

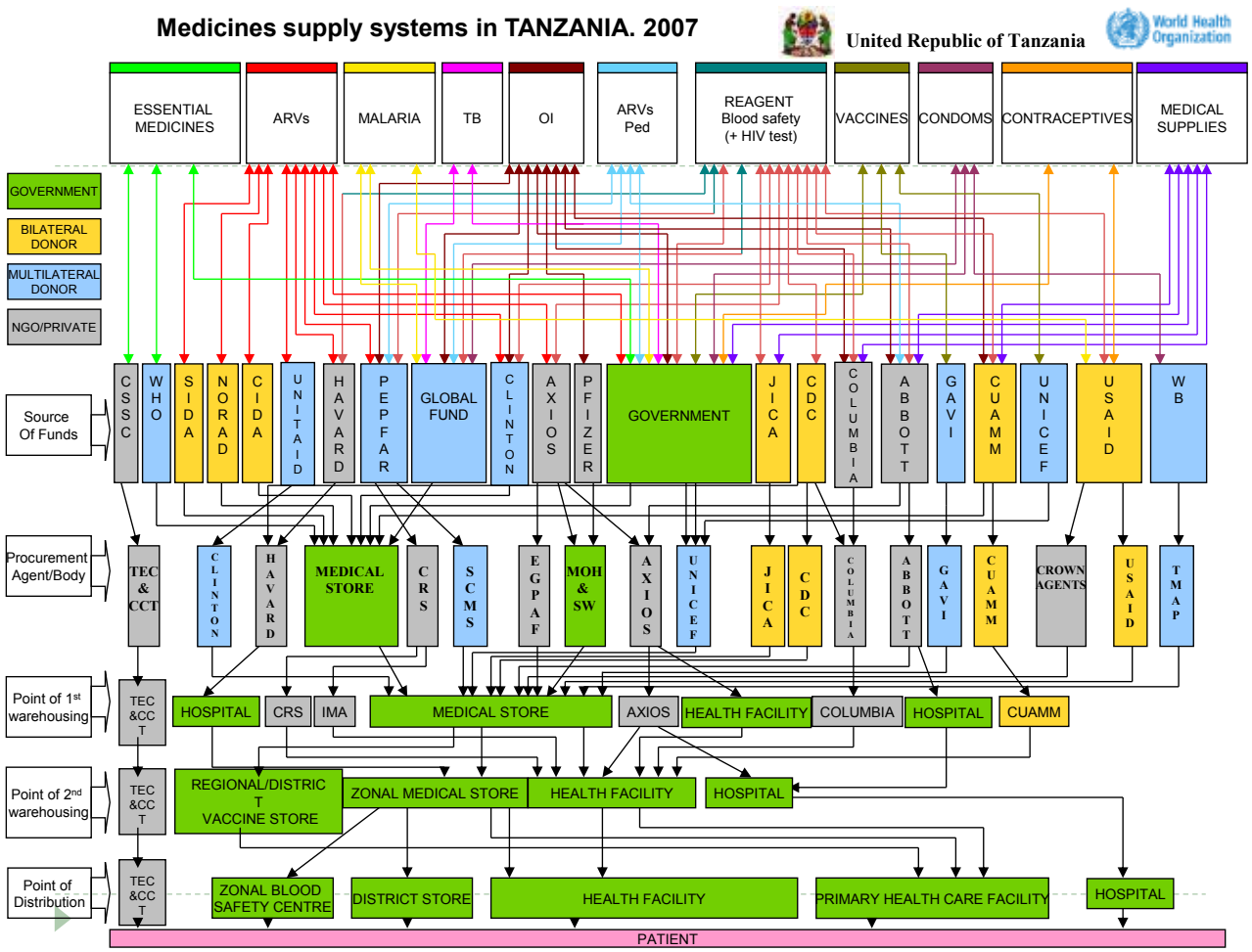
LMU

This is a Logistic Management Unit established in 2013 to coordinate with all supply chain stakeholders with the following objectives;

1. Coordinate logistics management activities of all commodity categories under one unit through harmonizing national health commodities supply chains throughout all Programs (HIV & AIDS commodities, PMTCT, RCHS etc.)

Supply Chain Actors in Tanzania





LMU

2. Strengthen logistics data management and visibility
3. Link different organization levels and partners within supply chain to improve health commodities availability at the national level
4. Identify supply chain bottlenecks, brainstorm mitigation strategies and collaborate with key players involved to implement those interventions.

LMU

- Currently the LMU staff are located in all MSD zones to ensure timely data availability and implement MOHSW vision and Mission to ensure uninterrupted supply of Health commodities.

LMU functions

- Logistics Data Management
- Quantification Coordination to all vertical Programs and MSD
- Monitoring & Evaluation
- Coordination and Collaboration
- Supply Chain Intervention Planning (Review and Advice)
- Training & Capacity Building
- Supervision

LMU Benefits to All SC stakeholder

- Improved data quality and visibility for all programs
- Improved inventory management system
- Strengthened supply chain management at lower levels
- Improved coordination and collaboration
- Improved commodity availability

Topics of my interests in the course

- Promoting GMP standards for local industries and measure to improve local productions of pharmaceuticals
- Improving Pharmaceutical Supply Chain Systems
- Measures to curb Substandard/Spurious/ Falsely-labelled /falsified /Counterfeit Medical Products

CONCLUSION

Drug management strengthening is an important and sensitive health systems entity that requires systematic interventions to avoid stock outs that cause negative effects on the population.