Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

Country Reports

Japan International Corporation of Welfare Services (JICWELS)

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Good Governance of Medicines for National Pharmaceutical Regulatory *Authorities*

China

Good Governance of Medicines for National Pharmaceutical Regulatory Authorities (JFY 2013)

Format for Job Report

Country: China
Organization/Department/Division: Xi'An Food and Drug administration

1. Overview of your country and organization

1-1. Please briefly describe legislation on pharmaceutical administration in your country (Name and outline of the law(s)).

China has established a legislation of pharmaceutical administration. Classified by the legal department, the legislation on pharmaceutical administration belongs to the category of administrative law, composed by the laws, administrative regulations, departmental rules and normative documents, which is given priority to with departmental rules. According to statistics, 90% of the legislative documents are departmental rules issued by the Ministry of Health and the CFDA.This system of legislation covers the administrative licensing, standard certification, pharmaceutical supervision, drug safety and administrative enforcement and other aspects.

1. According to Administrative Permission Law, which is the main block of pharmaceutical administrative permission, 11 transactions are involved to the pharmaceutical examination and approve, such as Pharmaceutical production license, Pharmaceutical supply license and Pharmaceutical import and export license.

2. The system of Good practice of pharmaceutical administration includes: Good Supply Practice, (GSP), Good Hospital Preparation Practice(GPP), Good Agricultural Practice (GAP), Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacturing Practice, (GMP)

3. Pharmaceutical supervision is the backbone of pharmaceutical legislation, which includes the supervision of pharmaceutical R&D, production, supply and employ.

4. safety is the ultimate goal of pharmaceutical legislation, in addition to the drug administration law and its implementation, the pharmaceutical safety management system also includes Drug quality management norms", Drug registration management approach", Supervision and administration of drug production and other laws and regulations, China also established the adverse drug reaction monitoring, such as drug recall law system.

1-2. Please attach the organizational chart at national/state and local levels and briefly describe each role and responsibility on pharmaceutical administration.

CFDA undertakes the following works: To formulate and monitor the policy and regulation of pharmaceutical safety administration; To formulate and monitor the policy and regulation of pharmaceutical safety administration; To administrate the pharmaceutical registration, draft the pharmaceutical standard, apply the ADR monitoring; To Participate in establishment of national essential medicine list; To supervise the pharmaceutical quality safety, publish the information of pharmaceutical quality safety; To invest and dispose the illegal behavior in pharmaceutical operation; To instruct the local pharmaceutical administration; To formulate the qualification of licensed pharmacists.

1-3. Please briefly describe priority issues at maximum three (3) on pharmaceutical regulatory services in your organization. Please provide with relevant background data.

- There are loopholes in the current pharmaceutical regulation system. For example, explicit stipulations of pharmaceutical excipients, Chinese herbal medicine, raw material medicine are absent in the pharmaceutical research and development.
- Regulations on medical institution pharmacy practitioner's qualification is not clear. Most of the small-size medical institutions such as village hospitals have an issue on lack of professional pharmacist.

2. Statistical data

Please fill in with latest data in your country when available

a) Number of Pharmacists

Data (Year)

b) Number of Inspector (National and Local)： 15175

Based on Data 2011 (Year)

c) Number of pharmaceutical manufacturers / manufacturing sites: 19675

Based on Data 2012 (Year)

d) Number of traditional medicine manufacturers / manufacturing sites: 103

(when there were special category for the traditional medicine manufacturers/ manufacturing sites)

Based on Data 2012 (Year)

e) Number of pharmaceutical importers: 238

Based on Data 2012 (Year)

f) Number of Pharmaceutical wholesalers: 16295

Based on Data 2012 (Year)

3. Introduction of your work

3-1. Please briefly describe regulatory services that you are engaged in.

I was graduated from University of International Business and Economics in July 2007, majored in Jurisprudence and got my bachelor's degree. I've got two years' work experiences of Pharmaceutical Legislation, and two year's work experiences of implement emergency reuse of food and drug safety incidents.

3-2. Please describe your interests topics at maximum three (3).

- Pharmaceutical Legislation
- Pharmaceutical Inspection in Japan
- Pharmaceutical Advertise Regulation in Japan

Overview of China pharmeceutical administration: based on legislation and prefecture

Xi'An FDA,ShaanXi Province

legislation on pharmaceutical administration in China

- China has established a legislation of pharmaceutical administration.
- Classified by the legal department, the legislation on pharmaceutical administration belongs to the category of administrative law

- The pharmaceutical legislation is composed by the laws, administrative regulations, departmental rules and regulatory documents, which is given priority to with departmental rules.

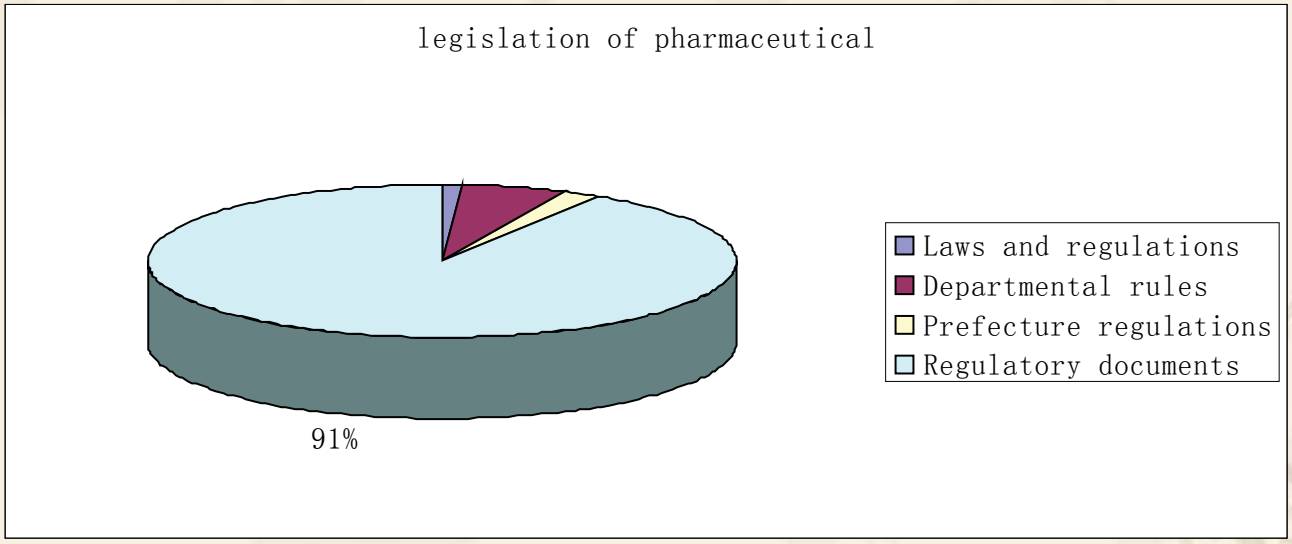
Overview of pharmaceutical administration law

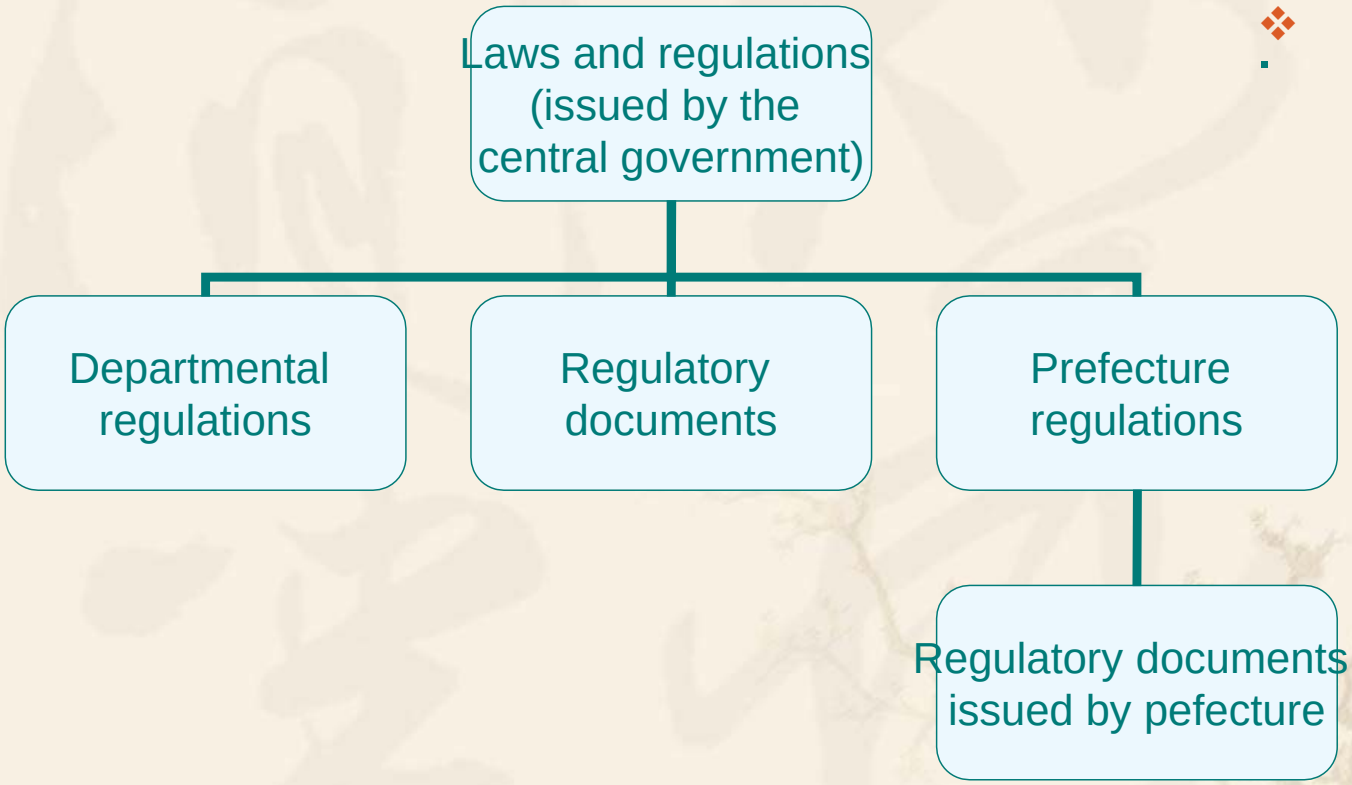
Laws and regulations:14

Departmental rules:68

Prefecture regulations:24

Regulatory documents:1081





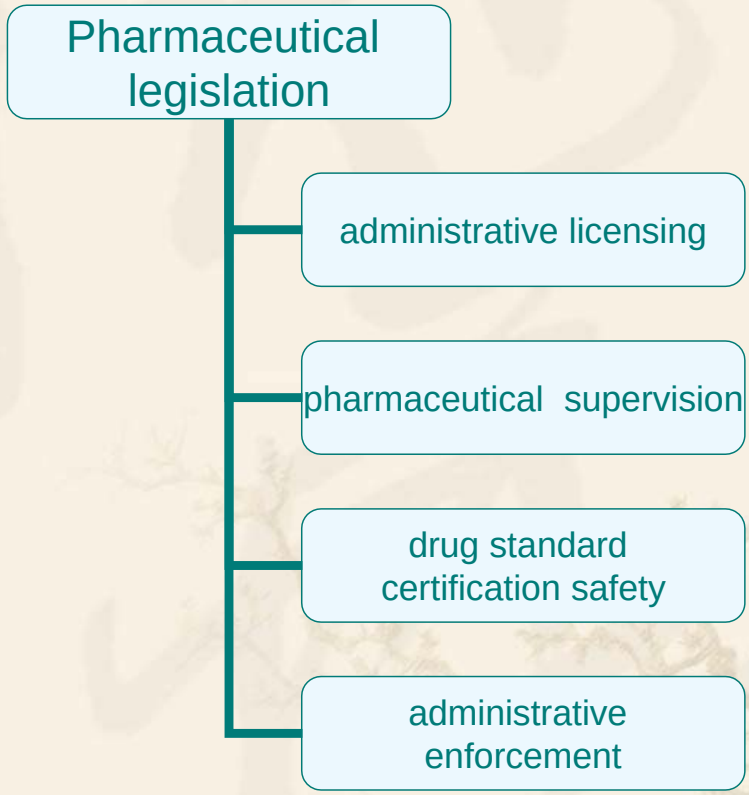
Overview of pharmaceutical administration law

Outlines of pharmaceutical Administration Law

- Chapter I General Provisions
  Chapter II Control over **pharmaceutical** Manufacturers
  Chapter III Control over **pharmaceutical** Distributors
  Chapter IV Control over Pharmaceuticals in Medical Institutions
  Chapter V Control over Drugs
  Chapter VI Control over Drug Packaging
  Chapter VII Control over **pharmaceutical** Pricing and Advertising
  Chapter VIII Inspection of **pharmaceutical**
  Chapter IX Legal Liabilities
  Chapter X Supplementary Provisions

Overview of pharmaceutical administration law

- From its contents, the legal system can be divided into the following categories:



Overview of pharmaceutical administration law

- administrative licensing
-


中华人民共和国

药品生产许可证

（副本）

编　　号：青20100041

企业名称：青海春天药用资源科技利用有限公司

注册地址：青海省西宁市经济技术开发区东新路1号

法定代表人：肖　融

企业负责人：肖　融

企业类型：有限责任公司

分 类 码：Y

有效期至：2015 年 12 月 31日


中华人民共和国

药品经营许可证

证　　号：琼AA0100114

企业名称：海南华健药业有限公司

经营方式：批　发

注册地址：海口市滨海大道3号

经营范围：中成药；化学原料药及其制剂；抗生素原料药及其制剂；生化药品；生物制品；二类精神药品…

法定代表人：吕良卡

企业负责人：

质量负责人：马曙光

仓库地址：海口市滨海路3号（保亭县保城镇新兴西路22号、保亭县沿河东路、陵水县人民武装部原民兵仓库、陵水县解放路1号）

发证机关：

有效期至　2009 年 12 月 31 日　　2005 年 1 月 1 日

Overview of pharmaceutical administration law

- Pharmaceutical Good practice certification

中华人民共和国

药品经营质量管理规范认证证书

证书编号：B-SH08-017

企业名称：上海华源大药房连锁经营有限公司

地　址：上海市杨浦区宜阳路353号2-3楼

认证范围：零售连锁

经审查，符合《药品经营质量管理规范》要求，特发此证。

发证机关：

有效期至 2014 年 01 月 17 日　　2011 年 03 月 29 日

国家食品药品监督管理局制　　No 0612587

中华人民共和国

药品GMP证书

CERTIFICATE OF GOOD MANUFACTURING PRACTICES FOR PHARMACEUTICAL PRODUCTS

PEOPLE'S REPUBLIC OF CHINA

证书编号：HN20120017

Certificate No.

企业名称：湖南省新晃县龙脑开发有限责任公司

Manufacturer: Hunan Xinhuang county borneol development limited liability company.

地　址：湖南省新晃县波洲镇暮山坪

Address: Mushanping, Bozhou town, Hunan Xinhuang county

认证范围：中药饮片（天然冰片）

Scope of Inspection: Prepared Slices of Chinese Cruds Drugs

经审查，符合中华人民共和国《药品生产质量管理规范》要求。

特发此证。

This is to certify that the above-mentioned manufacturer complies with the requirements of Chinese Good Manufacturing Practices for Pharmaceutical Products.

有效期至 2015 年 12 月 31 日

This certificate remains valid until 31/12/2015

发证机关：

Issued By

Date for Issuing 11/11/2012　　2012 年 11 月 11 日

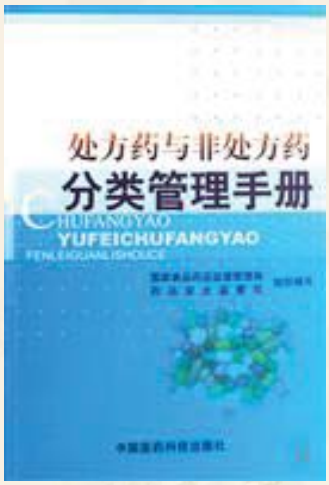
国家食品药品监督管理局制

PRINTED BY STATE FOOD AND DRUG ADMINISTRATION

Overview of pharmaceutical administration law

- pharmaceutical supervision
- Pharmaceutical supervision is the backbone of pharmaceutical legislation, which includes the supervision of pharmaceutical R&D, production, supply and employ.

- Pharmaceutical safety regulation
  - safety is the ultimate goal of pharmaceutical legislation

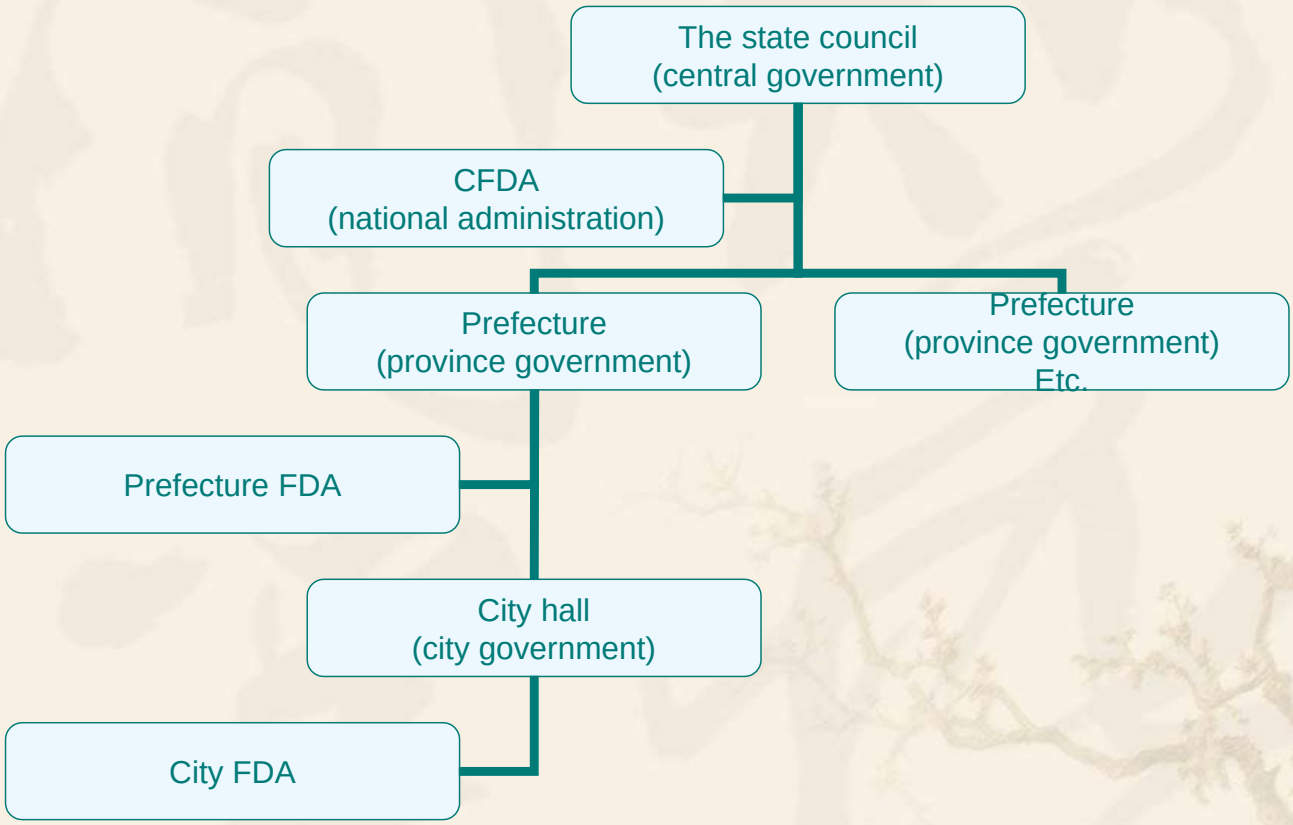


Prefecture administration of pharmacy

Prefecture administration of pharmacy

- Introduction of China's government and administration system:
- State council——CFDA
- Prefecture——FDA

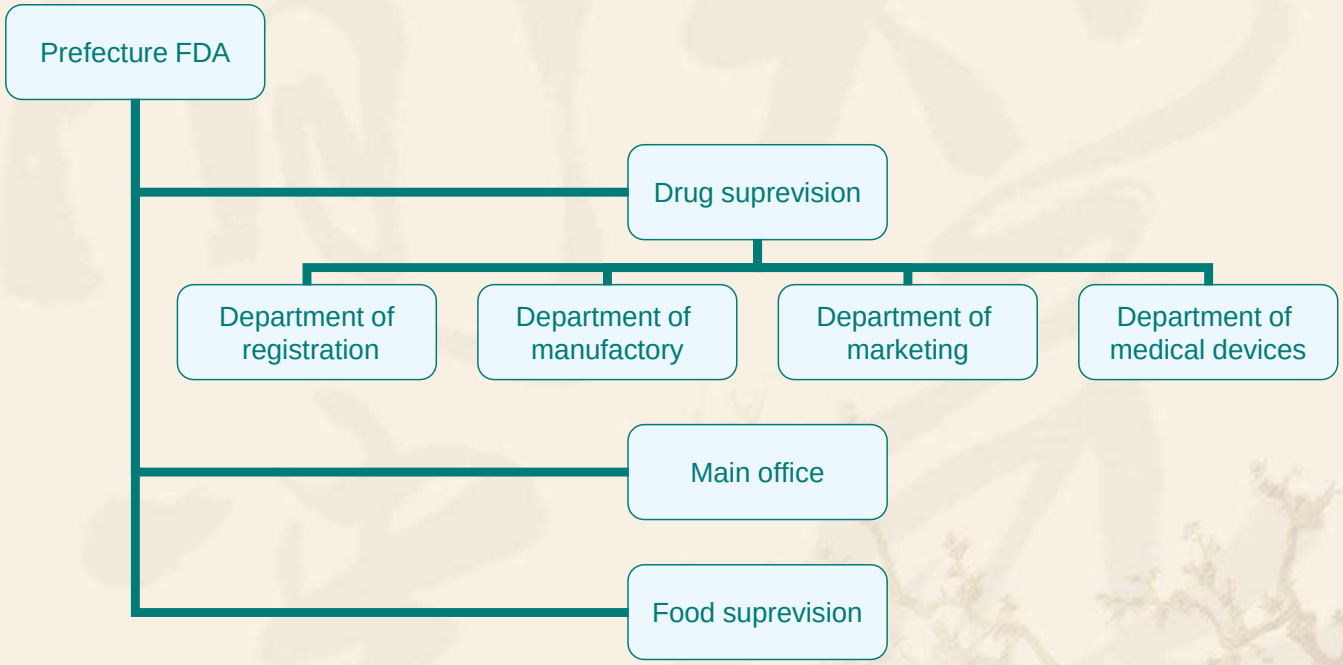
Prefecture administration of pharmacy



Prefecture administration of pharmacy

- Responsibilities of prefecture FDA are mainly related to the categories as below:
  - implementation of the national standard and drug management and the quality control standard
  - Responsible for first review and re-approval of drugs
  - Responsible for drugs and cosmetics safety evaluation 。
  - Implement of ADR monitoring and re-evaluation。
  - Market access and certification of pharmaceutical wholesalers 。
  - Registration and monitor of medical devices

Prefecture administration of pharmacy



Prefecture administration of pharmacy

- Responsibilities of prefecture FDA:
  department of drugs and cosmetics registration
  - implement the national drug standards, including packaging material and container, medicinal requirements and standards,
  - First review and re-evaluation of drug registration
  - to guide the formulation of traditional medicine local standards, supervise the implementation of Chinese herbal medicine processing; implementation of the TCM protection system.
  - supervise the implementation of drug non-clinical research, clinical trials of drug quality management standard

Responsibilities of prefecture FDA
department of drugs and cosmetics manufactory supervision

- drug and cosmetic safety evaluation;
- participate in the recommendation of the national essential drug list;
- implementation of drug classification system organization;
- Monitor of radioactive pharmaceuticals,narcotics, toxic drugs and psychotropic drugs, pharmaceutical precursor chemicals
- Implement of adverse drug reaction monitor and evaluation

Responsibilities of prefecture FDA
department of drugs and cosmetics marketing supervision

- Monitor of GSP compliance, including prescription drugs, OTC drugs, and Chinese herbal medicine
- Certification of pharmaceutical wholesalers access
- Supervision of local pharmaceutical market and logistics, provide guidance to drug
- Supervision of cosmetics marketing.

Responsibilities of prefecture FDA
department of medical devices supervision

- Registration and supervision of local medical devices, optimize the registration process.
- Approval of the change request of domestic medical devices belong to class3 which do not change the product quality.
- Monitor and re-evaluation of medical devices ADR

Thanks for your attention and happy new year~

Overview of Drug Supervision System in China

Affiliation:Nanjing Food and Drug Administration ,Jiangsu province ,China

Drug Supervision System（Ⅰ）

- **Central level**

  China food and drug administration (CFDA for short) is in charge of administrative supervision and technical supervision over the research, production, distribution and use of drugs and medical devices.

Drug Supervision System (Ⅱ)

- **Local level**

  Drug regulatory departments have been established in provincial、municipal and county levels.

Drug Supervision System (Ⅲ)

- The drugs administrated by durg supervision system include Chinese crude drugs, prepared slices of Chinese crude drugs, traditional Chinese medicine preparations, chemical drug substances and their preparations, antibiotics, biochemical drugs, radioactive pharmaceuticals, serum, vaccines, blood products and diagnostic agents.

Drug Supervision System (Ⅳ)

- According to China's **Regulations for the Supervision and Administration of Medical Devices**, these productions are divided into 3 classes----class I, Class II and Class III----depending on their clinical risks.
- Class III----high risk; Class I----low risk;
- Class II----between

Drug Supervision System (Ⅴ)

- Respective Responsibilities

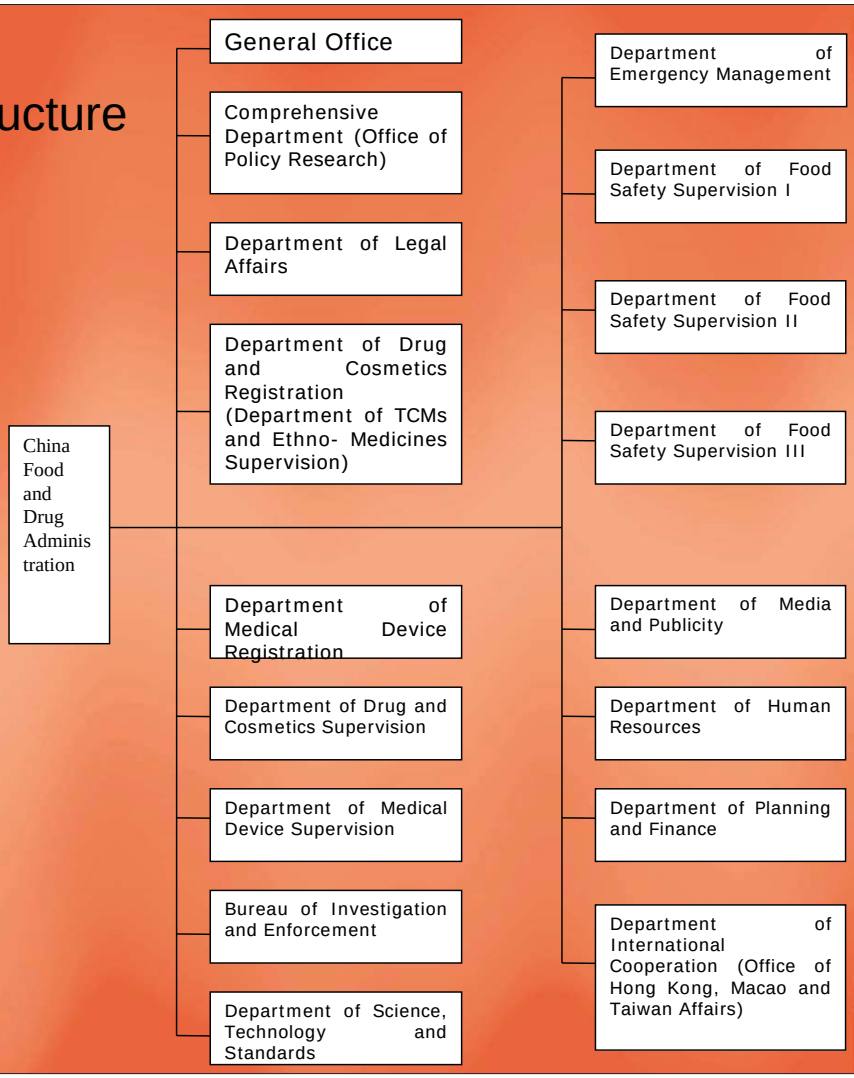
Levels	Main Responsibilities	
	registration	licensing
CFDA	**①Approval of drugs (domestic and imported)** **②Registration of medical devices (class III)**	
Provincial drug regulatory departments	**Registration of medical devices(class II)**	**To give license to:** **①pharmaceutical manufactures** **②medical device manufactures (class II and III)** **③pharmaceutical wholesalers**

Drug Supervision System (Ⅵ)

- Responsibilities respectively

Levels	Main Responsibilities	
	registration	licensing
Municipal drug regulatory departments	**Registration of medical devices (class I)**	**To give license to:** **①pharmaceutical retailers** **②medical device sellers**
County drug regulatory departments		

The inner structure of CFDA



Drug Supervision System (Ⅶ)

- The main affiliated institutions with CFDA
- 1）Center for Drug Evaluation (CDE)
- 2）Center for Certification of Drug (CCD)
- 3）National Center for ADR Monitoring
- 4）National Institutes for Food and Drug Control

5) Chinese pharmacopoeia commission

Drug Supervision System (Ⅷ)

- Center for Drug Evaluation(CDE) is an agency which is in charge of the technical evaluation of drug approvals. (new drugs, generic drugs, and imported drugs)

Drug Supervision System (Ⅸ)

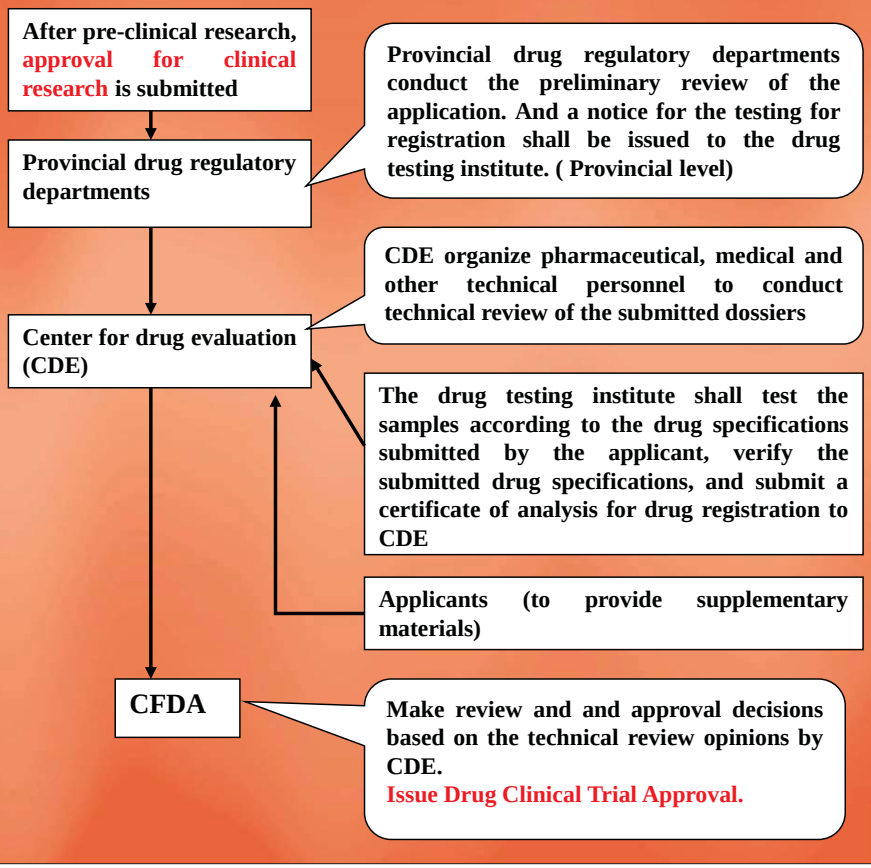
- Center for Certification of Drug (CCD) is responsibel for conducting GMP certification of pharmaceutical producers in China. It also carry out GMP certification of medical device producers, GAP (good agricultural practice) certification, GCP certification of medical institutions, GLP (good laboratory practice) certification of drug research institutions.

Drug Supervision System (Ⅹ)

- The missions of National Institutes for Food and Drug Control
- 1) to undertake registration testing of drug
- 2) to carry out the post market surveillance testing, contract testing, sampling testing, and safety evaluation of drug
- 3) to organize the re-testing and technical evaluation of drug

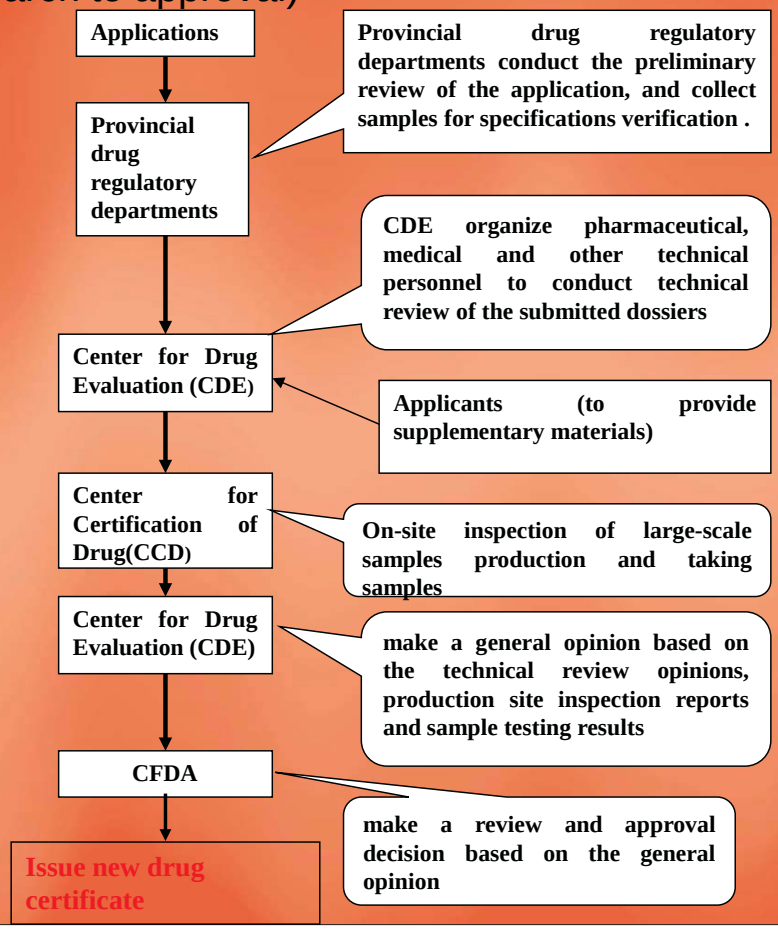
Brief Flow Chart of Drug Approval

(from pre-clinical research to clinical research)



Brief Flow Chart of Drug Approval

(from clinical research to approval)



Drug Safety Legal System (Ⅰ)

- **1. Main Laws and administrative regulations in this field**
- 1) Drug Administration Law
- 2) Regulations for the Implementation of the Drug Administration Law
- 3) Regulations for the Supervision and Administration of Medical Devices

Drug Safety Legal System (Ⅱ)

- 4) Regulations for the Control of Narcotic Drugs and Psychotropic Drugs
- 5) Measures for the Control of Radioactive Drugs
- 6) Regulations for the Control of Blood Products
- 7) Regulations for the Administration of Distribution of Vaccines and Vaccination

Drug Safety Legal System (Ⅲ)

2. Outlines of Drug Administration Law

- Chapter I General Provisions
  Chapter II Control over Drug Manufacturers
  Chapter III Control over Drug Distributors
  Chapter IV Control over Pharmaceuticals in Medical Institutions
  Chapter V Control over Drugs
  Chapter VI Control over Drug Packaging
  Chapter VII Control over Drug Pricing and Advertising
  Chapter VIII Inspection of Drugs
  Chapter IX Legal Liabilities
  Chapter X Supplementary Provisions

Drug Safety Legal System (Ⅳ)

2. Outlines of Regulations for the Supervision and Administration of Medical Devices

- Chapter I General Provisions
  Chapter II The Administration of Medical Devices
- Chapter III Administration of Production, Distribution and Use of Medical Devices
  Chapter IV Supervision of Medical Devices
- Chapter V Penalties
  Chapter VI Supplementary Provisions

Drug Safety Legal System (Ⅴ)

- **3. Outlines of Chinese Pharmacopoeia(2010 edition, 3 volumes)**
- **Volume I** 2,136 monographs including Chinese crude drugs, prepared slices of Chinese crude drugs, herbal oil, fats and extracts, and compound and single prescriptions
- **Volume II** 2,220 chemical drugs, antibiotics, biochemicals, radioactive pharmaceuticals and pharmaceutical excipients
- **Volume III** 131 biological products

Malaysia

GOOD GOVERNANCE OF MEDICINES FOR NATIONAL PHARMACEUTICAL REGULATORY AUTHORITIES (JFY 2013)

POSITION : **SENIOR ASSISTANT DIRECTOR**

NAME OF ORGANISATION : **NATIONAL PHARMACEUTICAL CONTROL BUREAU, MINISTRY OF HEALTH**

COUNTRY : **MALAYSIA**

1. PHARMACEUTICAL LEGISLATION

1.1 Legislation on Pharmaceutical Administration

List of laws / regulation covering pharmaceutical affairs: Under the law,

- the importation, manufacturing, sale and use of poisons (including psychotropic substances and dangerous drugs) and products (medicines, health supplements and cosmetics)
- the practice of pharmacists, and
- advertisements relating to products, medical skills and services

are regulated and controlled by the following Acts and Regulations:

i. Poison Act 1952 and its regulations
ii. Dangerous Drugs Act 1952 and its regulations
iii. Sale of Drugs Act 1952 (Revised 1989) & Control of Drugs and Cosmetics Regulation 1984
iv. Registration of Pharmacists Act 1951 (Revised 1989) and its regulations
v. Medicines (Advertisement and Sales) Act 1956 (Revised 1983) and its regulations

1.2 Organizational Structure

- Ministry of Health Organization Chart (refer Figure 1)
- National Pharmaceutical Control Bureau Organization Chart (refer Figure 2)

The role of national/state pharmaceutical administrative organizations

The National Pharmaceutical Control Bureau (NPCB) is a government agency in Malaysia that regulates pharmaceutical, natural (traditional) and cosmetic products. The NPCB is responsible for ensuring the quality, efficacy and safety of pharmaceutical products, as well as the quality and safety of natural (traditional) products and cosmetics marketed in the country. With the promulgation of the Control of Drugs and Cosmetics Regulations 1984 (CDCR), the Drug Control Authority (DCA) was established in 1985. The NPCB which acts as the secretariat to the DCA achieves its objectives through its registration and licensing scheme. The roles and functions of NPCB are:

i. To implement the drug registration / cosmetic notification scheme through evaluation of technical data, laboratory analysis, research and information received from international agencies.

ii. To carry out analytical, pharmaceutical, microbiological and pharmacological tests on drugs and cosmetics to determine quality, efficacy and safety of such products.

iii. To implement the regulatory scheme on quality of pharmaceutical products in the market through random sampling and carrying out analytical tests.

iv. To implement the licensing scheme for pharmaceutical manufacturers, importers and wholesalers including a licensing scheme for clinical trial.

v. To encourage and assist local pharmaceutical manufacturers to upgrade manufacturing standards to levels equivalent to the requirements of Good Manufacturing Practice as recommended by the World Health Organization (WHO).

vi. To manage the Adverse Drug Reaction Monitoring Program and participate in the WHO International Adverse Drug Reaction Monitoring Program.

vii. To manage the product recall scheme for pharmaceutical products which are found to be substandard or dangerous to consumers.

viii. To disseminate information on policies/news of the Drug Control Authority (DCA) via the newsletter as well as provide service in the aspect of explaining to the public on the process of on-line registration, information on registered products and other queries pertaining to NPCB.

ix. To carry out research on methodology and basic research for the purpose of evaluating quality, efficacy and safety of drugs/ cosmetics.

x. To establish a reference standard system especially for use in this country generally and for neighboring countries through a scheme of cooperation in the field of pharmaceuticals among ASEAN countries.

xi. To carry out training for pharmaceutical officers, other professional officers and other semi-professional officers who are placed in this institution from time to time through local training scheme or international co-operational scheme. There are seven centres under the NPCB:

- Centre for Product Registration •

Centre for Post-Registration

- Centre for Compliance and Licensing •

Centre for Quality Control

- Centre for Investigational New Product •

Centre for Organizational Development

- Centre for Administration

The establishment of the Pharmaceutical Services Division in January 1974, under the Ministry of Health Malaysia, has remarkably led to the expansion in the role and functions of the overall pharmacy services, which contributed towards development of the healthcare sector. The Pharmaceutical Services Division currently undertakes three component activities namely Quality Assurance of Pharmaceutical Products, Pharmacy Enforcement and Licensing, and Pharmaceutical Care. The Pharmaceutical Services Division in the Ministry of Health ensures that the Malaysian public is accessible to quality, safe, efficacious and affordable pharmaceutical and healthcare products including advice in using medicines rationally.

1.3 Priority Issues on Pharmaceutical Regulatory Services

a. Handling of product complaints

The number of queries as well as complaints received by the organization is continuing to increase over time. This is in line with the abundance of products promoted in the market via various channels such as the internet, newspaper, magazines, etc. With the advancement of technology, this queries and complaints are also received through various channels such as Facebook, direct complaints, newspaper, e-mails and so forth. As an example, via one of the methods i.e. e-mail (Pharmacy1) coordinated by the Pharmaceutical Services Division, the average number of complaints received per month is 300 whereas direct queries received by NPCB's Helpdesk averages at 544 per month. A major issue that arises due to this is how to handle and manage the high number of queries/complaints received through such diverse methods.

b. Classification of interphase products

Currently, there are a vast number of products in the market, whereby some of these products fall in the grey area between different categories. These are known as interphase products. Examples of such products include beverages which contain conventional food ingredients such as sugar and milk in addition to registrable

ingredients such as collagen, herbs and etc. Such products need to be classified to determine whether they are considered as food (which is under the purview of the Food Safety and Quality Division in Malaysia) or a registrable pharmaceutical / traditional product (which is under the purview of the NPCB in Malaysia). When more than one organization carries out product classification for such products, there is duplication of work as well as high risk of contradicting decisions being made for a particular product.

c. Challenges faced in product safety monitoring

The main challenges faced in product safety monitoring is the low number of reports on adverse drug reactions (ADRs) received from the private healthcare sector, especially retail pharmacists and general practitioners. This under-reporting will affect the detection of ADR signals and hence national drug safety decisions. In addition, a large number of reports received are not of good quality in terms of completeness. When incomplete reports are received, the reporter has to be re-contacted to provide further details to allow more accurate causality assessment. Detection of ADR signals is done manually, resulting in slower identification of signals. Currently, there is no efficient automated system to analyze ADR data and generate early signals which would enable risk minimization or regulatory action to be taken on products with safety issues. Although the number of ADR reports received has been growing steadily over the years, the increase in the number of staff has not been proportional to the workload. The backlog in processing cases results in difficulties in obtaining further information and tracing reporters.

2. STATISTICAL DATA (2013)

(a) Number of Pharmacists and Inspectors

	Data
Pharmacist	11,372
Inspectors	22

(b) Number of Manufacturers / Manufacturing Sites

Pharmaceutical	**Over the Counter**	**Traditional**	**Veterinary**	**Total**
35	54	169	5	94

(c) Number of Pharmaceutical Importers / Wholesalers

	Poison	Non Poison	Traditional	Veterinary	Health Supplement	Total
Importers	110	132	143	5	0	390
Wholesalers	602	353	191	4	-	1150

3. INTRODUCTION OF WORK

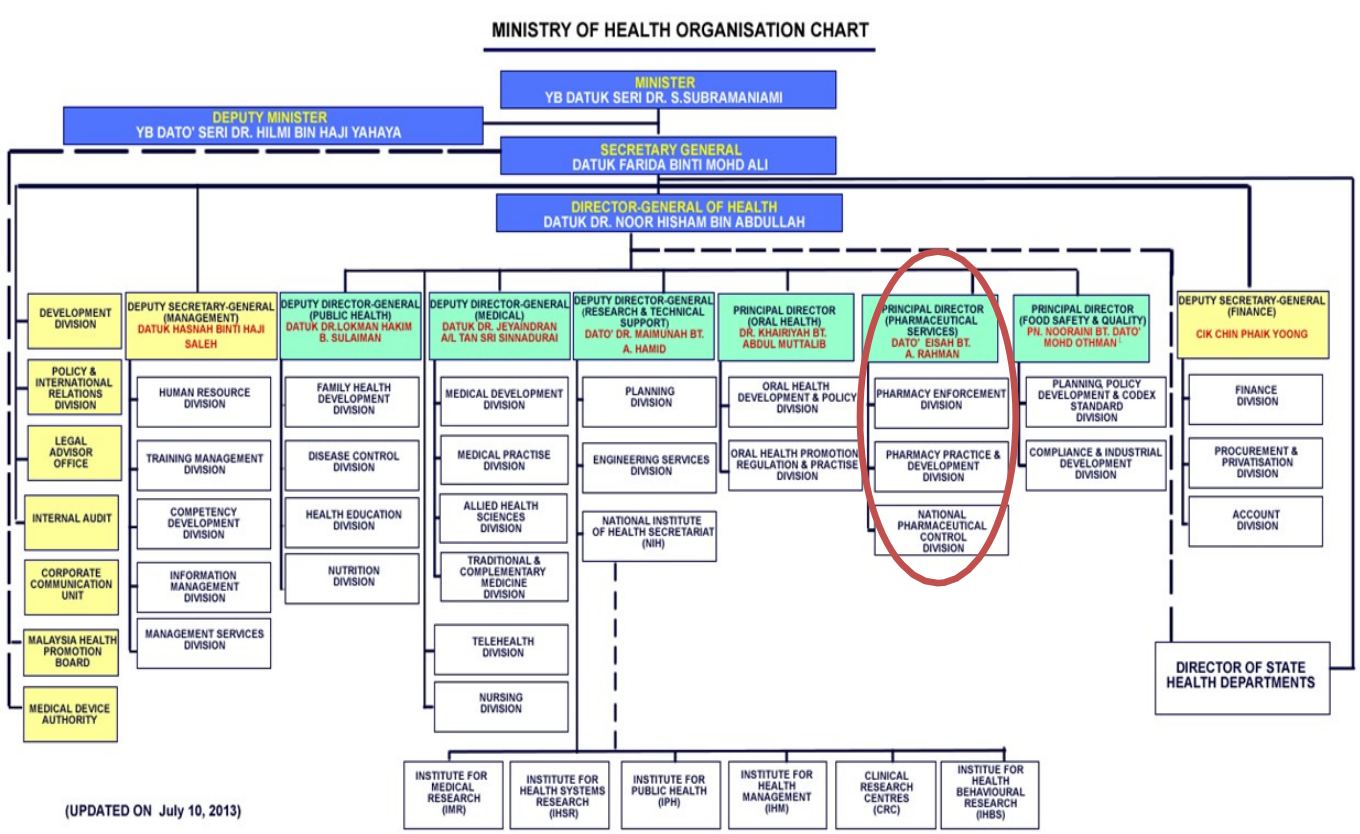
3.1 Engagement in Regulatory Services

- Working in the Centre for Organizational Development which oversees the overall organizational needs and policy implementation. The responsibility focuses on overseeing and following up all issues and aspects regarding to ISO 9001 Quality Management System in NPCB.
- Also acts as the Liaison Officer for NPCB in all matters regarding to implementation of GGM.
- Head of Internal Audit Core Team, thus manages / oversees all internal as well as external audits.
- Investigation and handling of complaints received from customers, other relevant agencies, relevant industries, internal staff, etc.

3.2 Interest Topics

- Strengthening and enhancing the quality of services with specific focus on ISO and quality issues.
- To re-evaluate the work processes to continually improve and strengthen the implementation of Good Governance of Medicines in this organization.
- To strengthen and improve the services delivered by the NPCB especially with regards to handling queries and complaints.

Figure 1: Ministry of Health Organization Chart



Job Report Presentation

Good Governance of Medicines for National Pharmaceutical Regulatory Authorities (JFY 2013)

Quality Coordination, Competency and Communication Section
Center for Organizational Development
National Pharmaceutical Control Bureau
Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor

Website : www.bpfk.gov.my

WHO Collaborating Centre
for Regulatory Control of Pharmaceuticals

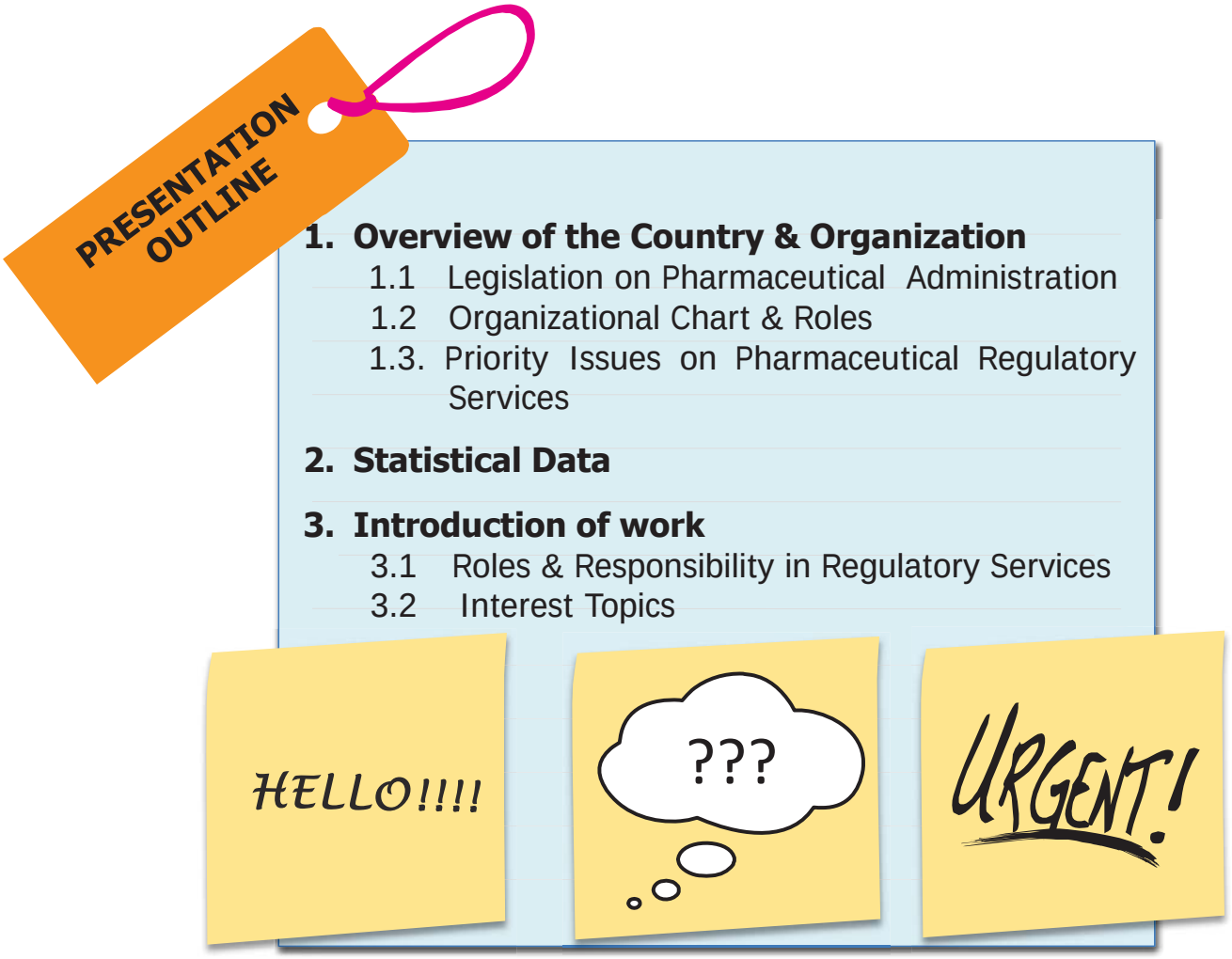
QUALITY SYSTEM
SIRIM
Certified to ISO 9001:2008
Cert. No.: AR 2293

PIC/S
Member of Pharmaceutical
Inspection Co-operation Scheme

STANDARDS MALAYSIA
ACCREDITED LABORATORY
MS ISO/IEC 17025:2005
NO: SAMM 450

OECD
Non-Organisation for Economic
Cooperation And Development (OECD)

National Pharmaceutical Control Bureau
MINISTRY OF HEALTH MALAYSIA



OUTLINES

1. **Overview of the Country & Organization**
2. Legislation on Pharmaceutical Administration
3. Organizational Chart & Roles
4. Priority Issues on Pharmaceutical Regulatory Services
5. Statistical Data
6. Introduction of work
7. Roles & Responsibility in Regulatory Services
8. Interest Topics

COUNTRY PROFILE (MALAYSIA)

Malaysia : Country Profile

Capital	Kuala Lumpur
Land Area	329,847 square kilometres (127,350 sq mi) It consists of thirteen states and three federal territories
Population	28.25 million (2010)
Government Type	Constitutional Monarchy
Currency	Malaysian Ringgit (RM 3.00 to 1 USD)
Major Language	Malay (official), English, Chinese, Tamil
Major Religions	Islam, Buddhism, Taoism, Hinduism, Christianity.
Major Imports	Manufacturing inputs, machinery & transport equipment, metal product
Major Exports	Electronic equipment, petroleum & liquefied natural gas, chemicals, palm oil, wood & wood products, rubber, textiles.

Sources: Department of Statistics, Malaysia

OUTLINES

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LEGISLATION ON PHARMACEUTICAL ADMINISTRATION

List of laws / regulation covering pharmaceutical affairs:

- **Poison Act 1952 and its regulations**
  (An act to regulate the *importation, possession, manufacture, compounding, storage, transport, sale and use of poisons).*
- **Dangerous Drugs Act 1952 and its regulations**
  (*An Act to make further and better provision for the regulating of the importation, exportation, manufacture, sale, and use of opium and of certain other dangerous drugs and substances).*
- **Sale of Drugs Act 1952 (Revised 1989) & Control of Drugs and Cosmetics Regulation 1984**
  (*An Act relating to the sale of drugs*-**Regulation 7(1):** No person shall manufacture, sell, supply or import any product unless, the **product** is a registered product ; the person holds the appropriate **licence** issued under this regulation)
- **Registration of Pharmacists Act 1951 (Revised 1989) and its regulations**
  (*An Act relating to the establishment of a Pharmacy Board and the registration of pharmacists).*
- **Medicines (Advertisement and Sales) Act 1956 (Revised 1983) and its regulations**
  (*An Act to prohibit certain advertisements relating to medical matters and to regulate the sale of substances recommended as a medicine).*

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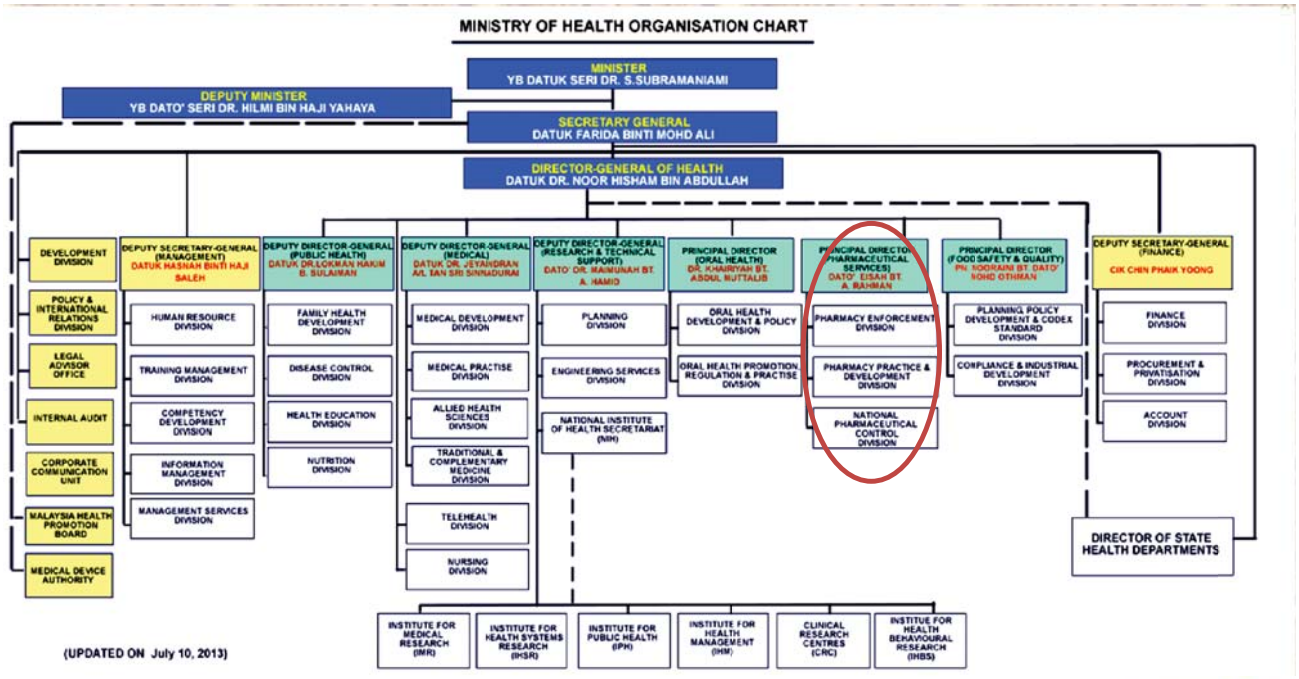
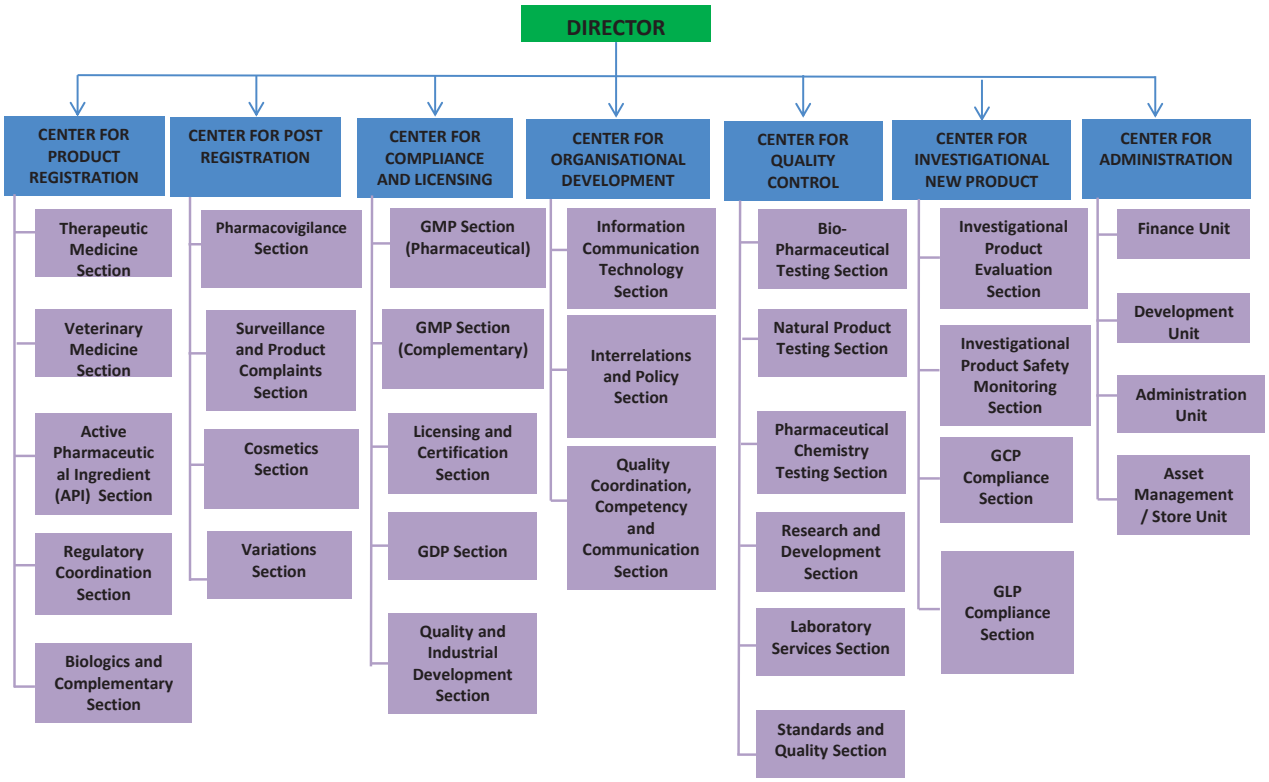
ORGANISATION CHART MINISTRY OF HEALTH MALAYSIA



ORGANIZATION STRUCTURE OF NATIONAL PHARMACEUTICAL CONTROL BUREAU



Core Functions of NPCB

- **Evaluate and register products** *(Evaluation of dossiers, BA/BE Study Reports – Prescriptions / non, Health Supplements, Traditional, NCE and Biotechnology)*
- **Notification of Cosmetics**
- **Analysis of samples** *(Pre-registration, Post-Market Surveillance, Enforcement-Screening for Adulterants)*
- **Inspect premises** *(surveillance, verification, investigation, pre-licensing)* **and issue licenses** *(Manufacturers, Importers, & Wholesalers)*
- **Issue Clinical Trial Import License**
- **Post-registration market surveillance**
- **Adverse drug reaction (ADR) monitoring**
- **Disseminate product information**
- **Training** *(local and international visitors in areas relating to manufacturing practices, pharmaceutical analysis, product registration, and the licensing system practiced in the country)*
- **Collaboration at international and regional level**

The NPCB has successfully played its role as the Secretariat to the Drug Control Authority or DCA, to ensure that therapeutic products approved for the local market are safe, effective and of quality, and also to ensure that traditional medicines and cosmetics approved are safe and of quality.

DRUG CONTROL AUTHORITY (DCA)

- Established in 1985 under The Control of Drugs and Cosmetics Regulation (CDCR) 1984
- The main objective of DCA is to ensure that pharmaceuticals, marketed in Malaysia are safe, efficacious and of quality and that the traditional medicines, health and personal care products are safe and of quality.
- National Pharmaceutical Control Bureau (NPCB) set up in 1978, currently serves as Secretariat to DCA

Members of DCA

Members are appointed by the Minister of Health for a period of 3 years but eligible for re-appointment.

Members consist of the;

- Director General of Health (Chairman),
- Director of Pharmaceutical Services (Alternate Chairman),
- Director of NPCB,
- and 8 other members
  - ✓ A consultant physician in the public service,
  - ✓ A pharmacist in the public service,
  - ✓ 3 persons from any local universities with expertise in pharmaceutical sciences
  - ✓ 2 fully registered medical practitioners
  - ✓ A veterinarian in the public service

The Secretary is a pharmacist in the public service.

Functions of the DCA

The DCA is empowered by law to:

(i) review matters related to PRODUCT REGISTRATION

(ii) consider recommendations proposed by Secretariat and;

- register any product subject to such conditions as it may impose
- reject any application for the registration of any product
- grant exemptions
- issue such certification required by any country importing such a product
- suspend or cancel registration of any product
- make decisions related to REGULATORY POLICIES

(iii) Maintain a register of the products registered

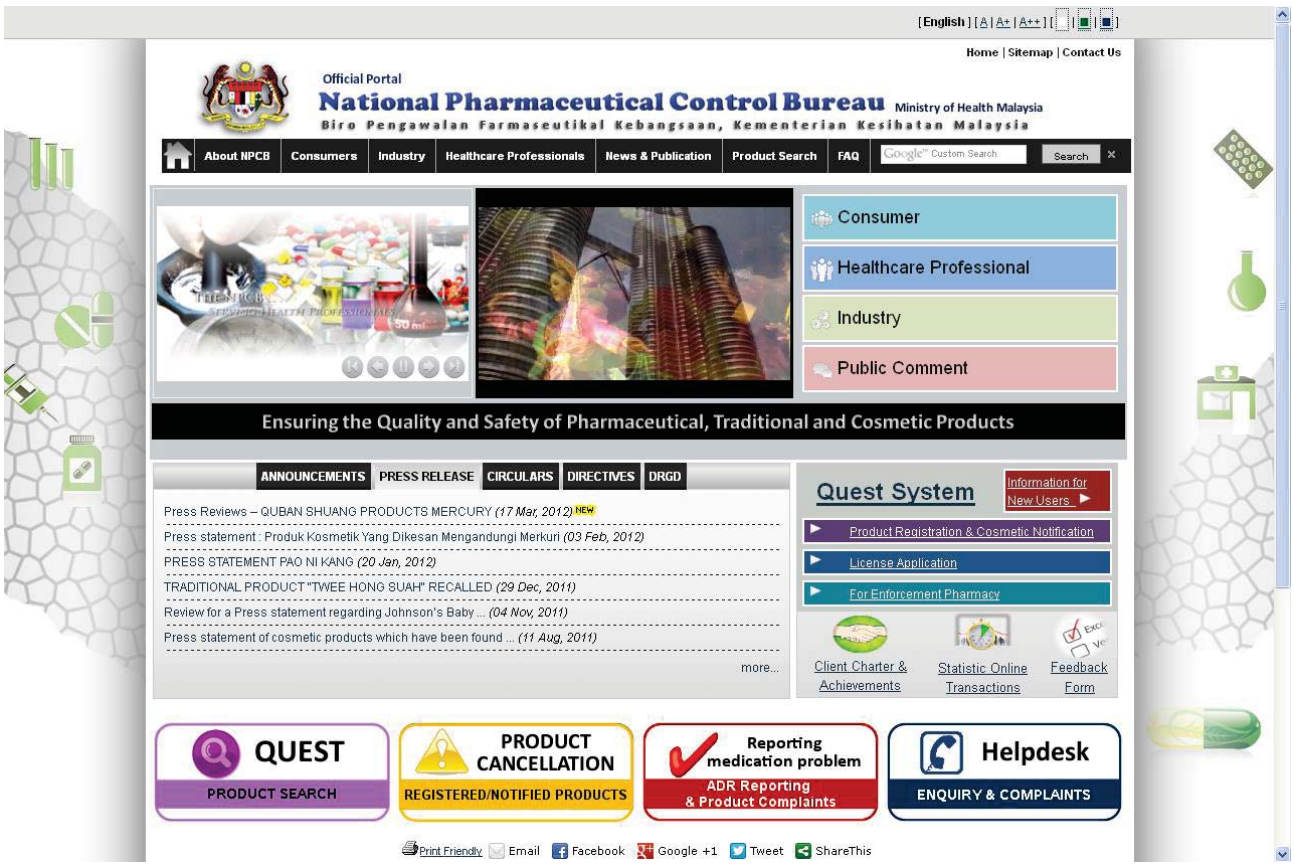
(iv) Impose REQUIREMENTS for registration of products

ON-LINE REGISTRATION (QUEST)

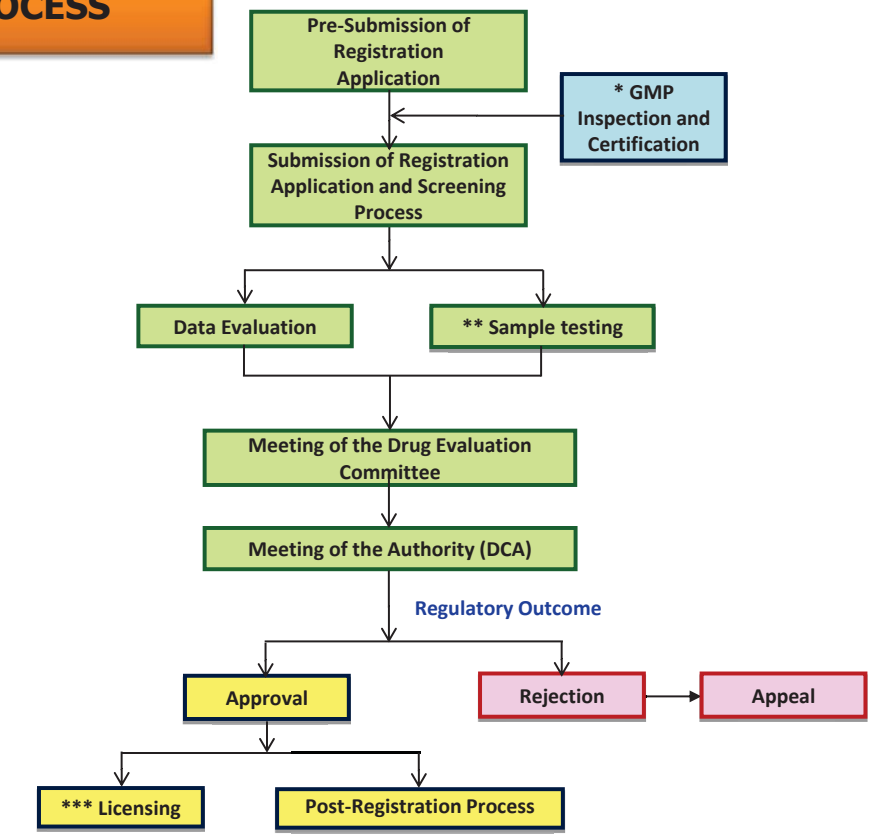
- On-line web-based system since:
  - 2002 – QUEST 2
  - 2010 – QUEST 3

- Submission of data can be done at anytime - 24 hrs a day, 365 days a year, from any part of the world
- QUEST 2 is an online registration system for all categories of products (A, X, T and K) except for New Chemical Entity and Biotechnology products.
- It was then upgraded to QUEST 3 system starting end of 2010 – online registration for all category of products

NPCB Website www.bpfk.gov.my



REGISTRATION PROCESS



* Good Manufacturing Practice (GMP) Certification
** For natural products only
*** Application for Manufacturer, Import and/or Wholesale License

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PRIORITY ISSUES ON PHARMACEUTICAL REGULATORY SERVICES

- **Handling of Product Complaints**
  - queries and complaints are received through various channels such as face book, direct complaints, newspaper, e-mail and so forth
- **Classification of Food-Drug Interface Product**
  - some of the products are not clearly marketed as “food” or “drugs” and include a variety of so-called health products. Such products need to be classified before undergone the registration process.
- **Challenges in Product Safety monitoring**
  - low number of reports on adverse drug reactions (ADRs) received from the private healthcare sector, especially retail pharmacists and general practitioners.

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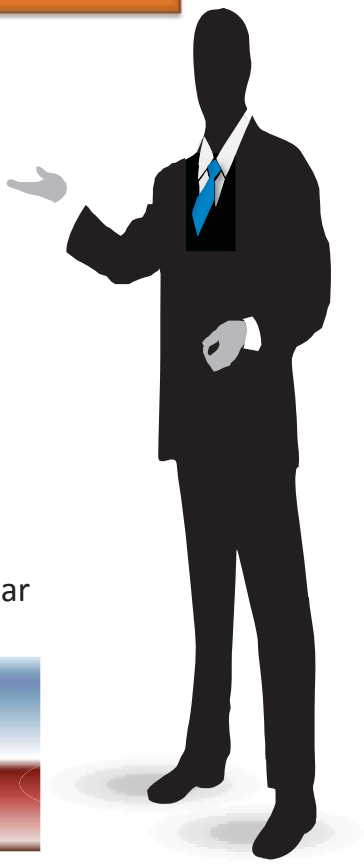
Statistical Data

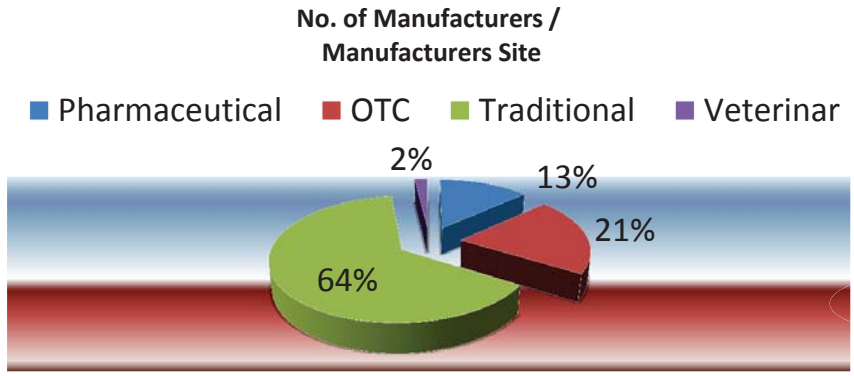
a) Number of Pharmacists and Inspectors

	Data
Pharmacist	11,372
Inspectors	22



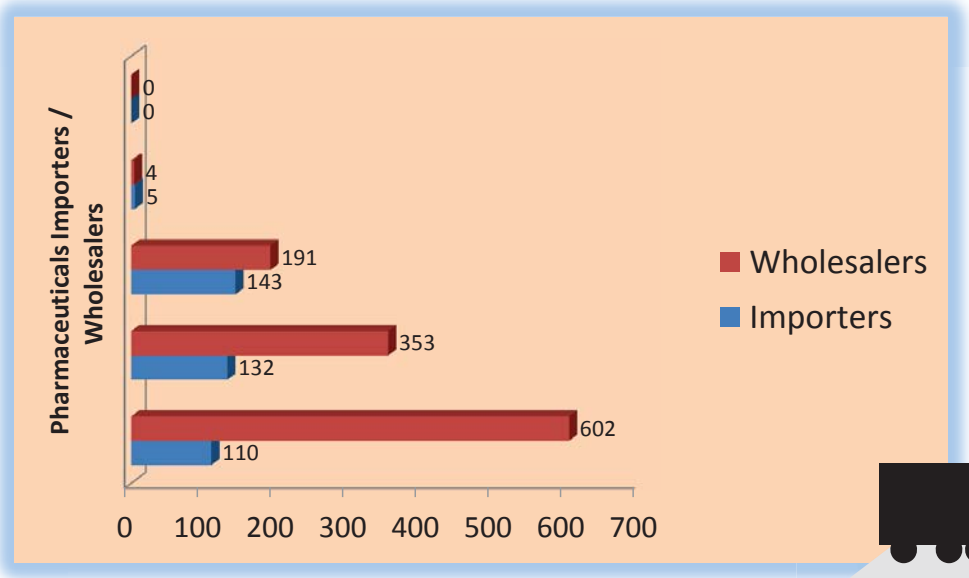
b) Number of Manufacturers / Manufacturing Sites

Pharmaceutical	Over the Counter	Traditional	Veterinary	Total
35	54	169	5	94



c) Number of Pharmaceuticals Importers / Wholesalers

	Poison	Non Poison	Traditional	Veterinary	Health Supplement	Total
Importers	110	132	143	5	0	390
Wholesalers	602	353	191	4	-	1150



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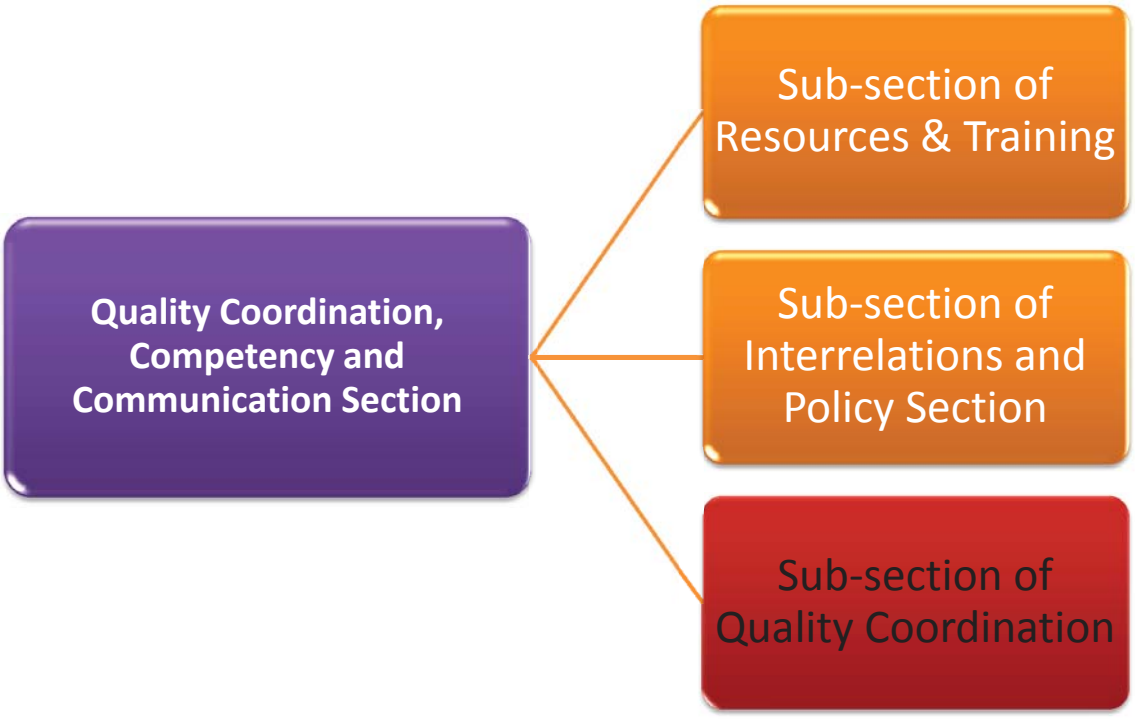
Quality Coordination, Competency and Communication Section



QUALITY COORDINATION, COMPETENCY AND COMMUNICATION SECTION

QUALITY SYSTEM

SIRIM

- Activity:
  - Quality Management System (MS ISO 9001)
  - Quality Policy
  - Internal Audits - Planning, implementation & verification
  - Management Review Meeting (JKKSP) twice a year
    - NPCB's Client charter (8 major Indicators)
    - Quality Objectives (19 indicators)
    - Customer complaints
    - Customer satisfaction survey
    - Human resource / projection
    - Work environment
    - Process performance and product conformity
    - Status of preventive and corrective actions
  - Document Control System (DCC_online)
    - Allows documents / quality procedures (QP) to be accessed by all NPCB staff. On-line version is the only official, authorized version
  - External agency meeting
    - National Indicator Meeting
    - Innovation and Creativity Meeting
    - Quality Initiatives

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Roles & Responsibility in Regulatory Services

Oversees the overall organizational need and policy implementation. The responsibility focuses on overseeing and follows up all issues and aspect regarding to ISO 9001 Quality Management System in NPCB.

Liaison Officer for NPCB in all matters regarding implementation of GGM

Head of Internal Audit Core Team and look after internal and other external audits.

Investigation and handling of complaints received from customer, other relevant agency, industry, internal staff, etc.

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NATIONAL PHARMACEUTICAL CONTROL BUREAU

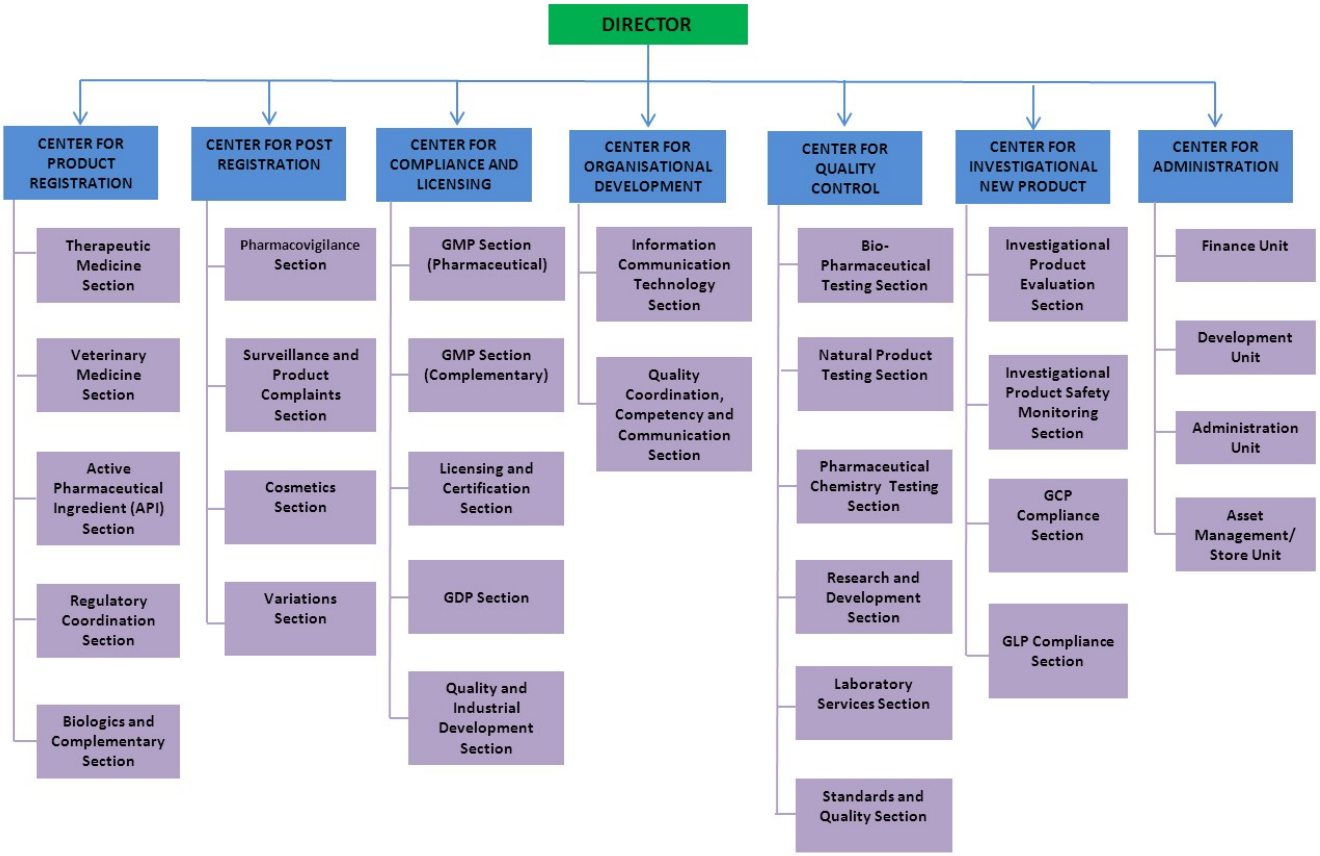
QUALITY COORDINATION, COMPETENCY AND COMMUNICATION SECTION

INTEREST TOPICS

- ✓ Strengthening and enhancing the quality of services with specific focus on ISO and quality issues.
- ✓ To re-evaluate work process to continual improve and strengthening the implementation of Good Governance of Medicines in this organization.
- ✓ To strengthen and improve the services delivered by NPCB especially in handling queries and complaints.


TERIMA KASIH
Thank You
MALAYSIA TRULY ASIA

Figure 2: National Pharmaceutical Control Bureau Organization Chart



GOOD GOVERNANCE OF MEDICINES FOR NATIONAL PHARMACEUTICAL REGULATORY AUTHORITIES
(JFY 2013)

JOB REPORT

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

1. Overview of Organization

1.1 Overview of Legislations 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.

1.2 The Role and Responsibility of Pharmaceutical Administration at National/ State and Local Levels

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)**

(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 optimized 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.

1.3 Priority Issues on Pharmaceutical Regulatory Services

(a) **Adulteration of Pharmaceutical Products and Food Supplements**

The emergence of traditional medicines and food supplements which are deliberately mixed with controlled medicine. **(Appendix C)**

(b) **Sale of Pharmaceutical Products via Internet**

There are demands from retailer pharmacies to provide sale of pharmaceutical products via the internet. Currently, there is no provision of the laws or guideline issued to regulate such kind of sale.

(c) **Importation of Pharmaceutical Products**

There are an increase number of pharmaceutical products imported via mail and courier screened by the Pharmacy Enforcement at the entry point. **(Appendix D)**

2. Statistical Data

No.	Subject	Data	Year
(a)	Number of Pharmacists	11,372	2013
(b)	Number of Inspectors (National and Local)	22	2013
(c)	Number of Pharmaceutical Manufacturers/ Manufacturing Sites	94	2013
(d)	Number of Traditional Medicines Manufacturers/ Manufacturing Sites	169	2013
(e)	Number of Pharmaceutical Importers	390	2013
(f)	Number of Pharmaceutical Wholesalers	1,150	2013

3. Introduction to National Regulatory Services

3.1 Description of Regulatory Services

Organization and manpower of the Pharmacy Enforcement is divided into five (5) main activities, namely:

(a) **Intelligence, Operation and Audit** - conduct intelligence, raids and audits based on the information received/ gathered.

(b) **Licensing and Control at Entry Point** - processing relevant licenses/ permit/ authorization, coordinate and monitor screening and inspection activities on imported products and controlled substances at the entry points.

(c) **Legislation** - regulate the activities of legislation involves gazette, amendments, processing special exemptions, conduct and monitoring the progress of investigation and prosecution under the Acts in force.

(d) **Advertisement and Innovation** – process medicinal products and services advertisement approval, monitor advertisements advertised, conduct and monitoring the progress of investigation and prosecution, compile and coordinate enforcement statistics and coordinate the activities and training of Pharmacy Enforcement officers.

(e) **Protection and Consumer Awareness** –coordinate and monitor consumer awareness regarding the usage of registered products, research and development activities, conduct analysis on the sample of products available in the market and prepare and publish materials related to the consumer awareness campaign.

3.2 Interest Topics

(a) **Measures to Address Adulteration in Pharmaceutical Products and Food Supplements**

Identification of action and implementation of effective legislative measures taken on offenders and adulterated medicines including revised approaches to ensure that standards for quality, safety and efficacy are implemented and distribution chains effectively controlled.

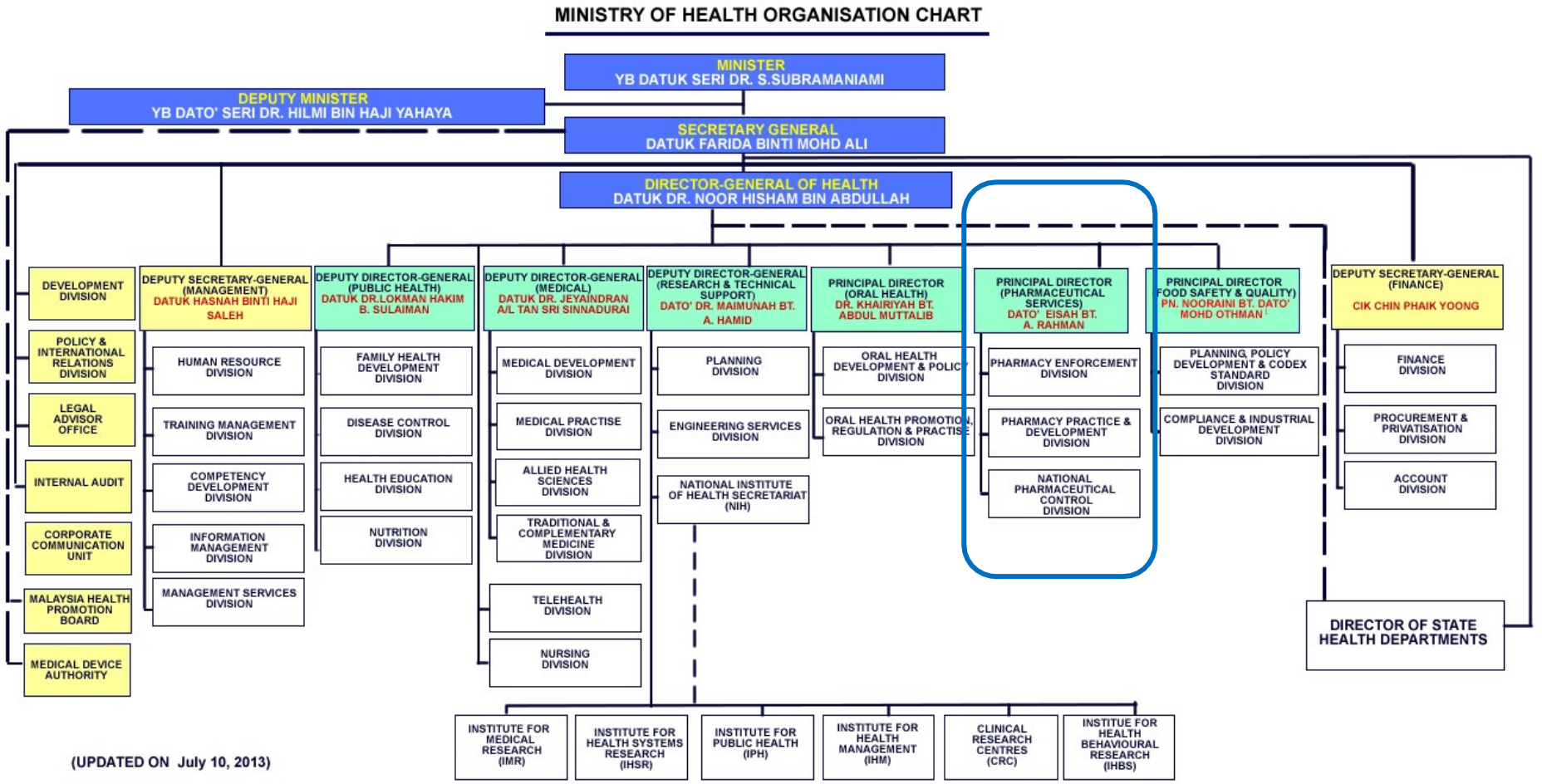
(b) **Drafting and Implementation of Legislation and Guideline to Regulate Sale of Pharmaceutical Products via Internet**

The development of legislation and guideline that regulate the sale of pharmaceutical products via internet while continuing to assure safety and efficacy of pharmaceutical products.

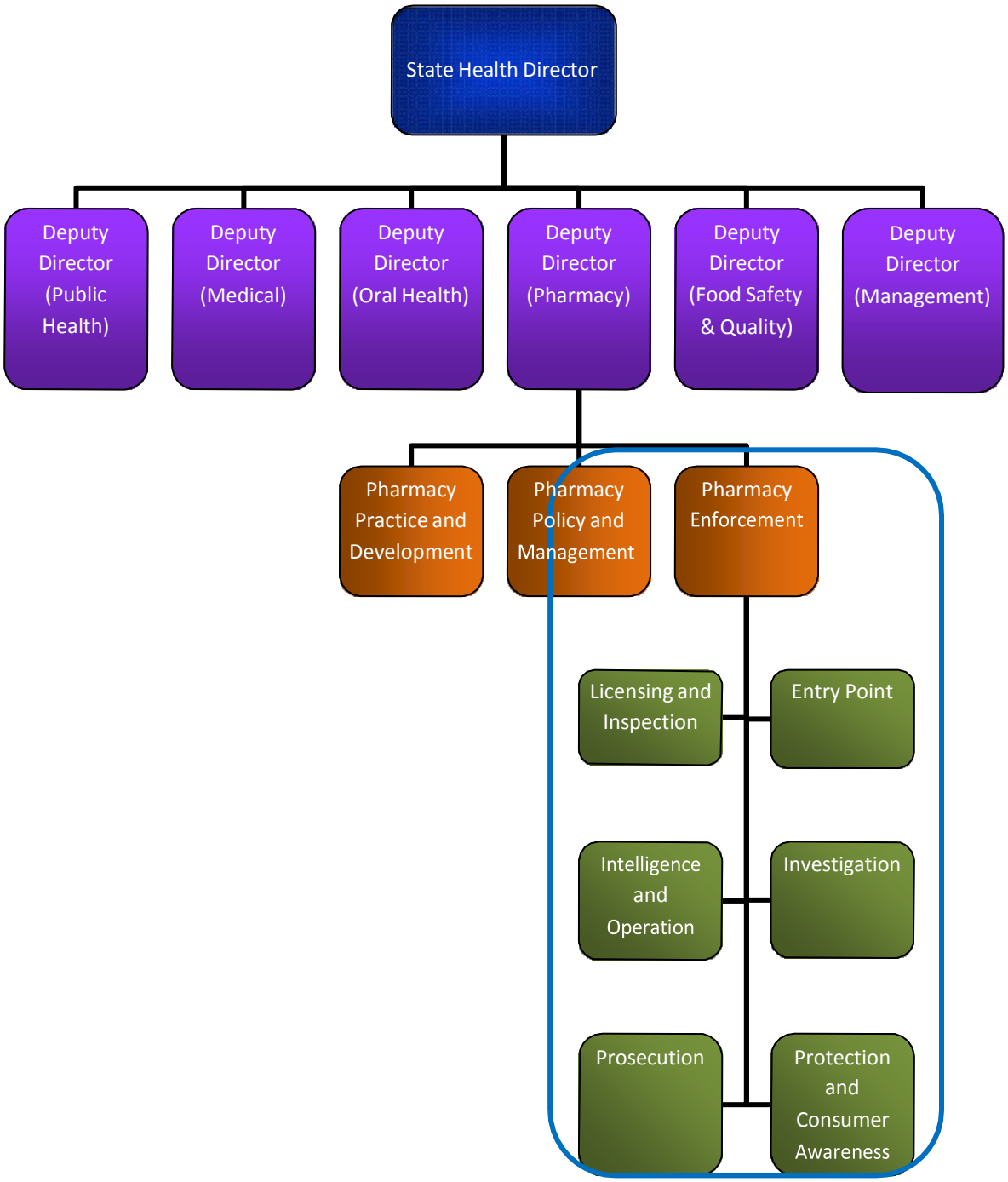
(c) **Issuance of Guidelines Procedure**

There are numbers of guidelines issued from time to time to the pharmaceutical industry players and health care professionals relating to the updates of control of pharmaceutical products in the market. It is crucial to identify a systematic procedure to issue these guidelines for the better implementation.

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



(i) **State Level** Appendix B



List of Adulterants Detected in Sample Analysis

NAMA UBAT/ADULTERAN YANG DIKESAN MELALUI ANALISA SAMPEL 2012

No.	Nama Ubat / Adulteran	Bilangan	No.	Nama Ubat / Adulteran	Bilangan
1	Analgesics (e.g: Propyphenazone, PCM)	15	12	Melamine	0
2	Anesthetic (e.g: Lignocaine, Ketamine, Lidocaine)	2	13	Methadone	1
3	Antibiotics	9	14	Nicotimide	0
4	Antidiabetic (e.g: Glibenclamide)	4	15	Nicotine	4
5	Antiepileptic (e.g: Phenobarbital)	0	16	NSAID (e.g: Phenylbutazone, Ponstan, Indocid)	39
6	Antihelmintic (e.g: Diethylcarbamazine)	1	17	Sibutramine	79
7	Antihistamine (e.g: Chlorpheniramine, Promethazine)	37	18	Sildenafil dan/atau Analog	164
8	Caffeine	40	19	Steroid	56
9	Dextromethophan	2	20	Taladafil dan/atau Analog	42
10	Heavy Metals (e.g: Pb, Merkuri)	14	21	Tretinoin	12
11	Hydroquinone	32	22	Triethanolamine	0
				Jumlah	**553**

Sumber: CPFL (pind. 2009) Manual – Pensampelan
*Bilangan ubat/adulteran yang dikesan ≠ Bilangan sampel yang dikesan positif; 1 produk mungkin mengandungi lebih daripada satu adulteran

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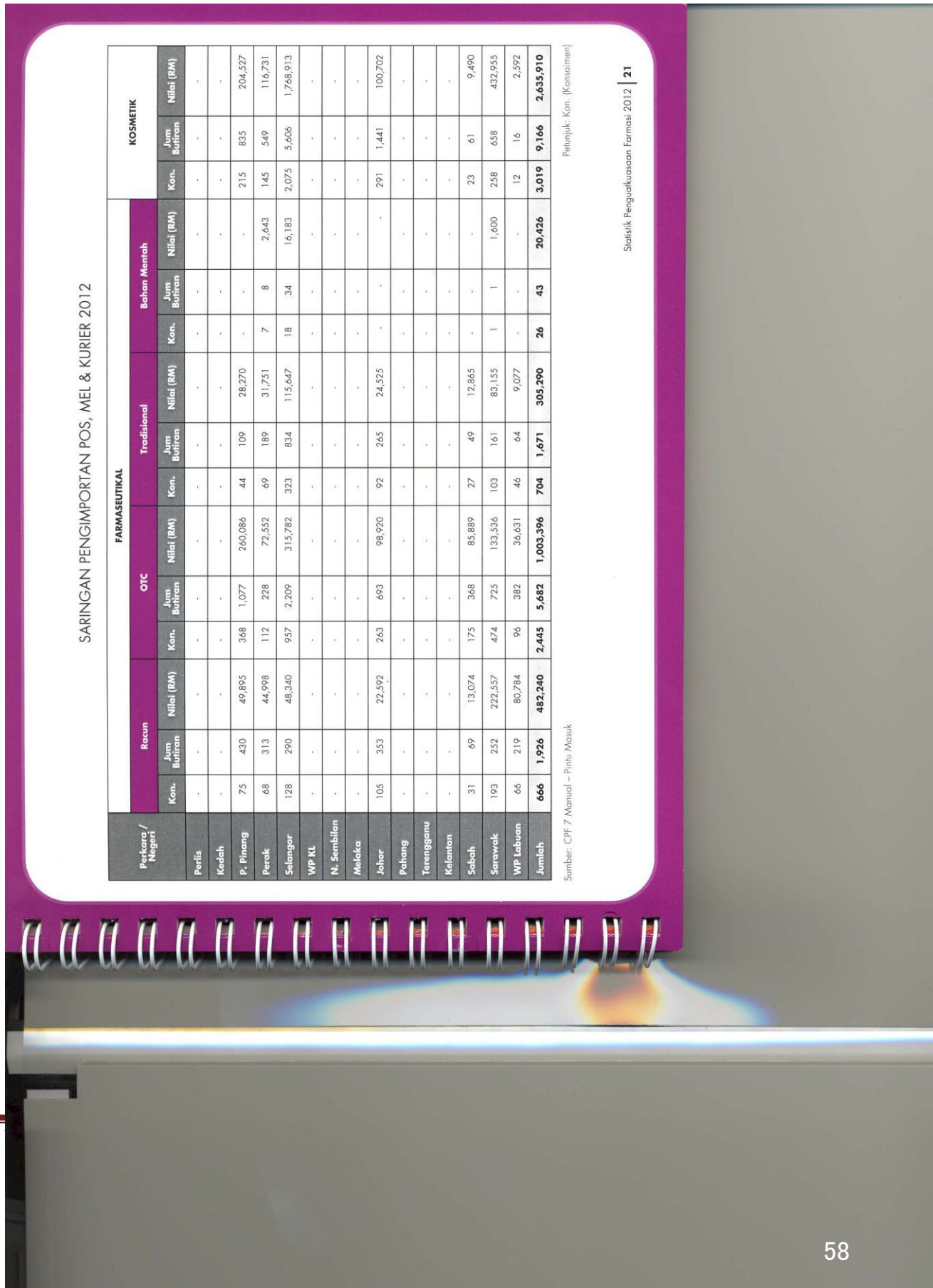
Appendix D

Screening of Importation via Postal, Mail & Courier



SARINGAN PENGIMPORTAN POS, MEL & KURIER 2012

Perkara / Negeri	FARMASEUTIKAL										KOSMETIK		
	Racun		OTC			Tradisional			Bahan Mentah				
	Kon.	Jum Butiran	Nilai (RM)	Kon.	Jum Butiran	Nilai (RM)	Kon.	Jum Butiran	Nilai (RM)	Kon.	Jum Butiran	Nilai (RM)	Kon.	Jum Butiran	Nilai (RM)
Perlis	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Kedah	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
P. Pinang	75	430	49,895	368	1,077	260,086	44	109	28,270	-	-	-	215	835	204,527
Perak	68	313	44,998	112	228	72,552	69	189	31,751	7	8	2,643	145	549	116,731
Selangor	128	290	48,340	957	2,209	315,782	323	834	115,647	18	34	16,183	2,075	5,606	1,768,913
WP KL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
N. Sembilan	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Melaka	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Johor	105	353	22,592	263	693	98,920	92	265	24,525	-	-	-	291	1,441	100,702
Pahang	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Terengganu	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Kelantan	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Sabah	31	69	13,074	175	368	85,889	27	49	12,865	-	-	-	23	61	9,490
Sarawak	193	252	222,557	474	725	133,536	103	161	83,155	1	1	1,600	258	658	432,955
WP Labuan	66	219	80,784	96	382	36,631	46	64	9,077	-	-	-	12	16	2,592
Jumlah	**666**	**1,926**	**482,240**	**2,445**	**5,682**	**1,003,396**	**704**	**1,671**	**305,290**	**26**	**43**	**20,426**	**3,019**	**9,166**	**2,635,910**

Petunjuk: Kon. (Konsainen)

Sumber: CPF 7 Manual – Pintu Masuk

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GOOD GOVERNANCE OF MEDICINES FOR NATIONAL PHARMACEUTICAL REGULATORY AUTHORITIES (JFY 2013)

JOB REPORT

MALAYSIA
PHARMACEUTICAL SERVICES DIVISION,
MINISTRY OF HEALTH MALAYSIA

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- Overview of Legislations
- Introduction to Pharmaceutical Services Division
  - Role and Organization Chart
    - Ministry of Health Malaysia
    - Pharmaceutical Services Division
    - Pharmacy Enforcement Division
  - Priority Issues
- Statistic

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- Introduction to Pharmacy Enforcement Division
  - Description of Activities
  - Interest Topics
- Others
  - Achievement

J13-00832

OVERVIEW OF LEGISLATIONS

J13-00832

LEGISLATIONS

- There are 5 Acts enforced by the Pharmacy Enforcement Division under the Pharmaceutical Services Division, Ministry of Health Malaysia.
  - Registration of Pharmacists Act 1951 (Act 371) and Regulations - the registration of pharmacists and the establishment of a Pharmacy Board.
  - Poisons Act 1952 (Act 366) and Regulations - the importation, possession, manufacture, compounding, storage, transport, sale and use of poisons.

J13-00832

LEGISLATIONS

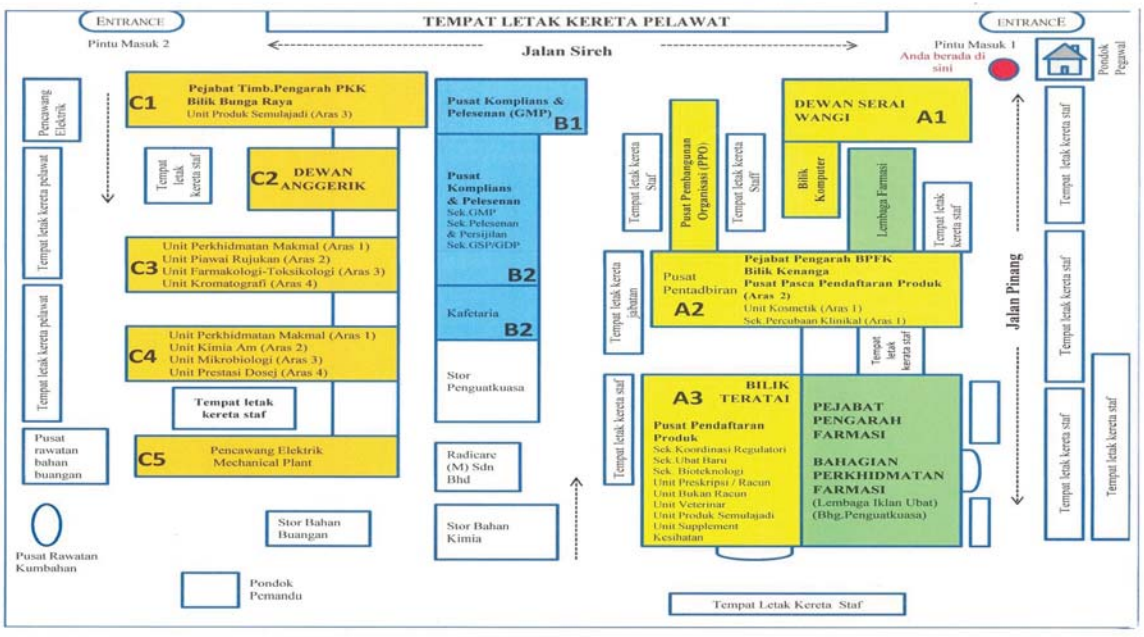
- Sale of Drugs Act 1952 (Act 368) and Regulations - the sale of drugs.
- Medicines (Advertisement and Sale) Act 1956 (Act 290) and Regulations - prohibiting certain advertisements relating to medical matters and to regulate the sale of substances recommended as a medicine.
- Dangerous Drugs Act 1952 (Act 234) and Regulations - the import, export, manufacture, sale, and use of opium and of certain other dangerous drugs and substances.

J13-00832

INTRODUCTION TO PHARMACEUTICAL SERVICES DIVISION, MALAYSIA

J13-00832

LOCATION MAP OF OFFICE



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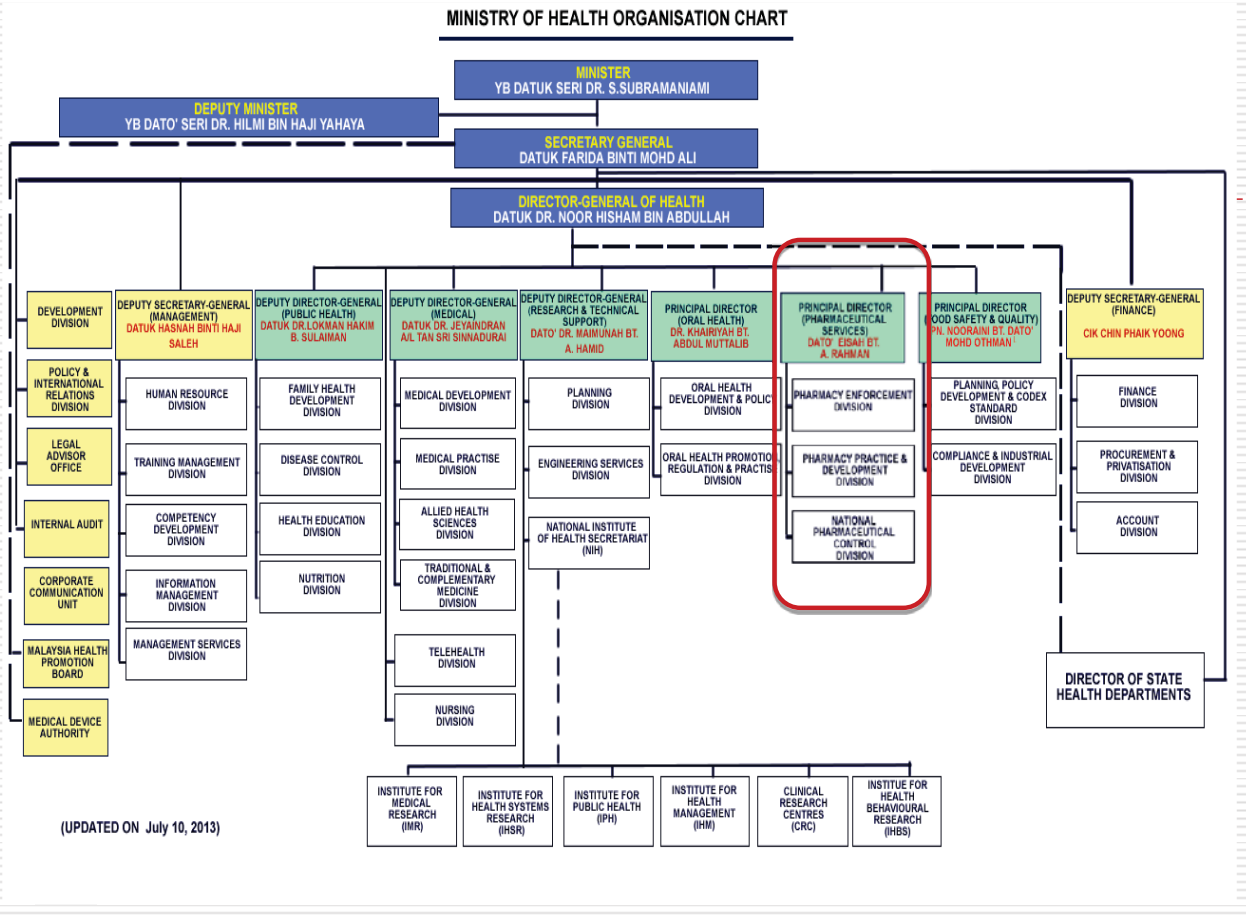
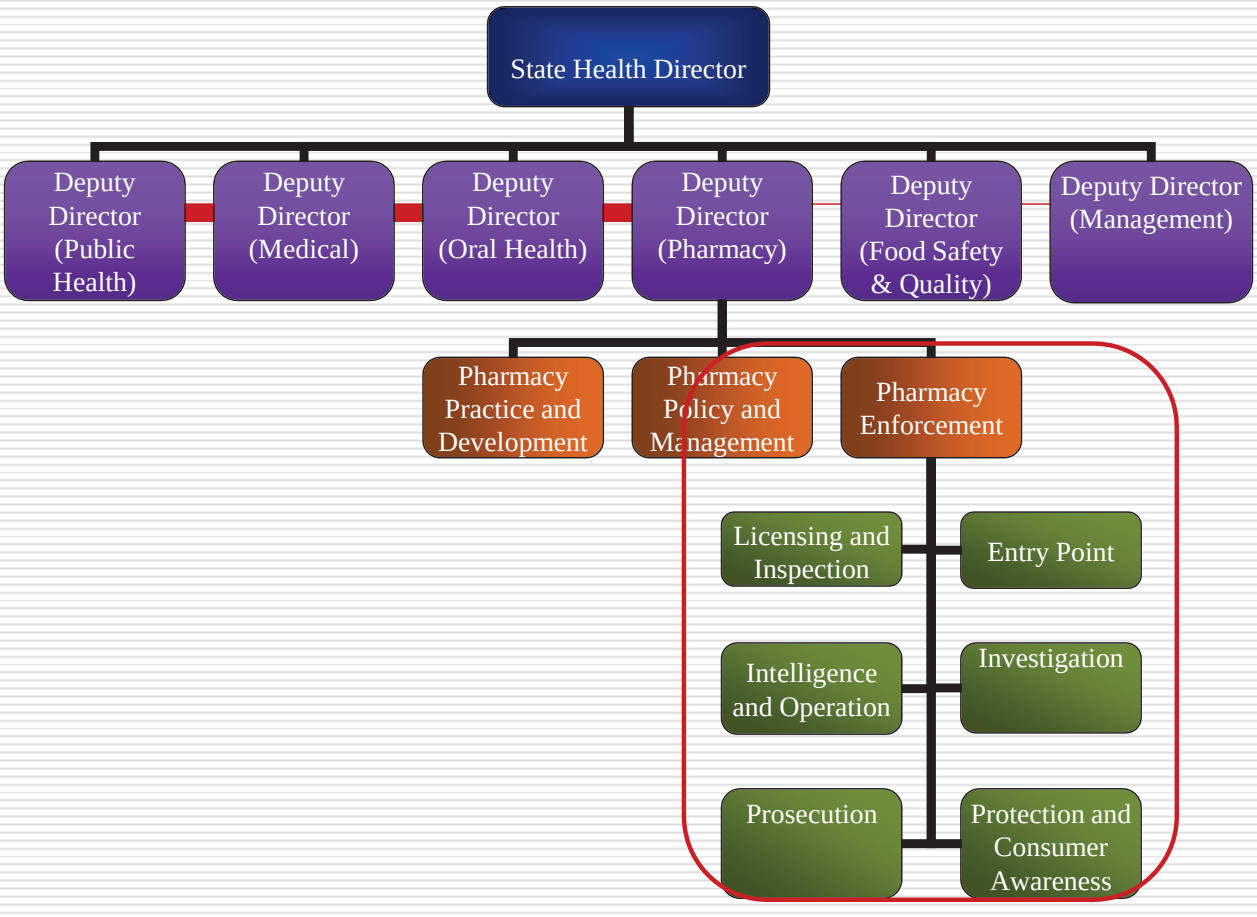
ROLE OF PHARMACEUTICAL SERVICES DIVISION

- The Pharmaceutical Services Division (PSD) as one of the main divisions under the Pharmacy programme carries out its responsibility through 3 activities namely Pharmacy Policy & Management, Pharmacy Practice & Development, and Pharmacy Enforcement.
  - Pharmacy Policy and Management is responsible for ensuring that pharmacy services strategic plan and policies are implemented accordingly.

ROLE OF PHARMACEUTICAL SERVICES DIVISION

- Pharmacy Practice and Development is responsible for ensuring optimised drug therapies and provides comprehensive pharmaceutical care.
- 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.


MINISTRY OF HEALTH ORGANISATION CHART
MINISTER
YB DATUK SERI DR. S.SUBRAMANIAMI
DEPUTY MINISTER
YB DATO' SERI DR. HILMI BIN HAJI YAHAYA
SECRETARY GENERAL
DATUK FARIDA BINTI MOHD ALI
DIRECTOR-GENERAL OF HEALTH
DATUK DR. NOOR HISHAM BIN ABDULLAH
DEVELOPMENT DIVISION
POLICY & INTERNATIONAL RELATIONS DIVISION
LEGAL ADVISOR OFFICE
INTERNAL AUDIT
CORPORATE COMMUNICATION UNIT
MALAYSIA HEALTH PROMOTION BOARD
MEDICAL DEVICE AUTHORITY
DEPUTY SECRETARY-GENERAL (MANAGEMENT)
DATUK HASNAH BINTI HAJI SALEH
HUMAN RESOURCE DIVISION
TRAINING MANAGEMENT DIVISION
COMPETENCY DEVELOPMENT DIVISION
INFORMATION MANAGEMENT DIVISION
MANAGEMENT SERVICES DIVISION
DEPUTY DIRECTOR-GENERAL (PUBLIC HEALTH)
DATUK DR.LOKMAN HAKIM B. SULAIMAN
FAMILY HEALTH DEVELOPMENT DIVISION
DISEASE CONTROL DIVISION
HEALTH EDUCATION DIVISION
NUTRITION DIVISION
DEPUTY DIRECTOR-GENERAL (MEDICAL)
DATUK DR. JEYAINDRAN A/L TAN SRI SINNADURAI
MEDICAL DEVELOPMENT DIVISION
MEDICAL PRACTISE DIVISION
ALLIED HEALTH SCIENCES DIVISION
TRADITIONAL & COMPLEMENTARY MEDICINE DIVISION
TELEHEALTH DIVISION
NURSING DIVISION
DEPUTY DIRECTOR-GENERAL (RESEARCH & TECHNICAL SUPPORT)
DATO' DR. MAIMUNAH BT. A. HAMID
PLANNING DIVISION
ENGINEERING SERVICES DIVISION
NATIONAL INSTITUTE OF HEALTH SECRETARIAT (NIH)
PRINCIPAL DIRECTOR (ORAL HEALTH)
DR. KHAIRIYAH BT. ABDUL MUTTALIB
ORAL HEALTH DEVELOPMENT & POLICY DIVISION
ORAL HEALTH PROMOTION REGULATION & PRACTISE DIVISION
PRINCIPAL DIRECTOR (PHARMACEUTICAL SERVICES)
DATO' ESAH BT. A. RAHMAN
PHARMACY ENFORCEMENT DIVISION
PHARMACY PRACTICE & DEVELOPMENT DIVISION
NATIONAL PHARMACEUTICAL CONTROL DIVISION
PRINCIPAL DIRECTOR (FOOD SAFETY & QUALITY)
PN. NOORAINI BT. DATO' MOHD OTHMAN
PLANNING, POLICY DEVELOPMENT & CODEX STANDARD DIVISION
COMPLIANCE & INDUSTRIAL DEVELOPMENT DIVISION
DEPUTY SECRETARY-GENERAL (FINANCE)
CIK CHIN PHAIK YOONG
FINANCE DIVISION
PROCUREMENT & PRIVATISATION DIVISION
ACCOUNT DIVISION
DIRECTOR OF STATE HEALTH DEPARTMENTS
INSTITUTE FOR MEDICAL RESEARCH (IMR)
INSTITUTE FOR HEALTH SYSTEMS RESEARCH (IHSR)
INSTITUTE FOR PUBLIC HEALTH (IPH)
INSTITUTE FOR HEALTH MANAGEMENT (IHM)
CLINICAL RESEARCH CENTRES (CRC)
INSTITUE FOR HEALTH BEHAVIOURAL RESEARCH (IHBS)
(UPDATED ON July 10, 2013)


State Health Director
Deputy Director (Public Health)
Deputy Director (Medical)
Deputy Director (Oral Health)
Deputy Director (Pharmacy)
Deputy Director (Food Safety & Quality)
Deputy Director (Management)
Pharmacy Practice and Development
Pharmacy Policy and Management
Pharmacy Enforcement
Licensing and Inspection
Entry Point
Intelligence and Operation
Investigation
Prosecution
Protection and Consumer Awareness

J13-00832

PRIORITY ISSUES ON PHARMACEUTICAL REGULATORY SERVICES

J13-00832

PRIORITY ISSUES

- Adulteration of Traditional Products, Cosmetics and Food Supplements
  - The emergence of traditional medicines (sildenafil, tadalafil, steroids), cosmetics (hydroquinone, tretinoin, mercury, azelaic acid) and food supplements (sibutramine) which are deliberately mixed with controlled medicine.
  - The use of these products without control or supervision by medical practitioner or pharmacist may lead to serious health problems or even death.

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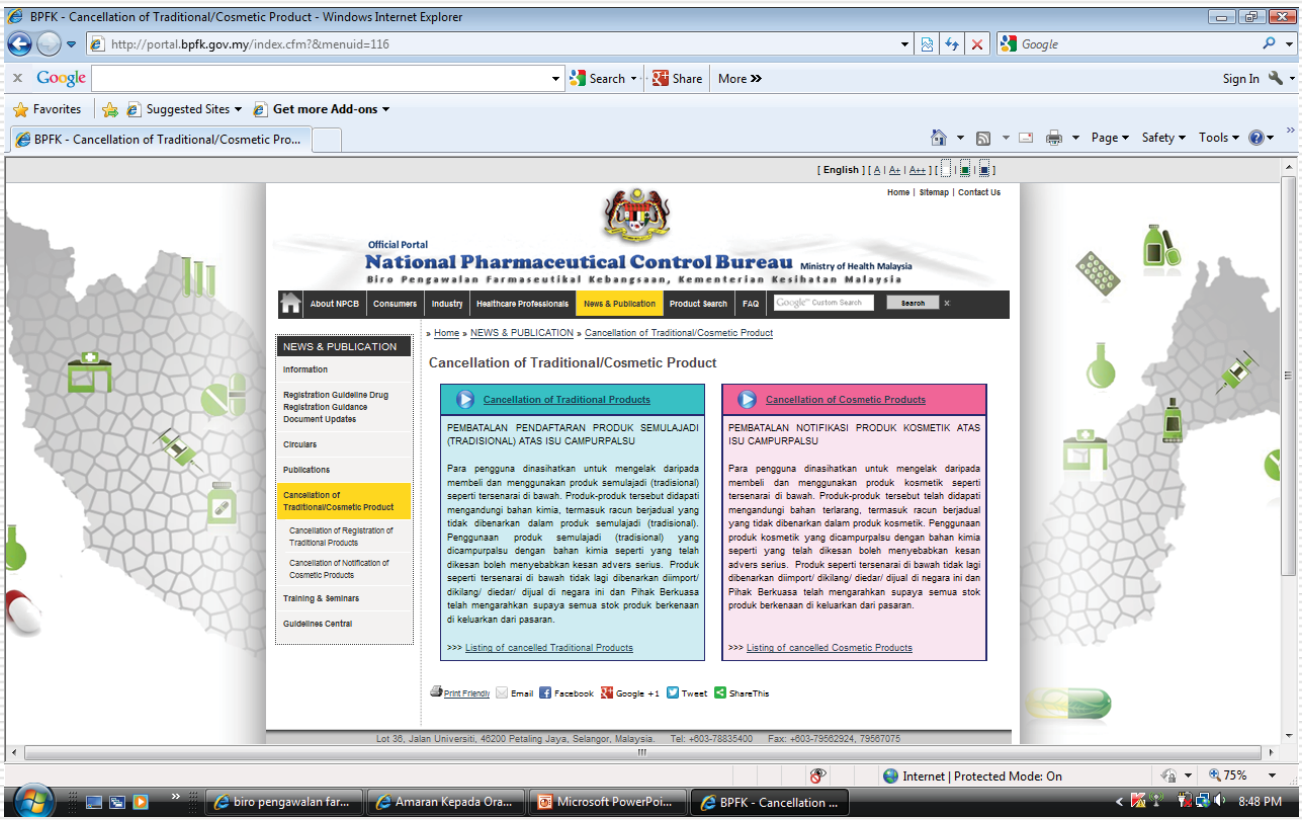


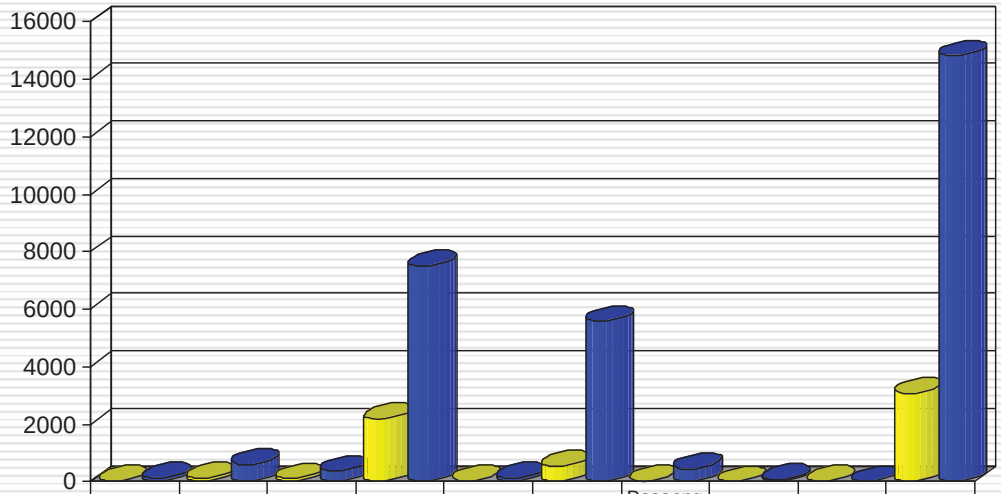
PRIORITY ISSUES

- Sale of Pharmaceutical Products via Internet
  - There are demands from retailer pharmacies to provide sale of pharmaceutical products via the internet.
  - The existing law states that every sale of poisons by retail shall be effected on the premises specified in the licence. (Poisons Act 1952)
  - Currently, there is no law or guideline issued to regulate such kind of sale for “over the counter” products.

PRIORITY ISSUES

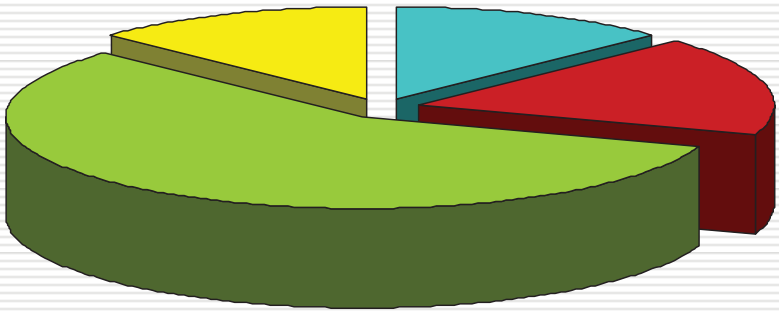
- Importation of Pharmaceutical Products
  - There is an increase number of pharmaceutical products imported via mail and courier screened by the Pharmacy Enforcement at the entry point.
  - This is due to the abundance of websites offering cheap and “effective” products over the internet.
  - The import of these products will be seized since unregistered products were not allowed to be imported.

SEIZURES AT ENTRY POINTS



	Port	Airport (Kargo)	Airport (Courier)	Post Office	Passengers (Sea)	Passengers (Air)	Passengers (Road)	Domestic (Road)	Containers)	Total
No. of Import	16	133	112	2184	39	539	47	2	13	3085
No. of Items Seized	115	611	365	7501	131	5580	444	64	0	14811

STATISTIC



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STATISTICAL DATA

No.	Subject	Data	Year
(a)	No. of pharmacists	11,372	2013
(b)	No. of inspectors	22	2013
(c)	No. of pharmaceutical manufacturers	94	2013
(d)	No. of traditional manufacturers	169	2013
(e)	No. of pharmaceutical importers	390	2013
(f)	No. of pharmaceutical wholesalers	1,150	2013

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INTRODUCTION TO PHARMACY ENFORCEMENT DIVISION

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INTRODUCTION

- The Pharmacy Enforcement Unit was formed on 1st January 1976 under the Pharmaceutical Services Division to carry out the enforcement of legislations pertaining to pharmacy and the pharmaceutical trade in the country in a more efficient approach.

- There are 14 branches of Pharmacy Enforcement Division in the country.

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PHARMACY ENFORCEMENT BRANCHES

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OBJECTIVES

- To ensure the pharmaceuticals, traditional medicines and cosmetics that are available in the market are genuine in terms of registration and notification.
- To ensure all pharmaceutical and health products are of quality, safe, efficacious.
- To ensure medicinal products and medical services advertisements comply to the rules and legislations enforced.
- To increase the consumers awareness on the usage of the registered products.

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DESCRIPTION OF ACTIVITIES

- The organisation of the Pharmacy Enforcement is divided into 5 main activities namely:
  - Intelligence, Operation and Audit - conduct intelligence, raids and audits based on the information received/ gathered.

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DESCRIPTION OF ACTIVITIES

  - Licensing and Control at Entry Point - processing relevant licences/ permit/ authorisation, coordinate and monitor screening and inspection activities on imported products and controlled substances at the entry points.

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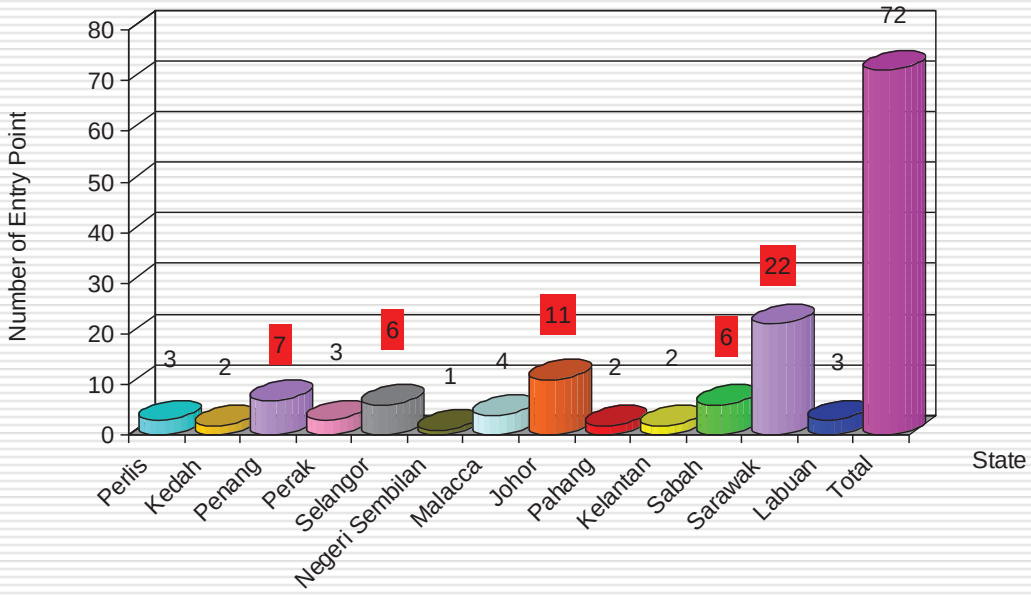
CONTROL AT THE ENTRY POINTS



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DESCRIPTION OF ACTIVITIES

- Legislation - regulate the activities of legislation involves gazette, amendments, processing special exemptions and authorization, conduct and monitoring the progress of investigation and prosecution under the Acts in force.

- Advertisement and Innovation – process medicinal products and services advertisement approval, monitoring advertisements, conduct and monitoring the progress of investigation and prosecution, coordinate enforcement statistics, the activities and training of Pharmacy Enforcement officers.

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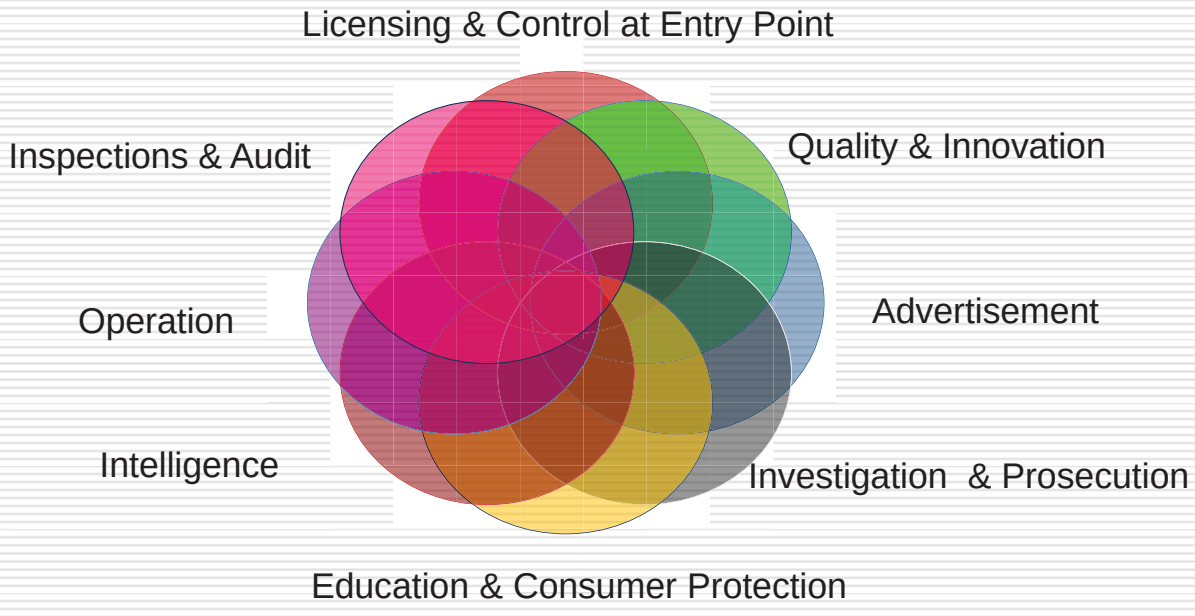
DESCRIPTION OF ACTIVITIES

- Protection and Consumer Awareness – coordinate and monitor consumer awareness regarding the usage of registered products, research and development activities, conduct analysis on the sample of products available in the market and prepare and publish materials related to the consumer awareness campaign.

CORE FUNCTIONS



INTEREST TOPICS

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INTEREST TOPICS

- Measures to Address Adulteration in Traditional Products, Cosmetics and Food Supplements
  - In terms of identification of action and implementation of effective legislative measures taken on;
    - offenders and
    - adulterated medicines.
    - including revised approaches to ensure that standards for quality, safety and efficacy are implemented and distribution chains effectively controlled.

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INTEREST TOPICS

- Implementation of Legislation and Guidelines to Regulate Sale of Pharmaceutical Products via Internet
  - There is a need to create guideline or amendment of current legislation to regulate the sale of pharmaceutical products via internet while continuing to assure safety and efficacy of pharmaceutical products.

INTEREST TOPICS

- Issuance of Guidelines Procedure
  - There are numbers of guidelines issued to the pharmaceutical industry players and health care professionals from time to time relating to the updates of control of pharmaceutical products in the market.
  - It is crucial to identify a systematic procedure to issue these guidelines for the better implementation.

REGISTRATION AND NOTIFICATION

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REGISTRATION OF PHARMACEUTICAL PRODUCTS AND COSMETICS

NEW PRODUCTS	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5	Phase 6
BIOTECHNOLOGY	Registration Aug 1985 (Prescription Drugs)	Registration 1988 (OTC)	Registration Jan 1992 (Traditional Medicine)	Registration Feb 2002 (Cosmetics)	Registration Aug 2007 (Veterinary)	Registration beginning with NCE Jan 2012 (API)**
VETERINARY MEDICINE	Licensing May 1987	Licensing 1992	Licensing Manufacturer Importers Jan 1999	Licensing Jan 2004	Licensing 1 July 2012*	No licensing Requirements as registration of API is linked to products
ACTIVE PHARMACEUTICAL INGREDIENTS	Surveillance 1990	Surveillance 1995	Licensing Wholesalers July 2002 Surveillance 2000	Surveillance 2005	Surveillance (to be announced)	Surveillance (to be announced)

1st January 2008 – Registration of Cosmetics replaced by NOTIFICATION

* 1st July 2012 – All manufacturers need to have GMP.
Meanwhile, sterile manufacturers need to have GMP, whilst non-sterile manufacturers can proceed to register

** Voluntary registration of API commenced in April 2011. Registration of generic API will be announced at a later date.

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REGISTRATION OF PHARMACEUTICAL PRODUCTS

- A registered drug is a drug that is approved by the Drug Control Authority (DCA) for sale/ use in Malaysia.
- This drug has been evaluated and tested for its quality, safety and efficacy.
- Every registered drug is given a registration number, which must be printed on its label or package. These numbers start with MAL. Example of a registration number is: MAL19976399X.

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REGISTRATION OF PHARMACEUTICAL PRODUCTS

MAL20022544A

Control Medicine is labeled with "A" at the end of the Product Registration Number

MAL20030080X

Over the Counter Medicine is labeled with "X" at the end of the Product Registration Number

MAL20024420T

Traditional Medicine is labeled with "T" at the end of the Product Registration Number

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HOLOGRAM SECURITY DEVICE

- The requirement for the affixation of this security device to product label is applicable to pharmaceuticals products, traditional products and health supplements.

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HOLOGRAM SECURITY DEVICE

Early version of hologram

Second version of hologram

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NOTIFICATION OF COSMETICS

- Effective 1st January 2008, the online registration procedure for all cosmetics products has been replaced with the online notification procedure.
- Companies intending to market new cosmetic products must notify National Pharmaceutical Control Bureau (NPCB) before placing the products in the local market.

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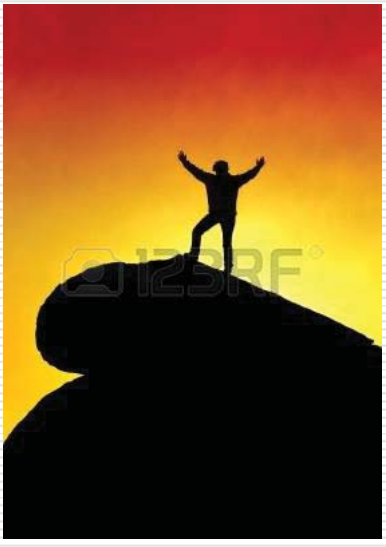
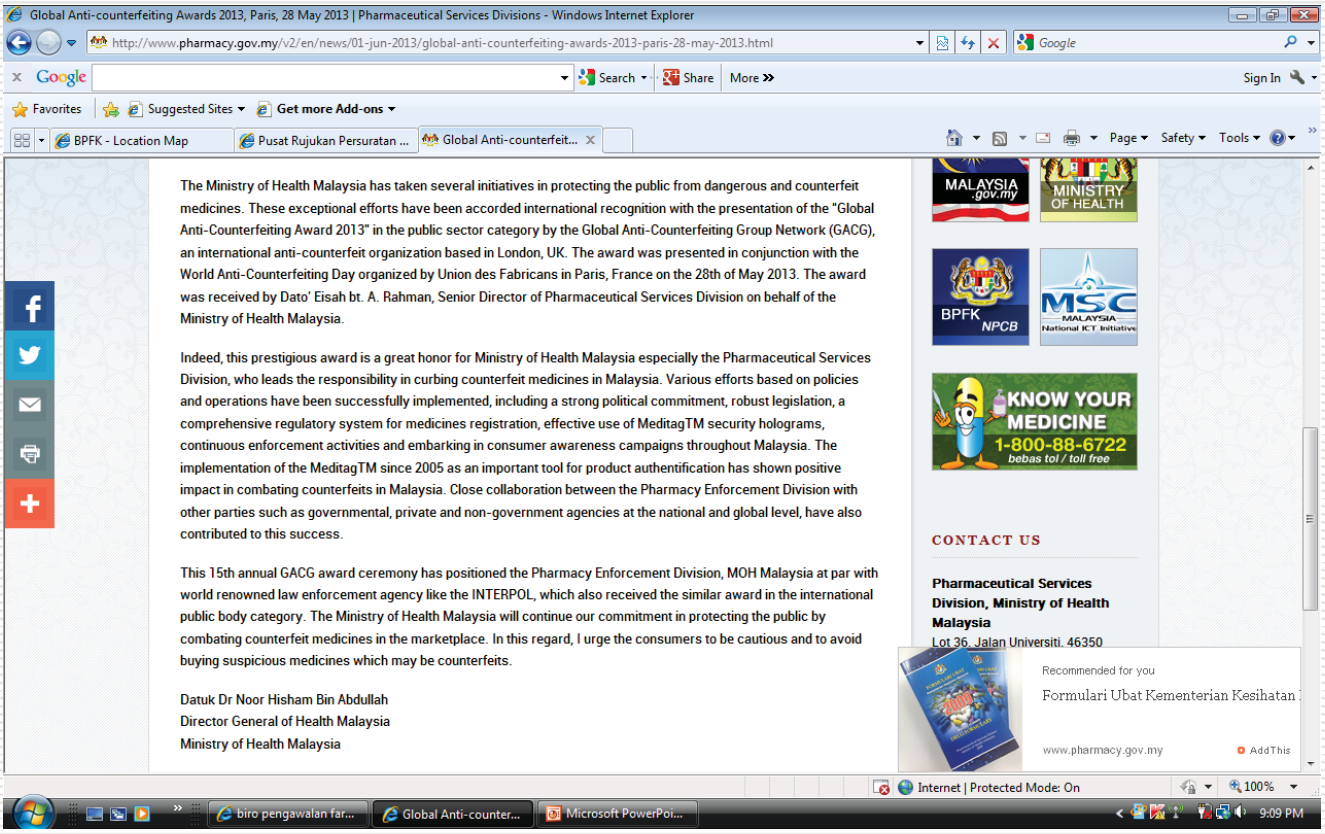
ACHIEVEMENT



J13-00832


Global Anti-counterfeiting Awards 2013, Paris, 28 May 2013 | Pharmaceutical Services Divisions - Windows Internet Explorer
http://www.pharmacy.gov.my/v2/en/news/01-jun-2013/global-anti-counterfeiting-awards-2013-paris-28-may-2013.html
Home
Global Anti-counterfeiting Awards 2013, Paris, 28 May 2013
Date: 25 June 2013 - 11:07am
News categories: Press Release
Released date: Friday, 31 May 2013
Source: Press Release by Director General Of Health Malaysia
GLOBAL ANTI-COUNTERFEITING GROUP
AUTHENTICATION NEWS
Global Anti-Counterfeiting Awards 2013
National Public Body Award
Search
Related FAQ
Does a pharmacist on study leave required to collect CPD points?
Can an unregistered product be imported into Malaysia?
Does MAB monitor and control pharmaceutical product advertisements made by direct selling companies?
How to apply for transfer within MOH facilities?
Must advertisements related to services offered at fitness centers get approval from the MAB?
Links


Global Anti-counterfeiting Awards 2013, Paris, 28 May 2013 | Pharmaceutical Services Divisions - Windows Internet Explorer
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.
Indeed, this prestigious award is a great honor for Ministry of Health Malaysia especially the Pharmaceutical Services Division, who leads the responsibility in curbing counterfeit medicines in Malaysia. Various efforts based on policies and operations have been successfully implemented, including a strong political commitment, robust legislation, a comprehensive regulatory system for medicines registration, effective use of MeditagTM security holograms, continuous enforcement activities and embarking in consumer awareness campaigns throughout Malaysia. The implementation of the MeditagTM since 2005 as an important tool for product authentification has shown positive impact in combating counterfeits in Malaysia. Close collaboration between the Pharmacy Enforcement Division with other parties such as governmental, private and non-government agencies at the national and global level, have also contributed to this success.
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. In this regard, I urge the consumers to be cautious and to avoid buying suspicious medicines which may be counterfeits.
Datuk Dr Noor Hisham Bin Abdullah
Director General of Health Malaysia
Ministry of Health Malaysia
MALAYSIA .gov.my
MINISTRY OF HEALTH
BPFK NPCB
MSC MALAYSIA National ICT Initiative
KNOW YOUR MEDICINE
1-800-88-6722
bebas tol / toll free
CONTACT US
Pharmaceutical Services Division, Ministry of Health Malaysia
Lot 36, Jalan Universiti, 46350
Recommended for you
Formulari Ubat Kementerian Kesihatan
www.pharmacy.gov.my
AddThis

J13-00832

Mali

Good Governance of Medicines for National Pharmaceutical Regulatory Authorities (JFY 2013)

Format for Job Report

Country: MALI

Organization/Department/Division: Department of Pharmacy and Medicines

1. Overview of your country and organization

1-4. Please briefly describe legislation on pharmaceutical administration in your country (Name and outline of the law(s)).

1- DPM:

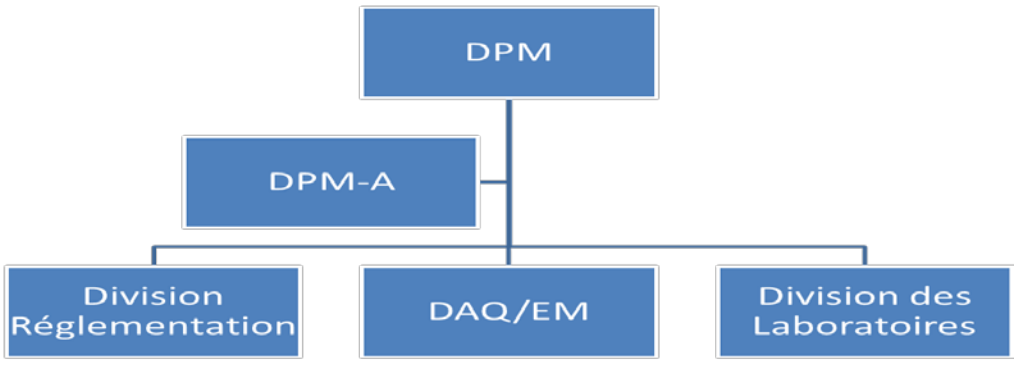
The Department of Pharmacy and Medicine (DPM) was established by Ordinance No. 00-39/P-RM of September 20, 2000, ratified by Law No. 01-040/NA of June 07, 2001. Its mission is to develop elements of the national policy of medicines to ensure the implementation, coordination and monitoring of services that contribute to the implementation of this policy.

Decree No. 2011-753/P-RM of November 17, 2011 fixed the organization and operating procedures of the department of pharmacy and medicines.

2- Health Inspection:

The Health Inspection was established according to Ordinance No. 00-058/P-RM September 28, 2000, ratified by Law No. 01-008/AN of May 28, 2001 which repeals Law No. 94 - 014/AN of April 25, 1994 establishing the inspection of health and social action.

1-5. Please attach the organizational chart at national/state and local levels and briefly describe each role and responsibility on pharmaceutical administration.



1-6. Please briefly describe priority issues at maximum three (3) on pharmaceutical regulatory services in your organization. Please provide with relevant background data.

- The quality control in the manufacture ,
- The pharmaceutical supply system,
- The quality assurance of medicines.

2. Statistical data

Please fill in with latest data in your country when available

a) Number of Pharmacists

Data 1150 included 178 government employees (2013)

b) Number of Inspector (National and Local)

Data 04 (2013)

c) Number of pharmaceutical manufacturers / manufacturing sites

Data 0 (2013)

d) Number of traditional medicine manufacturers / manufacturing sites
(when there were special categories for the traditional medicine manufacturers/ manufacturing sites)

Data 01 (2013)

e) Number of pharmaceutical importers

Data 66 (2013)

f) Number of Pharmaceutical wholesalers

Data idem (e) (2013)

3. Introduction of your work

3-1. Please briefly describe regulatory services that you are engaged in.

At the regulatory division, I am engaged to process dossiers for pharmaceutical establishment's installation in the private sector, medicines marketing authorizations and import permissions of medicines, psychotropic substances and narcotic.

3-2. Please describe your interests topics at maximum three (3).

- The quality control in the manufacture ,
- The pharmaceutical supply system,
- The quality assurance of medicines.

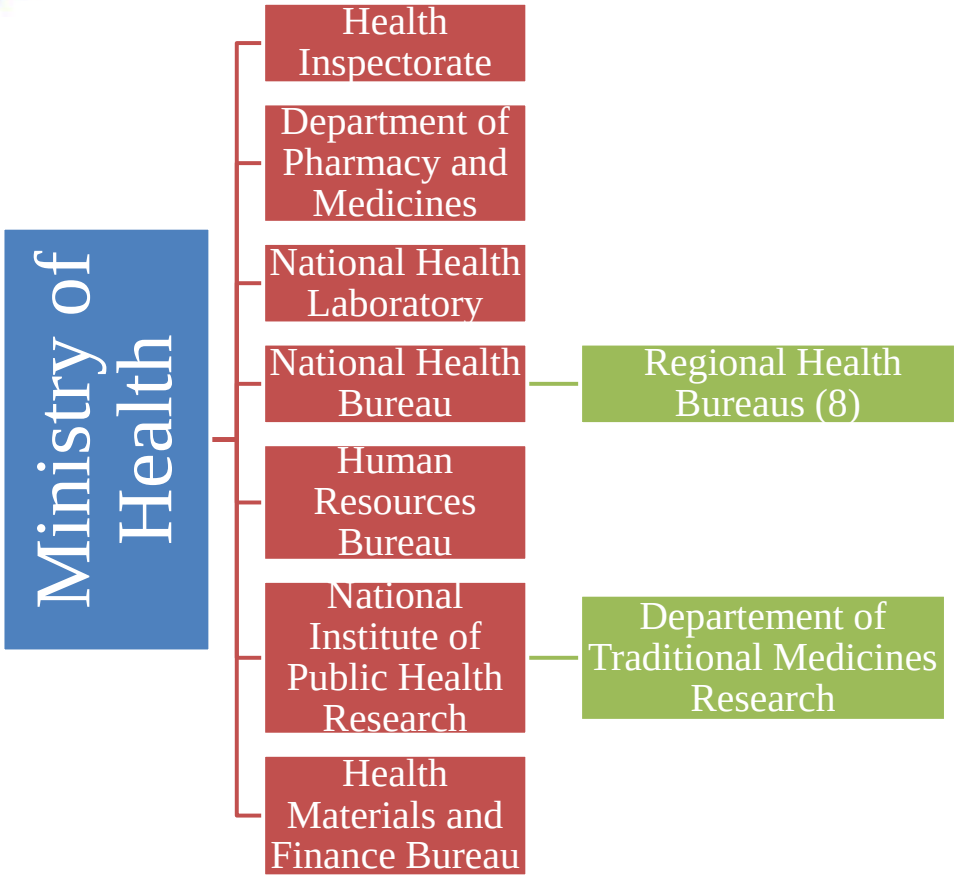
PHARMACEUTICAL ADMINISTRATION IN MALI

Regulation Division,

Department of Pharmacy and Medicines

Mali

NATIONAL HEALTH ADMINISTRATION IN MALI



GENERAL INFORMATIONS

MALI

- Surface area ≈ 1, 241,000 km²
- Population ≈ 14, 000, 000 (as of 2009)
- **Graduated pharmacists:** 1150 (from 1983 to 2013) with 178 public Employees.
- Pharmaceutical Inspectors: 04 (as of December 2013)
- Import and Wholesaller: 66 (as of December 2013)

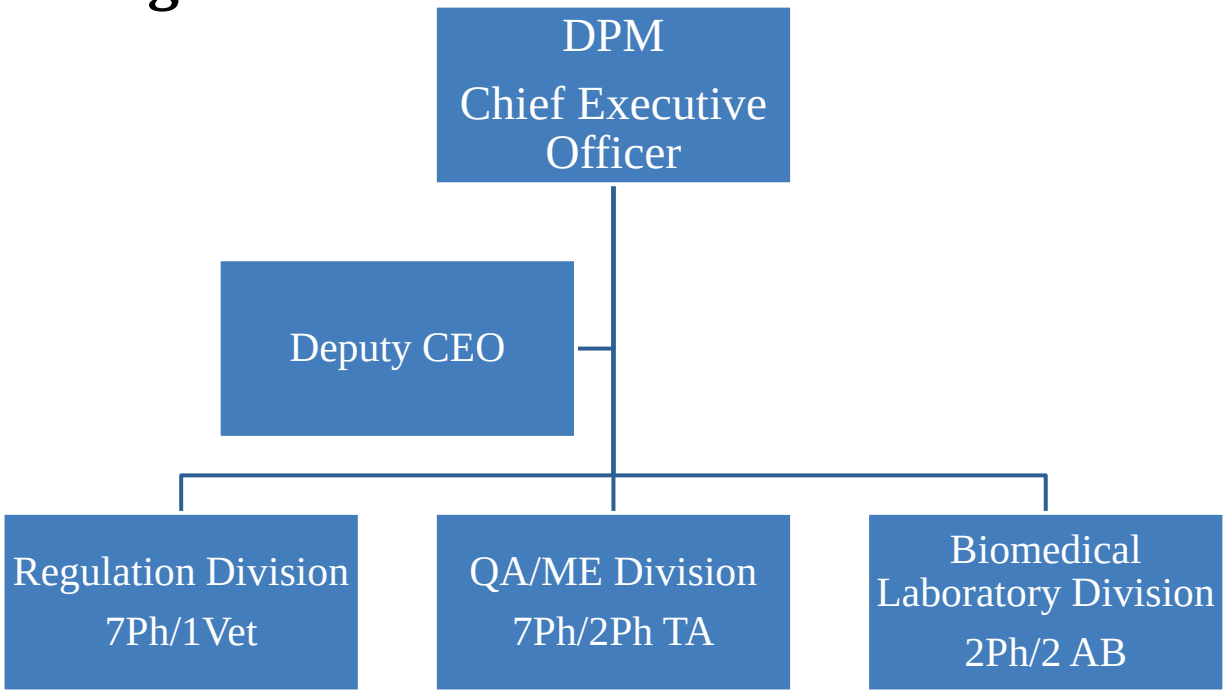
Department of Pharmacy and Medicines 1/7

CREATING:

- Creating by Ordinance No. 00-039 / P-RM of September 20, 2000, ratified by Law No. 01-040/NA of june 07, 2001.
- Decree No. 2011-753/P-RM of November 17, 2011 amending Decree No. 00-585/P-RM of November 23, 2000 laying down the operating and Organisation procedures.

Department of Pharmacy and Medicines 2/7

Organization



Department of Pharmacy and Medicines 3/7

Mission

- Develop elements of the national policy of medicines.
- Ensure the implementation, coordination and monitoring of services that contribute to the implementation of this policy.

Department of Pharmacy and Medicines 4/7

Regulation Division according to Decree No. 2011 – 753/P-RM

1. Define the policy of manufacturing, storage, distribution and destruction in case of damage of pharmaceutical products;

2. Ensure the implementation of international conventions and treaties on narcotic drugs and psychotropic substances;

3. Initiate the regulation of the practice of pharmacy profession;

4. Instruct the installation of private pharmaceutical companies;

26/05/2014

Department of Pharmacy and Medicines 5/7

Regulation Division according to Decree No. 2011 – 753/P-RM

5. Provide administrative control of the import of products and pharmaceutical drugs manufactured at the national level and outside the country;

6. Provide administrative control over the export of drugs manufactured at national level.

7. Prepare elements of analysis for the revision of the national list of essential drugs.

9. Process and investigate cases of marketing authorization application (MA).

Department of Pharmacy and Medicines 6/7

QA/ME Division

1. Instruct the clinical trial authorization.

2. Ensure the evaluation and monitoring of clinical trials.

3. Develop pharmacovigilance.

4. Develop a national system of training, pharmaceuticals information and communication.

5. Develop national tools to improve prescription and drugs dispensing.

6. Ensure the monitoring of essential drugs supply at all level of the national health system (GDP).

Department of Pharmacy and Medicines7/7

Biomedical Laboratory Division :

1. Define a list of essential biomedical analysis by level of national healthcare.

2. Initiate the regulation of the practice of the profession of biomedical analysis laboratory (GLP).

3. Develop an assessment of skills and the quality of biomedical analysis system.

4. Define a certification system of reagents for biomedical analysis and monitoring and periodic evaluation.

National Health Laboratory 1/3

Creeting:

Created by Ordinance No. 00 - 040/P-RM of September 20, 2000, ratified by Law N ° 01 - 050/NA of July 02, 2001.

National Health Laboratory 2/3

Mission:

According to Article 2 of this Act, the NHL is responsible for quality control of medicines, foods, beverages or other substances manufactured or imported in the Republic of Mali and for therapeutic purposes, dietetic or food for human and animal health safety.

National Health Laboratory 3/3

Mission:

1. Provide technical advice to the authorization or prohibition of the use of any product, drug, food or beverage treatment, diet or food.

2. Collect and analyze samples in any unit of manufacturing, import, distribution or storage of medications, water, other beverages, foods and other substances which can be introduced into the human and animal organism for therapeutic, nutritional or other purposes and contributing to the improvement or deterioration of humans and animals health safety.

3. Participate at the academic and postgraduate Training.

4. Undertake scientific and technical research.

5. Contribute to the development of standards and their enforcement.

National Inspectorate 1/2

❖ **Creeting:**

Creeted by ordinance No. 00-058/P-RM of September 28, 2000, ratified by Law No. 01-008/NA of May 28, 2001 which repeals Law No. 94 - 014/NA of April 25,1994 establishing the inspection of health and Welfare.

❖ Data (2013): 4 Pharmaceutical Inspectors

National Inspectorate 1/2

Mission:

1. Check the functioning and activities of departments and agencies of the Ministry of Health.

2. Monitoring the implementation of laws and regulations in both public and private or community health professions exercise.

3. Ensure compliance and enforcement of laws and regulations relating to administrative, financial and material management services and agencies of the Ministry of Health.

4. Attend services and health human resources by management consultancy or assistance to the organization or implementation of information or training programs.

National Pharmaceutical Committees

1. National committee of Marketing Authorization (Decree No. 04-557/P-RM of December 01, 2004): 13 Members.

2. National Committee against Counterfeit and illegal trade of medicines and narcotic drugs (Decree No. 02-075/P-RM of February 15, 2002): 10 Members.

3. Coordination and monitoring Technical committee of Essential Drugs Management (Ministerial Decision No. 2013-1582/MSHP-SG of December 27, 2013): 24 members.

NATIONAL PHARMACEUTICAL ADMINISTRATION

Thank you for your attention

Myanmar

Country's Profile

Location

The Republic of the 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, the Republic of India and on the west by the People's Republic of Bangladesh.

Geography

The country is divided administratively, into Nay Pyi Taw Union Territory and (14) States and Regions. 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 2011-2012 is estimated at 60.38 millions. About 70 percent 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.

Social Development

Development of social sector has kept pace with economic development. Expansion of schools and institutes of higher education has been considerable especially in the Regions and States. Expenditures for health and education have raised considerably, equity and access to education and health and social services have been ensured all over the country.

INCEPTION REPORT

Current Myanmar health care system

Myanmar health care system evolves with changing political and administrative system and relative roles played by the key providers are also changing although the
Ministry of Health remains the major provider of comprehensive health care. It has a pluralistic mix of public and private system both in the financing and provision. Health care is organized and provided by public and private providers, public and private system both in the financing and provision. Health care is organized and provided by public and private providers.

Health in transition state

The Government has embarked on a far reaching reform programme to

transform the country into a modern, developed and democratic nation that improves the livelihood of its people. The Government has aspired for people-centered development while staying focused on achievable results. It shall start modestly, but move decisively with international assistance to enlarge capacity and skill development to reduce incidence of poverty and achieve the Millennium Development Goals by 2015.

National Health Plan

Aiming towards the "Health for All Goal", series of National Health Plans based on primary health care services have been systematically developed and implemented. The Ministry of Health has formulated four yearly People's Health Plans starting from 1978. From 1991 onwards, successive National Health Plans have been formulated and implemented.

There are eight Department under Ministry of Health .Among them Department of Food and Drug Administration is one of them. Food and Drug Administration (FDA) established since 1995, takes care of the safety and quality of Food, Drugs, Medical Devices and Cosmetics. Food and drug control activities expanded with establishment of branches in Nay Pyi Taw, Yangon and Mandalay. Expanded branches in Muse (105) miles Border Trade Zone (near the China border) and Myawaddy Border Trade Zone (near the Thailand border) have been set up during September 2012.

The FDA division has been upgraded to a separate Department in April 2013. To enable the public to have quality and safety of food, drugs, medical devices and cosmetics, Food and Drug Administration is implementing the tasks complying with guidance from the National Health Committee, Ministry of Health and Myanmar Food and Drug Board of Authority according to National Drug Law 1992 and its provisions, National Food Law1997 and Public Health Law 1972.

FDA is responsible for issuing Heath 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, 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. FDA issues notification and import recommendation of medical devices and notification of cosmetics.

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 2012, under the guidance of Drug Advisory Committee and Central Food & Drug Supervisory Committee, Food & Drug Administration issued Drug Registration Certificates (DRC), Importation Approval Certificates (DIAC) and also rejected some drugs for registration from the aspect of quality, safety and efficacy. Drug Quality Control Test in FDA Laboratory.

Under guidance of Ministry of Health, FDA regularly notifies the public as well as State/ Regional Food 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.

Ministry of health aiming for the rational use of medicine .It require that patient received medications appropriate to their clinical needs, in dose that meets their own individual requirements for an adequate period of time, and the lowest cost to them and their community.

Irrational use of medicines is very prevalent and pose a serious health problem that cause significant patient harm in terms of antimicrobial resistance, unnecessary adverse drug reactions, medication errors, poor patients outcomes and wastes of resources. This contributes to enormous health loses and economic waste both at personal and national level.

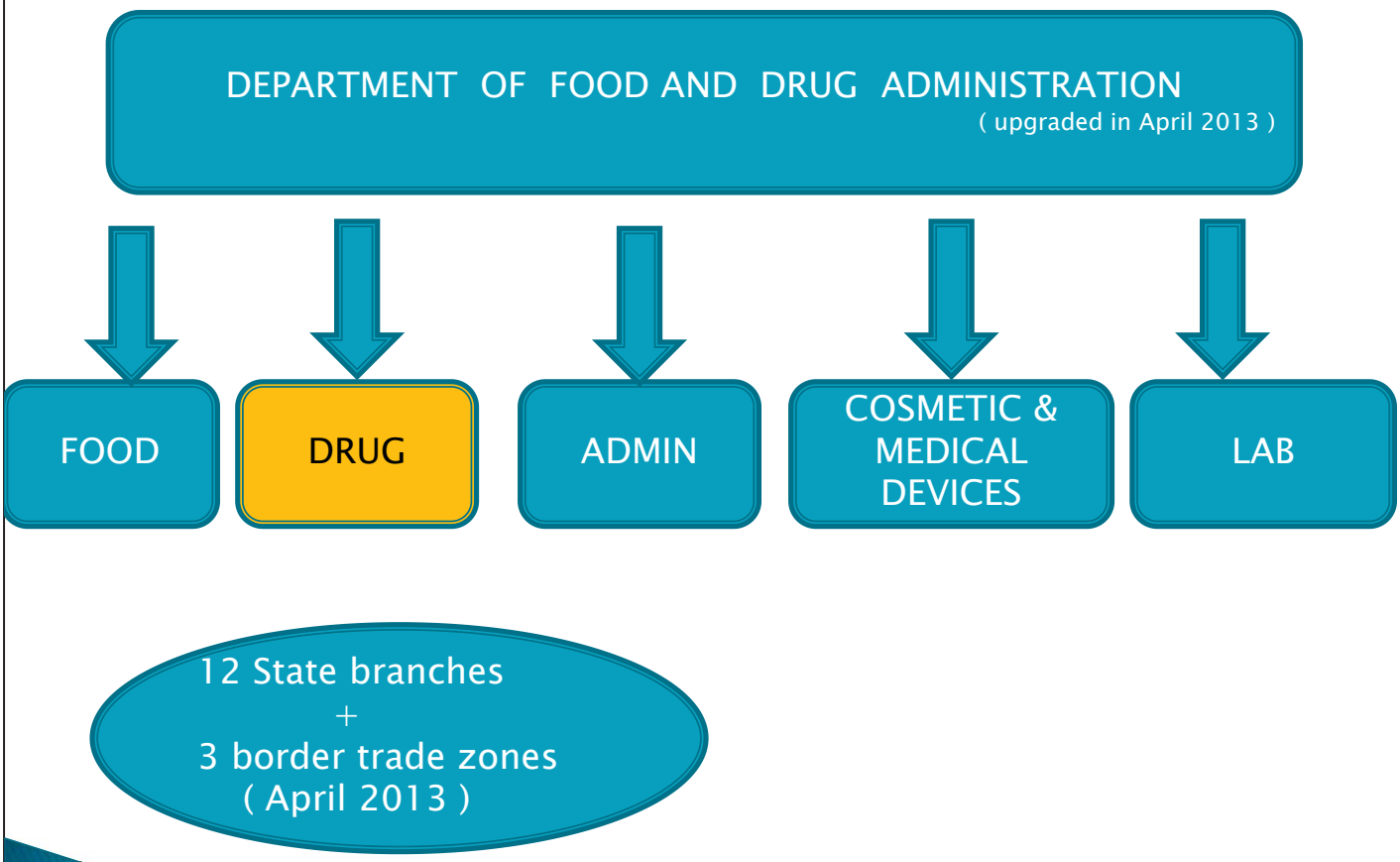
The important aspects of rational use o medicines-control medicine,

appropriate indication, appropriate medicine considering efficacy ,safety ,suitability for the patient ,and cost.appropriate dosage ,administration, duration. no contraindication ,correct dispensing, including, appropriate inormation for patients, patient adherence to treatment.

Drug Regulation System in Myanmar

Outline of Presentation

- Organization set up of FDA
- Food and Drug regulation system
- Duties & Responsibilities
- Licensing system



Food and Drug Regulation System

Myanmar Food and Drug Board of Authority		Ministry of Health
Central:	FDS Committee	Department of FDA
State/Regional:	FDS Committee	Health Department (14)
Township:	FDS Committee	Health Department (325)

(FDS Committee=Food and Drug Supervisory Committee)

Duties & Responsibilities of FDA {Drug Division}

- Drug Registration (new, renewal, variation, control drug)
- Drug Manufacturing (GMP)
- Drug Importation
- Advertising of Drugs{OTC}
- Training
- Cooperation & Coordination (Custom, Trade, Police)

Types of Licenses concerning with Pharmaceuticals

- Product License (Drug Registration Certificate)
  Validity-5yrs
- Manufacturer's License
  Validity-3yrs
- Importer's License (Drug Importation Approval Certificate)
  Validity-3yrs
- Drug Seller's License (Retailer, Wholesaler)
  Validity-3yrs

Drug Control Activities {2012/2013}

No	Drug Control Activities	2012	2013
1	Drug Registration application	2758	2600
2	Drug Registration approval {New}	1643	1232
3	Drug Registration approval {Renewal}	1052	1274
4	Drug Registration approval {Variation}	306	461
5	Inspection {manufacturing sites, storage & distribution sites}	73	100
6	Drug importation registration {New}	18	16
7	Drug importation registration {Renewal}	38	61
8	Punishment according to NDL	11	70
9	Departmental coordination {Custom, Police}	16	84

2013 Data

- Registered Drugs (16600)
- Importers (750)
- Local Manufactures (8)
- Vaccine Plant (1)
- Pharmacy (>10000)

Pre-market Control

- Drug Registration – Review of Dossiers
  – Laboratory analysis
  – Clinical trials
- Without registration, drugs cannot be imported nor sold.
- The registered drug bear Myanmar Registration number and customs authorities checked them at the port of entry.
- The drugs on Register books are also distributed to these departments concerned with drug importation.

Post market surveillance (PMS)

- Post Market Surveillance (PMS) was carried out by taking random sampling from the drugs shops and tested at drug quality control laboratory in FDA.
- ADR monitoring system
- This activity is done by inspector from the Department of FDA and health staffs.
- If spurious, sub-standards or counterfeit drugs were identified during the surveillance, action were taken according to National Drug Law (1992).

- Department of FDA also takes responsibilities for safety, efficacy & quality of drugs which are manufactured by local manufacturer according to the National Drug Law.
- For public awareness, the lists of unregistered and counterfeit medicines are published in the newspapers from time to time.
- The information on how to differentiate between the genuine and counterfeit medicine was also published to various level of Food and Drug Supervisory Committee & Health care professionals.

Destroyed Unregistered, Expired Drug and Expired Food Items

Thank you

Country Profile (Myanmer)

Outline of Presentation

- Country Profile of Republic of Union of Myanmar
- Health System
- Organization set up
- Drug law & Notification
- Set up of Committees & their members

Location

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

Geography

The country is divided administratively into

- **Nay Pyi Taw** Union Territory
- 14 States and Regions
- 70 Districts,
- 330 Townships
- 398 Towns
- 64,134 Villages.

Demography

- The population of Myanmar in 2011-2012 is estimated about **60.38** millions.
- About **70 percent** 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**

- (89.4%) of the population are **Buddhists.** The rest are Christians (4.9 %), Muslims (3.9%),Hindus (0.5 %) and Animists (1.2 %).

Myanmar Health Care System

- Myanmar health care system evolves with **changing political and administrative system**
- **Ministry of Health remains the major provider of comprehensive health care.**
- It has a **pluralistic mix of public and private system** both in the financing and provision.

History of Food & Drug Administration

- The Food and Drug Administration (FDA) established since 1995, takes care of the safety and quality of Food, Drugs, Medical Devices and Cosmetics.
- 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.In 2013,each States & Division and Border Trade(China , India , Thailand)

- To enable the public to have quality and safety of food, drugs, medical devices and cosmetics,
- Food and Drug Administration is implementing the tasks complying with guidance from Ministry of Health and **Myanmar Food and Drug Board of Authority** according to

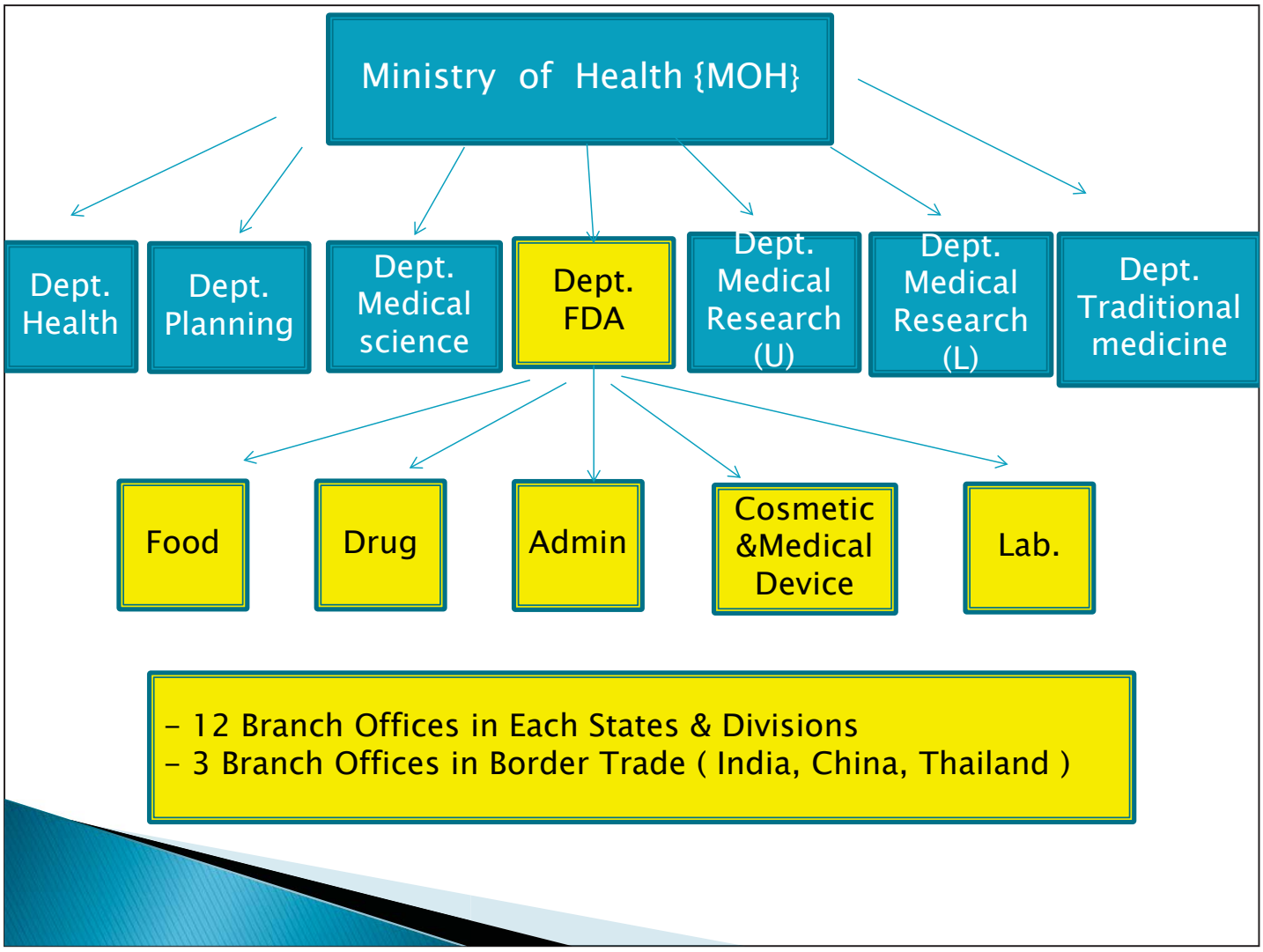
National Drug Law 1992

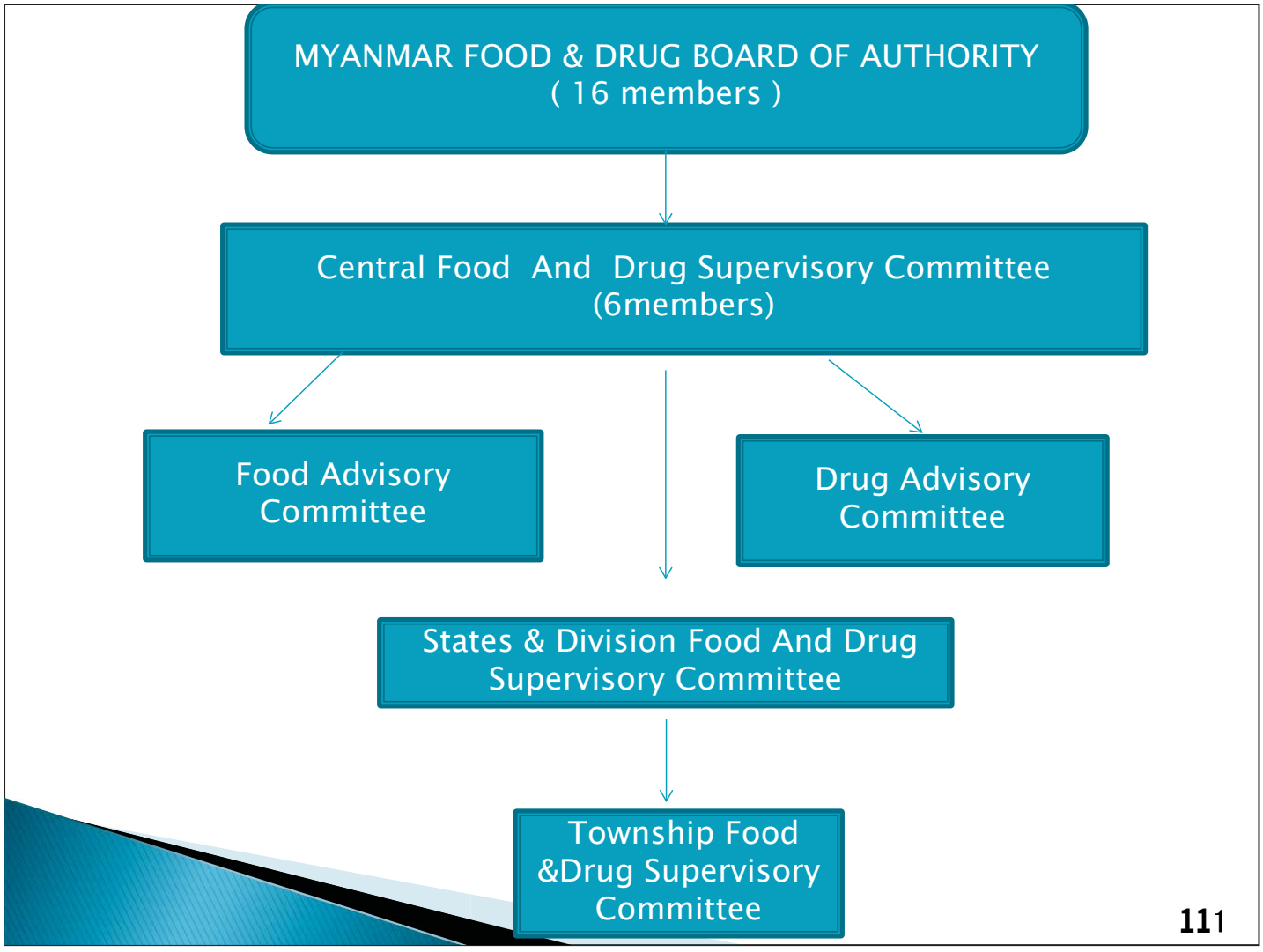
Public Health Law 1972

Notifications 1993

Registration ,Manuacturing ,Sales & Distribution,Importation,

Labeling & Advertisement


Ministry of Health {MOH}
Dept. Health
Dept. Planning
Dept. Medical science
Dept. FDA
Dept. Medical Research (U)
Dept. Medical Research (L)
Dept. Traditional medicine
Food
Drug
Admin
Cosmetic &Medical Device
Lab.
- 12 Branch Offices in Each States & Divisions
- 3 Branch Offices in Border Trade (India, China, Thailand)


MYANMAR FOOD & DRUG BOARD OF AUTHORITY
(16 members)
Central Food And Drug Supervisory Committee
(6members)
Food Advisory Committee
Drug Advisory Committee
States & Division Food And Drug Supervisory Committee
Township Food &Drug Supervisory Committee

Sixteen members(Myanmar Food And Drug Board of Authority)-6monthly

- Ministry of Health
- Ministry of Defense
- Ministry of Home Affair
- Ministry of Livestock Breeding & Fisheries
- Ministry of Trade
- Ministry of Industry
- Ministry of Agriculture
- Experts {Medical,Pharmaceutical,pharmacological,Veterinary,chemist, Pharmaceutical industries}

Six members(Central Food And Drug Supervisory Committee)-3monthly

- Dept. of FDA
- Dept. of General Affair
- Dept. of Health
- City Development Committee
- National Health laboratory

THANK YOU FOR YOUR ATTENTION

Sri Lanka

Good Governance of Medicines for National Pharmaceutical Regulatory Authorities (JFY 2013)
Job Report as a part of Requirements of the Programme

Country- Sri Lanka
Organization-State Pharmaceuticals Corporation of Sri Lanka

I. 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.

1.1 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.

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

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

Figure 1 Organization Chart of drug management

- **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.

1.3 Issues on pharmaceutical regulatory services –In view of State Pharmaceuticals 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

2. Statistical Data

Category	Data	Year
a) Number of pharmacists	6311	2013
b) Number of inspectors	55	2013
c) Number of pharmaceutical d) Manufacturers	30	2013
e) Number of traditional medicine manufacturers	n/a	n/a
f) Number of pharmaceutical importers	211	2013
g) Number of pharmaceutical wholesalers	57	2013

3. Introduction of work

Our organization is not directly involved in regulatory services. However being the largest pharmaceutical importer and distributor we do control the market by setting quality standards, controlling prices, doing post market surveillance and specially contributing to relevant policy formulations.

4. Interest topics

(i) Prevention of Inflow of substandard products to the country.

(ii) Best practices in Pharmaceutical distribution and regulating pharmaceutical distribution

(iii) Current trends and developments in selecting and procuring best quality products and post market surveillance.

Good Governance of Medicines for National Pharmaceutical Regulatory Authorities

Job Report as a part of Requirements of the Programme

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Over view of country and organization

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Healthcare System in Sri Lanka

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Legislation Govern the Pharmaceutical Administration in Sri Lanka.

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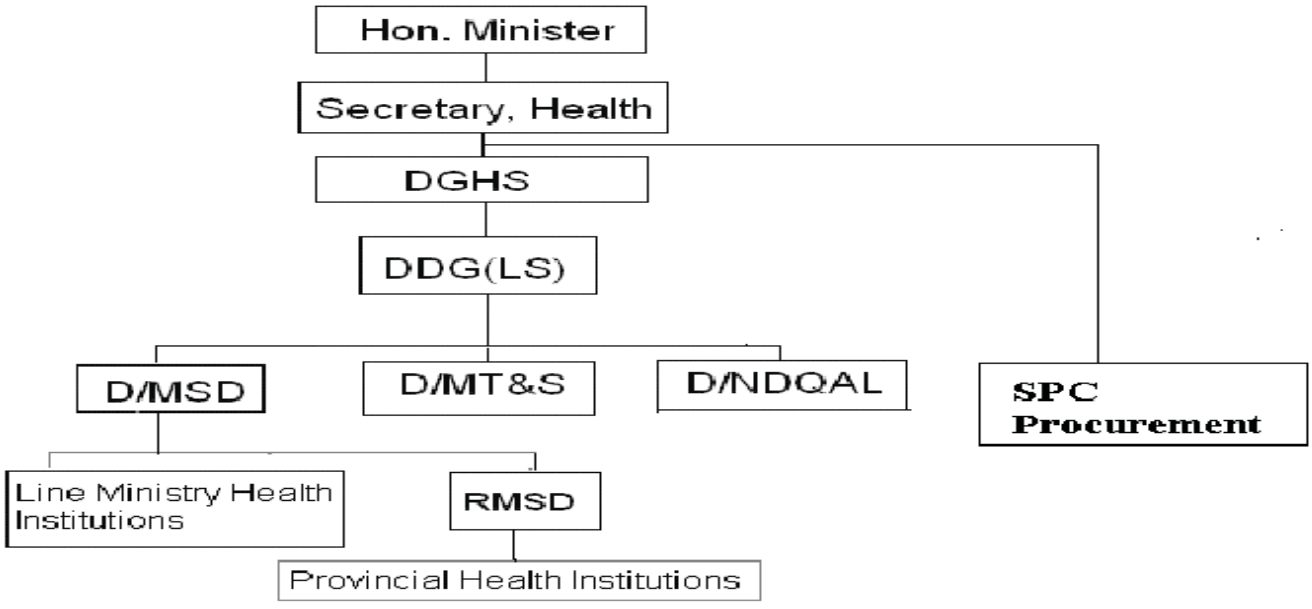
Organizational chart at National/State and Local level on pharmaceutical administration



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. Apart from its duty as the sole procurement agent of the government it is operating in the open market as largest importer and distributor in the open market

Procurement Procedure of SPC for Government Supplies

- Receiving orders from the Medical Supplies Division of the Ministry of Health
- Calling tenders
- Selecting suppliers
- Importing from selected suppliers
- Supplying to Medical Supplies Division
- Attending to post delivery issues

Role of the SPC in the open market

- Unofficial price controller in the market
- Promoting use of Generics
- Educating people on rational use of Pharmaceuticals
- Setting examples for good dispensing practices
- Helping Government healthcare institutions in their difficulties

Issues on pharmaceutical regulatory services – in Sri Lanka In view of State Pharmaceuticals 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

Good Government of Medicines for National Pharmaceutical Regulatory Authorities (JFY 2013)
Job Report as a part of Requirements of the Programme
State Pharmaceutical Manufacturing Corporation of Sri Lanka

I. Over view of country and organization

Sri Lanka is an Island in South Asia surrounded by the Indian Ocean with a Population of and land. Politically it is country govern by parliament Democracy and headed by an Executive President selected by people of the country.

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13. Reviewing and approving of advertisements.
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15. Recalling Pharmaceuticals from the market on safety grounds and all other relevant areas.
16. 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.

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Figure 2 Organization Chart of drug management

- **Minister of Health**- Policy making such as introducing necessary amendments to the act and making regulations.
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1.3 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.

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2. Statistical Data

Category	Data	Year
h) Number of pharmacists	6311	2013
i) Number of inspectors	40	2013
j) Number of pharmaceutical k) Manufacturers	30	2013

l) Number of traditional medicine manufacturers	Statistical data not available	
m) Number of pharmaceutical importers	211	2013
n) Number of pharmaceutical whole sellers	57	2013

3. 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.

4. 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.
- **Stability studies**- other than GMP audits I would also like to get the technical know-how of accelerated stability protocols and real time stability protocols. Such as how the samples are handles, storing, re-analyzing procedures, interpretation of the results, shelf life calculations using Arrhenius equation for different drug products etc.
- **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.

Good Governance of Medicine for National Pharmaceutical Regulatory Authorities

STATE PHARMACEUTICALS MANUFACTURING CORPORATION
Sri Lanka

OBJECTIVES

- About Sri Lanka
- Our health care system
- Our legislations on Pharmaceutical regulations
- National organizational levels
- State Pharmaceuticals Manufacturing Corporation (SPMC)
- Our enrollment
- Main issues

Sri Lanka

- Small island located in Indian Ocean
- 65,610 km^2
- Multi national, multi religious country
  - Majority Sinhalese, live with harmony with Tamil and Muslim minorities,
  - Mainly Buddhists, Hindus, Catholics and Muslims
- Population around 2 billion

Sri Lankan Health Care System

- Free medical services from government hospitals
  - National hospital-Colombo
  - General hospitals- in all major cities
  - Teaching hospitals
  - District hospitals
  - Base hospitals
  - Rural hospitals
  - Eye hospital
  - Cancer hospital
- Private sector hospitals and clinics available

Drug distribution

- For government hospitals
  - Ministry of Health
    - Medical supplies division
      - State Pharmaceuticals Corporation
      - State Pharmaceuticals Manufacturing Corporation
- For private sector hospitals
  - Procure from local whole sale dealers/distributors
  - Procure from State Pharmaceuticals Corporation
- Blood products should be procured from " National Blood Bank"

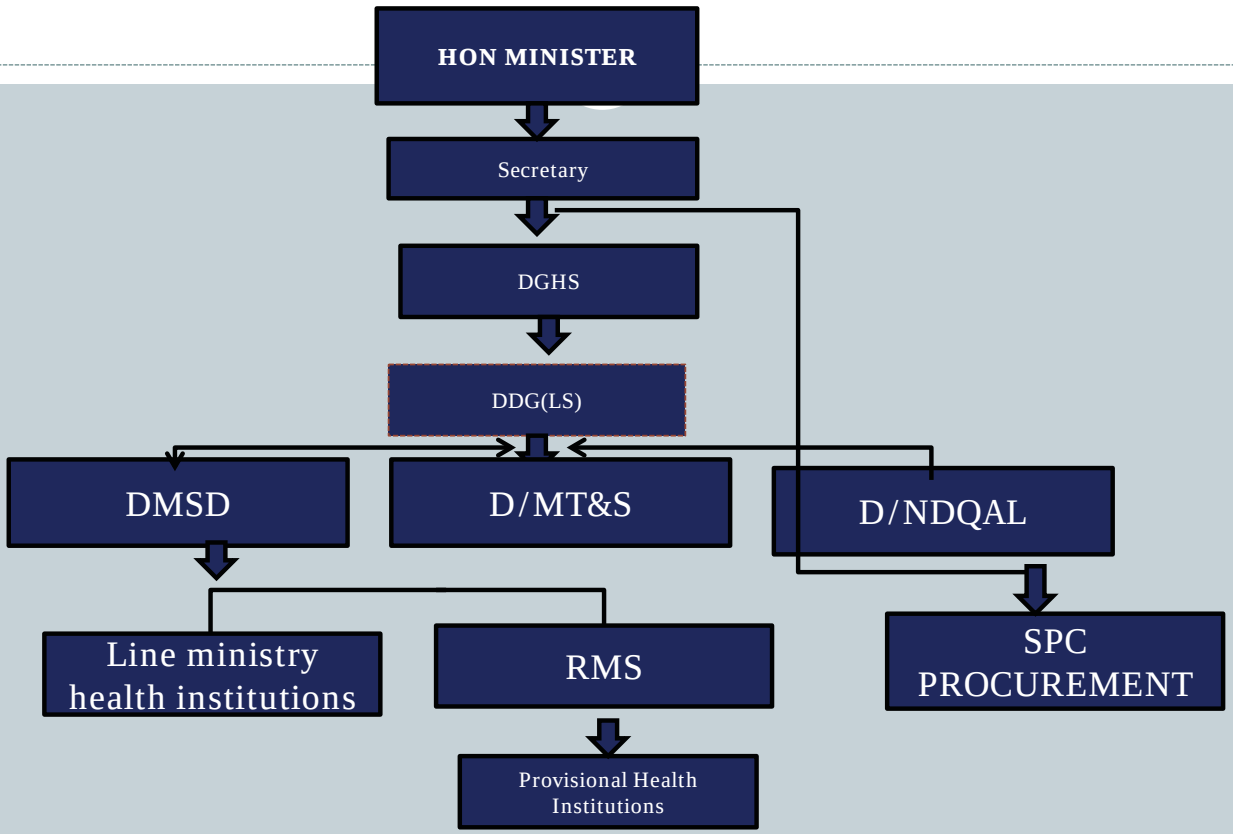
Legislation

- Cosmetics Devices and Drugs Act No 27 of 1980
- (Cosmetics Devices and Drugs Regulatory Authority)
  - Registration of Pharmaceuticals
  - Monitoring and approving changes to those products already approved.
  - Monitoring and Implementing good Manufacturing practices.
  - Licensing and monitoring of importation, manufacturing, sales advertisements and distribution surveillance of quality of drugs available in the market.
  - Reviewing and approving of advertisements.
  - Approving and Monitoring of clinical trials.
  - Recalling Pharmaceuticals from the market on safety grounds and all other relevant areas.
  - Approving, registering. Monitoring and regulating Pharmacists, wholesale and retail outlets, distributors.

Legislations cont

- Medical ordinances of 1928
- Poisons Opium and Dangerous Drug Ordinance of 1936 and amended by Act No. 13 of 1984" of the same ordinance
  - Police Narcotic bureau
  - National dangerous drug control board

Responsible persons



ADMINISTRATION OF CDDA

- Cosmetics Devices and Drugs Technical Advisory Committee
  - Advise the Minister on matters arising out of the administration of the Act and to carry out other functions assigned to it under this Act.
  - Appointing sub committees carry out some functions or duties.
  - About 15 committee members in the committee including pharmacologists, surgeons , physicians, representatives from manufactures, laboratories, etc.

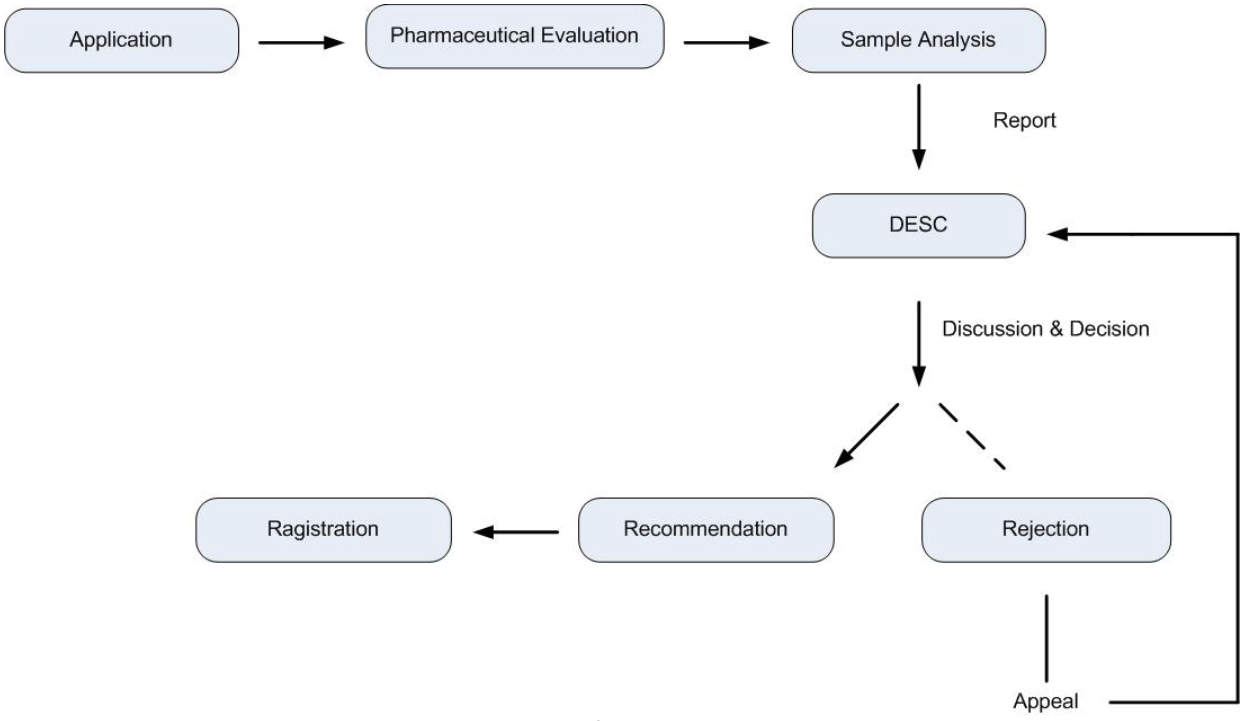


Figure 1: Evaluation process for Generic Drugs

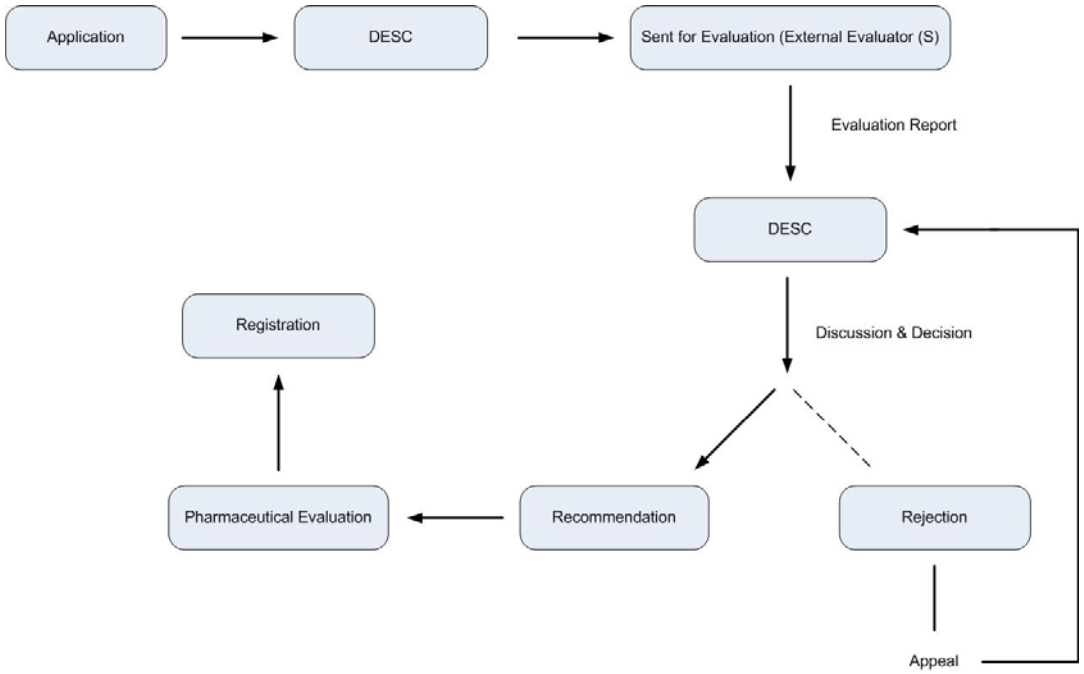


Figure 2: Evaluation process for New Drug/ Chemical entities

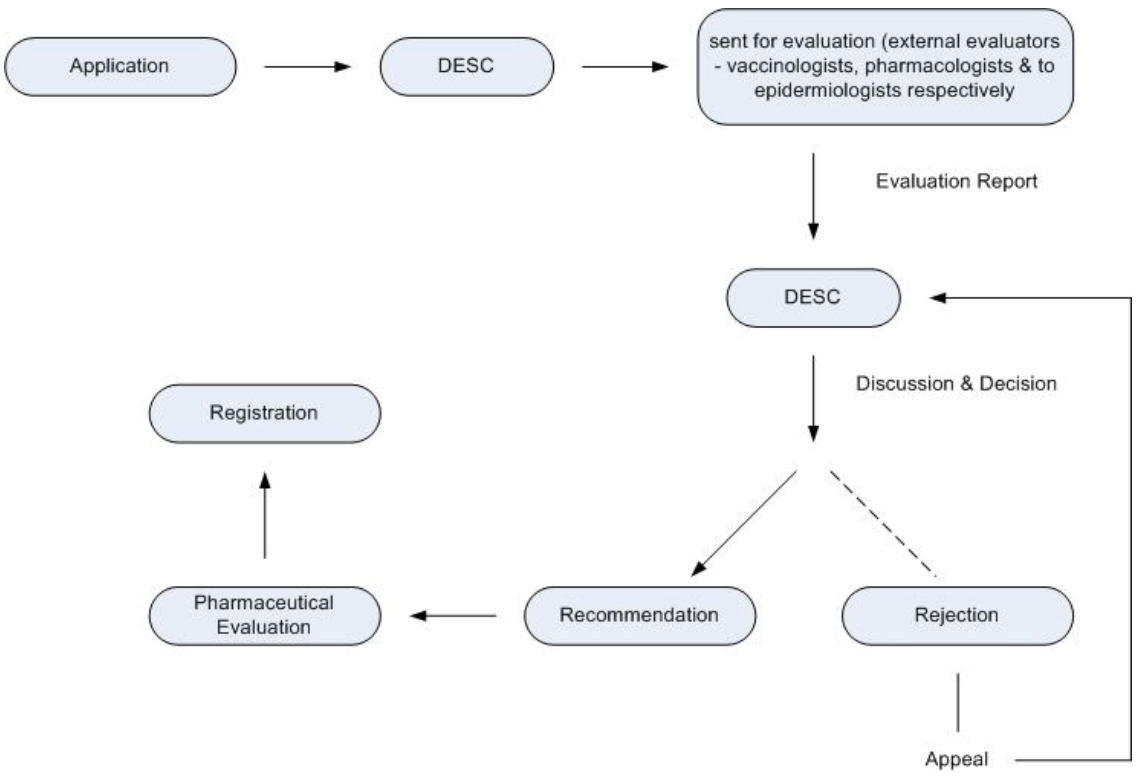


Figure 1: Evaluation process for vaccines

STATE PHARMACEUTICALS MANUFACTURING CORPORATIONA

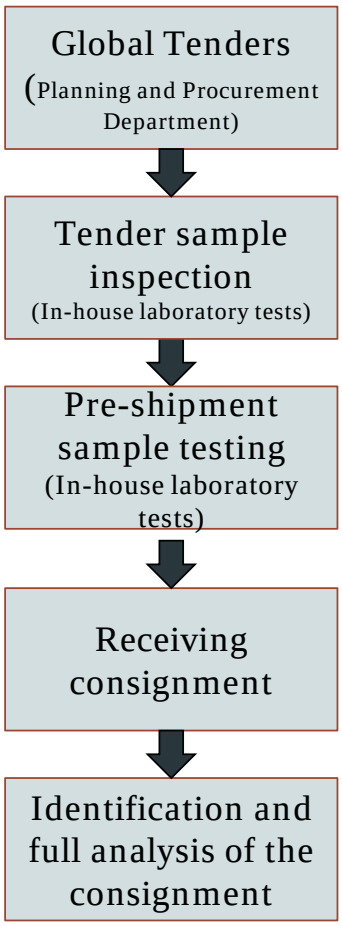
- Manufacturers of generic pharmaceuticals
- Established in 1987 as a donation by Japanese government with the aim of supplying essential drugs for the Sri Lankan community.
- Currently manufacturing 64 solid dosage forms for government hospitals, and local pharmacies

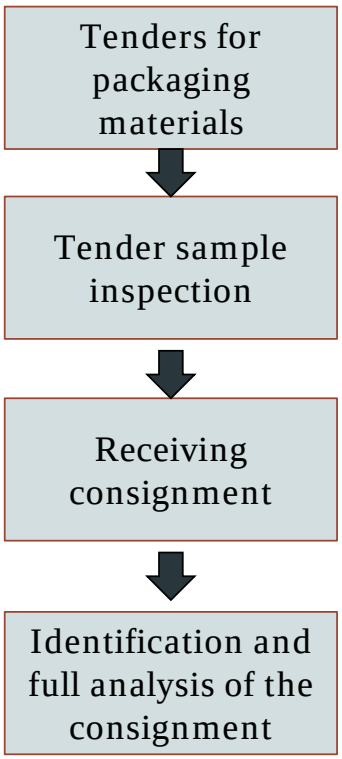
Our functions

- Supply essential drugs
- Affordable prices
- Maintain quality of drugs
- Maintain GMP in the premises and the processes
- Comply with the CDD Act

Approved standards in Sri Lanka

- Pharmacopoeia Internationalis
- The British Pharmacopoeia
- The pharmacopoeia of the United States of America
- The British Pharmaceutical Codex
- The British Veterinary Codex
- The Japanese Pharmacopoeia
- European Pharmacopoeia

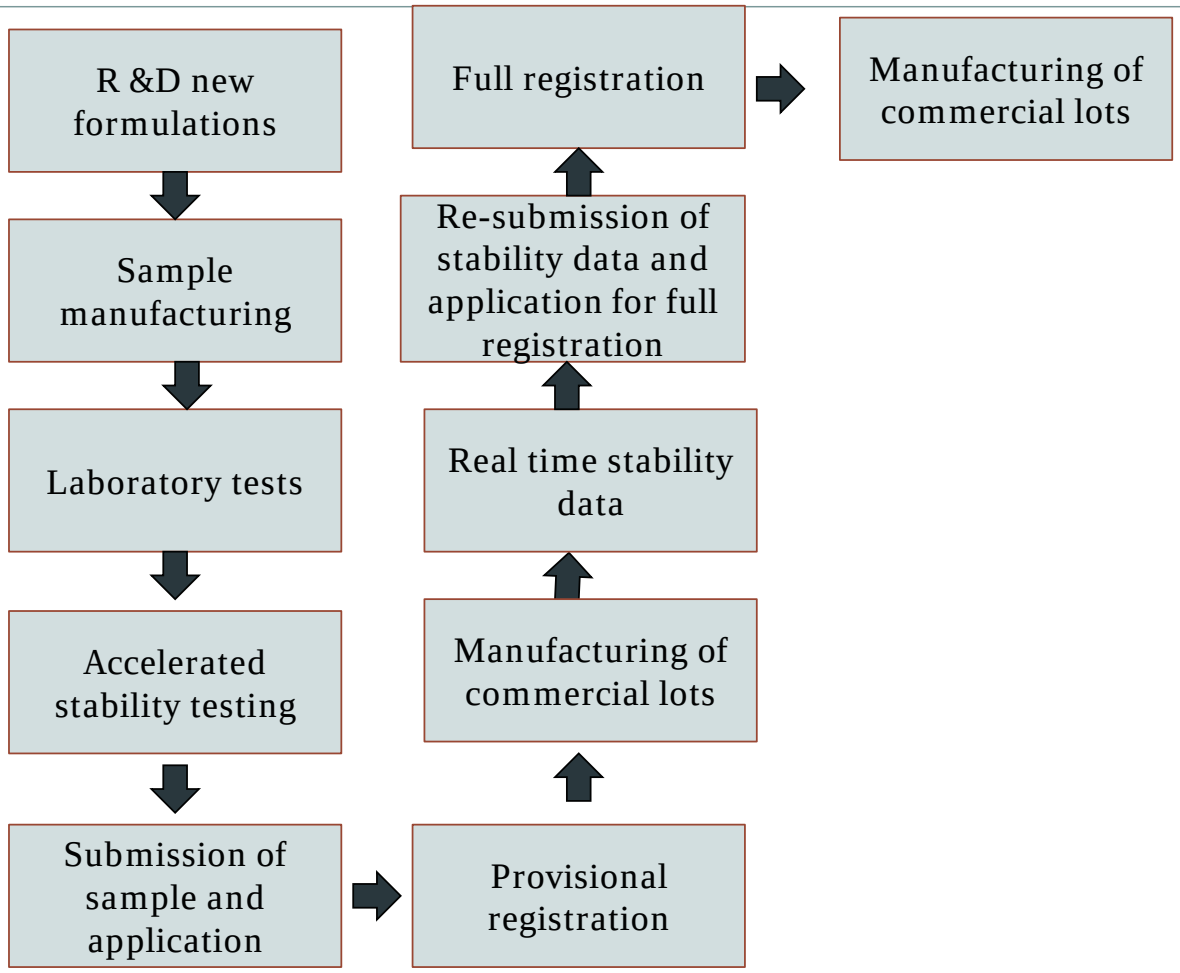




Quality control of products

- Quality control tests of raw materials and finished products are carried out in the following manner
  - Tender samples
  - Pre-shipment samples
  - Consignment samples
  - In-process quality testing of finished products
  - Final quality testing of the finished products

- Independent quality tests are done by National Drug Quality Assurance Laboratory (NDQAL)



Main issues

- Issues
  - Validation of processes are difficult
    - Raw materials are imported from different suppliers
    - Lack of equipment
  - Bioequalence studies are difficult to be carried out
    - Lack of funds and facilities
  - Lack of post marketing surveillance data
    - Still not implemented

出典：平成 25 年度 JICA 集団研修カントリーレポート

- 平成 25 年度 JICA 集団研修「薬事行政」

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

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公益社団法人国際厚生事業団（JICWELS）は、国際的な保健・福祉分野の国際協力に貢献することを目的として、1983 年（昭和 58 年）7 月 7 日に厚生省（現厚生労働省）から社団法人の認可を受け設立されました。開発途上国の行政官研修や WHO フェローの受入れ、調査企画や研究開発並びに情報の交換及び広報活動など、海外諸国との国際交流活動を推進しています。

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