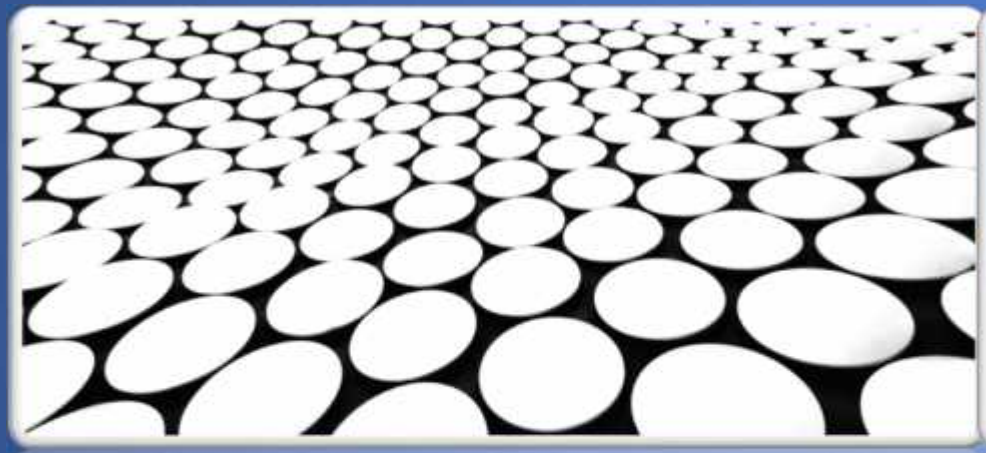
Food and Drug Department
Ministry of health
Lao's People Democratic Republic (Lao PDR)

Migrating from routine to risk based inspections-optimizing the human resources in post pandemic

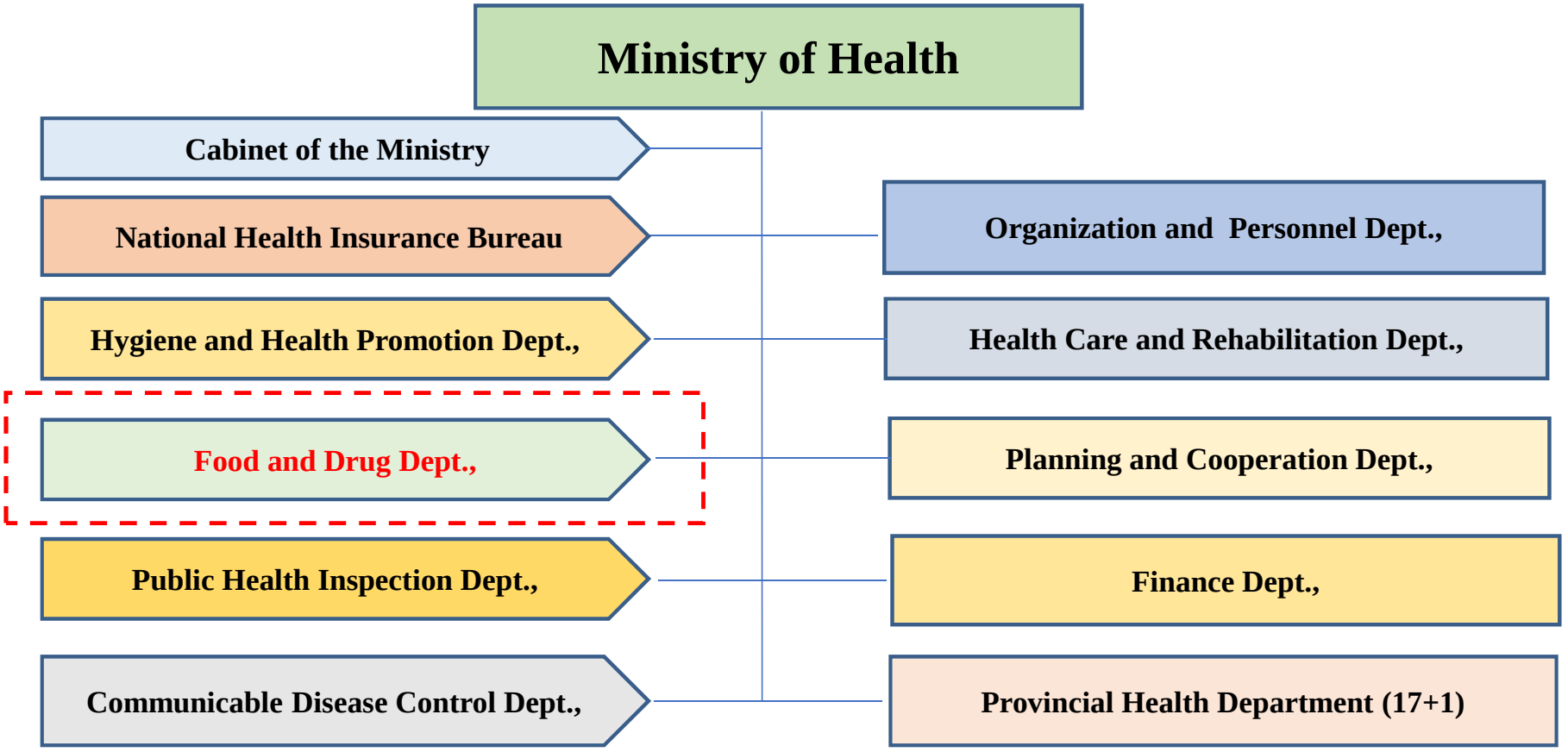


PRESENTED BY DR. BOUNXOU KEOHAVONG
FOOD AND DRUG DEPARTMENT, MINISTRY OF HEALTH, LAOS

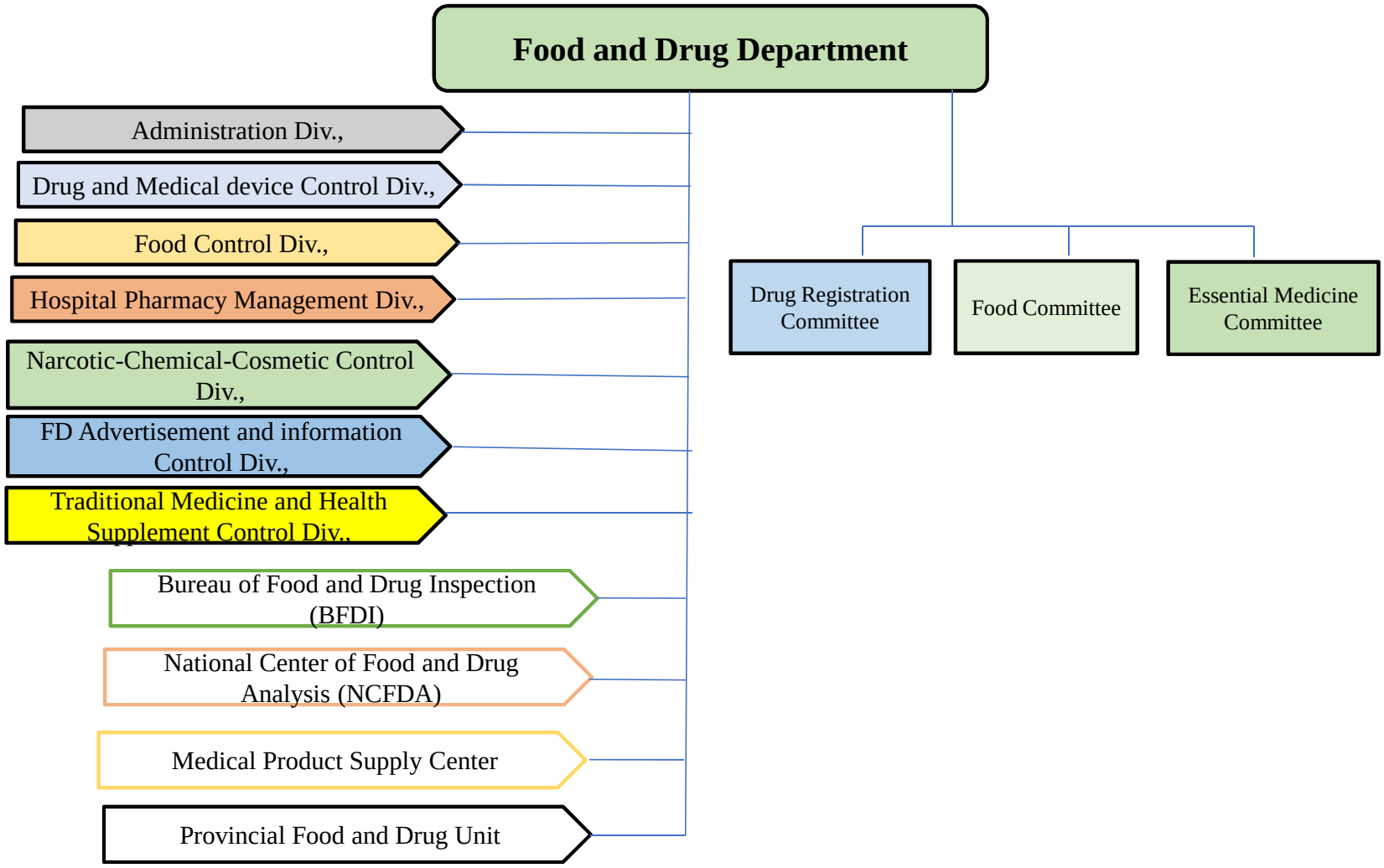
Outline

- *Organization chart of Ministry of Health and Food and Drug Department*
- *Law, Regulation and product registration requirements*
- *Pharmaceutical Factory establishment*
- *Current Local Manufacturer, licensed import-export company and number of product registration*
- *Post Market System and activities*
- *Challenges and limitations*

Organization chart of Ministry of Health



Organization Chart of Food and Drug Department(FDD)



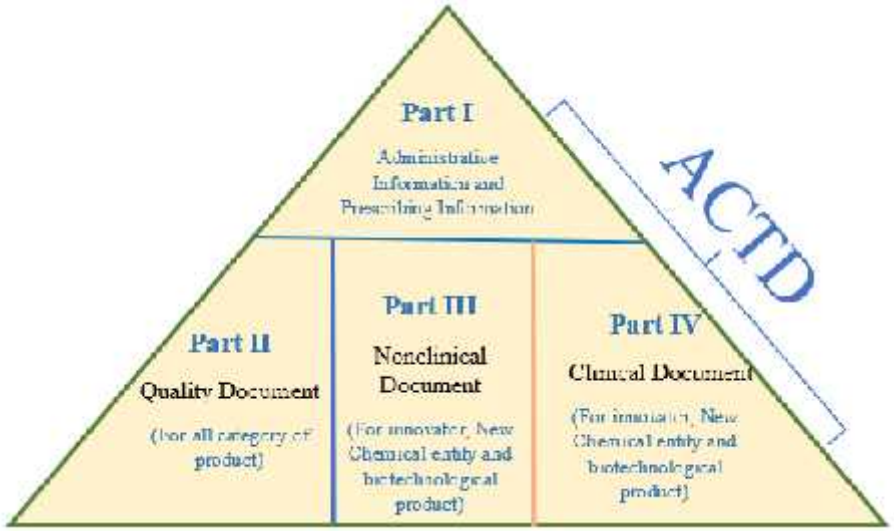
Law and Regulations

National Medicine Policy (1st Revision, 2003)
Law on Drug and Medical Products No: 07/NA ,rev. dated 21 December 2011
Regulation Governing Drug registration No. 1441, dated 13 Aug 2003
Regulation on specific controlled medicine and uncontrolled and OTC Drug No.2580, dated 25 Nov 2002
Regulation on drug and medical product manufacturing No. 937, dated 12 May 2004.
Regulation of Donation of Drugs and Medical Product No.2579 dated 12 Nov 2003
Regulation on the banned drug in Lao No.1018, 2003
Regulation for Pharmacy No. 2922, dated 21 Sep 2016
Regulation on business for Medicine and Medical Product Company No. 1820, dated 25 Aug 2017
Regulation for good manufacturing practice and quality control of drugs No. 1021, dated 11 Aug 1999
Regulation on Emergency Use Authorization approval No.0833, dated 18 Feb 2021.
Regulation on registration of traditional medicine No.169, dated 25 Jan 2022.

Registration Procedure

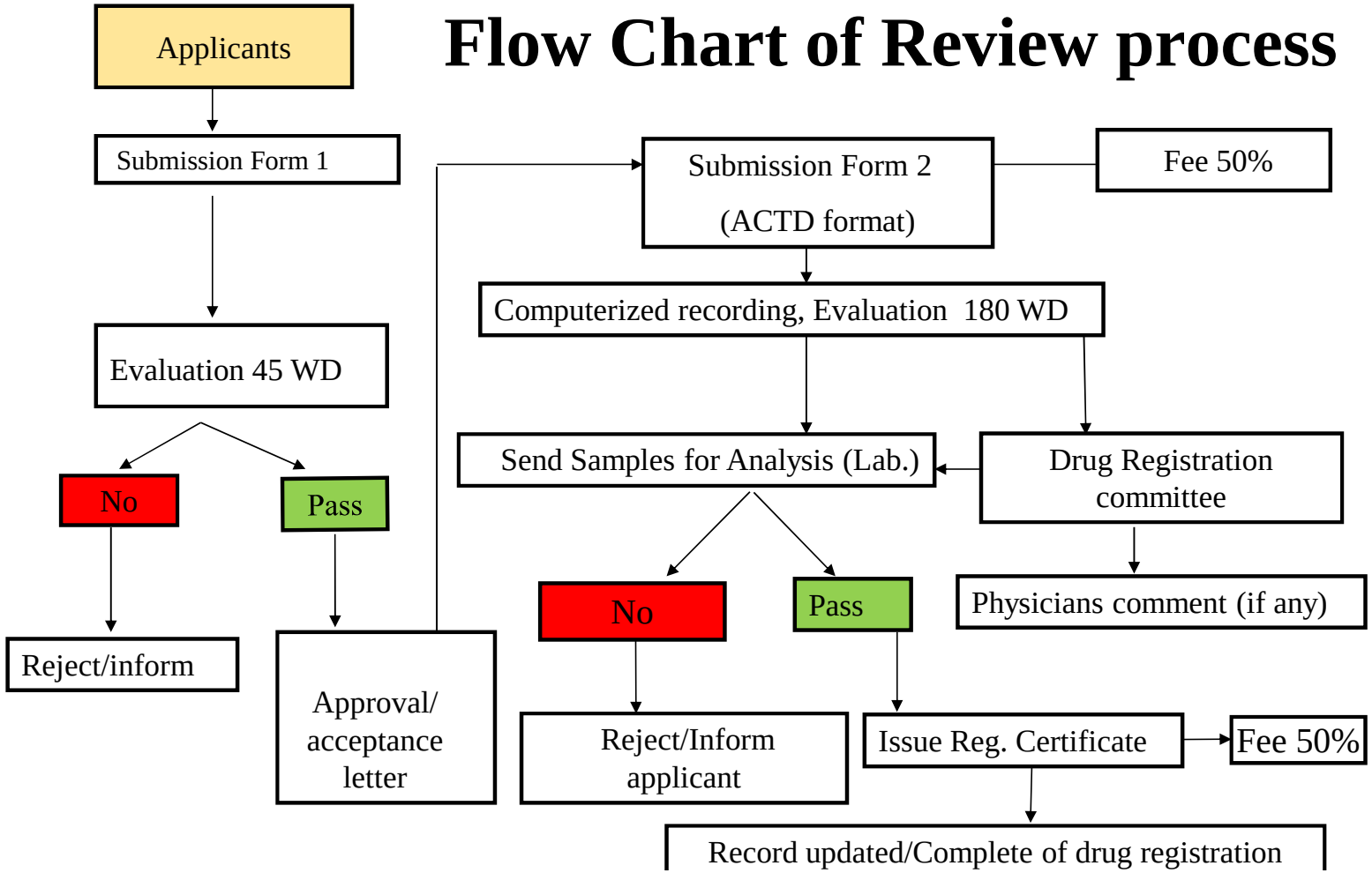
Step 1: Application for the permission to import or manufacture drug sample intended to be registered (Screening stage)

Step 2: Application for the Product Registration approval



➢Certificate need to be renewed every 3 years

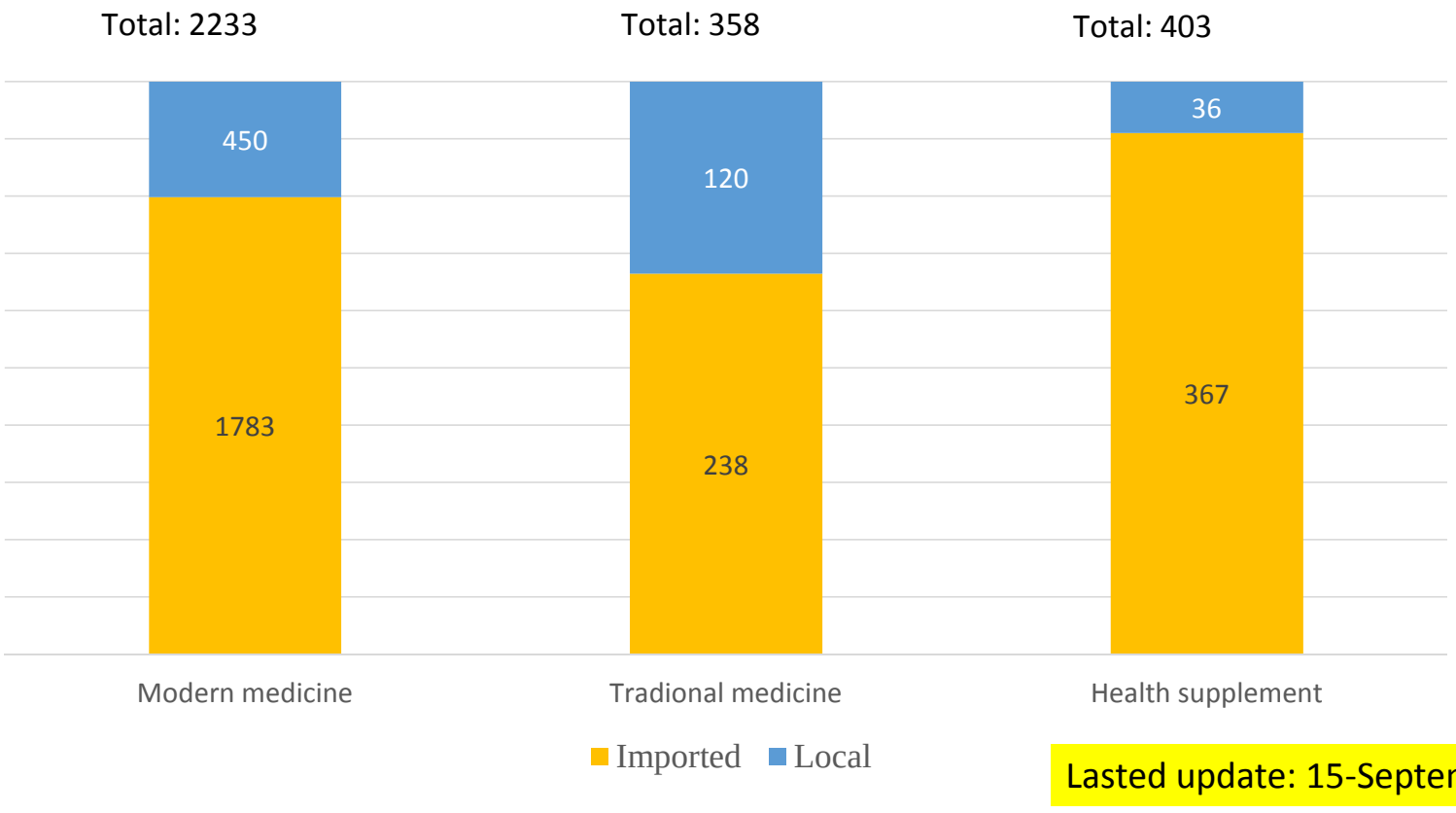
Registration Procedure



Current Local Manufacturer, company wholesaler and pharmacy

Licensed Import-Export Company	Local manufacturer for medicine	Local medical device manufacturer	Wholesaler	Private Pharmacy
96	14	6	9	3,502

Product registration



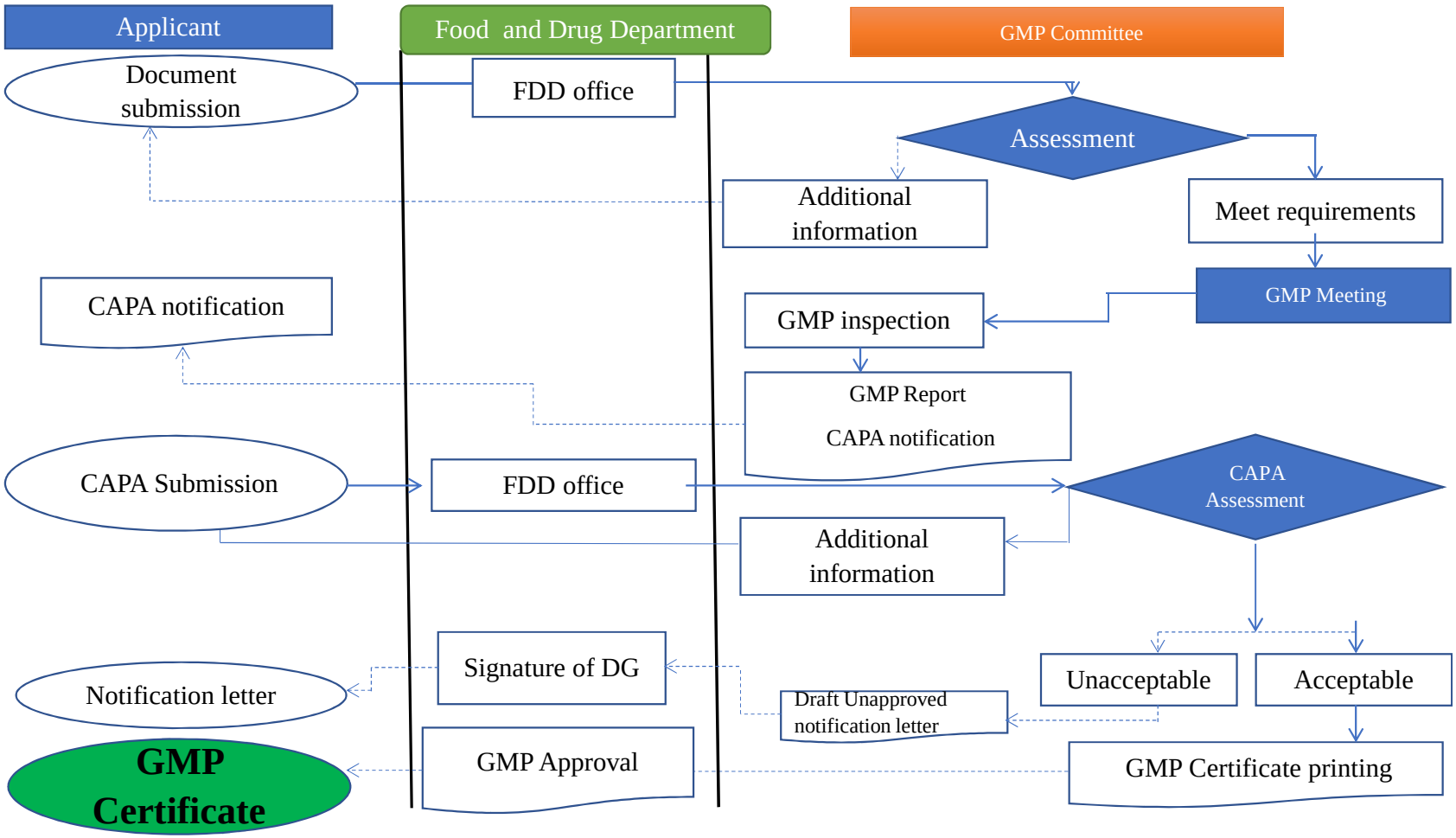
Lasted update: 15-September 2022

Pharmaceutical factory Establishment

- **Regulation on drug and medical product manufacturing**
- **Authorized person Conditions for pharmaceutical factory establishment**
- **Site master file**
- **Factory layout**
- **Location Condition**
- **Documentation**
- **Facility inspection**

- **GMP Committee**
- **Documents assessment/Evaluation**
- **Field visit**
- **Inspection report**
- **Certification (validity 2 years)**
- **Monitoring and supervision**

GMP application



Post Market System

1. Food and Drug Department:

- **Assure the actively implementation of Pharmacovigilance system**
- **Monitor the notification from WHO-Uppsala Monitoring Centre**
- **Monitor the notification from** ASEAN Post Marketing Alert System
- **Notification From Authorities, Manufacturers, and Local Company**
- **Notification to related office and Take action**

Post Market System

2. Bureau of Food and Drug Inspection (BFDI), FD Local authority: Key man to conduct:

Monitoring and inspect pharmaceutical products circulated in:

- State Hospital
- Private Hospital
- Private pharmacy
- Private clinic
- Imported company
- Wholesaler
- Convenient stores

Focus on:

- Quality defect product, unregistered product, illegal imported, banned product, falsified product.
- Sampling and collect sample for quality testing
- Law and regulation enforcement

Post Market System

3. National Center of Food and Drug Analysis (NCFDA) :
GLP, ISO/IEC 17025:2017

- **Test/analyze** the quality of:

- Food,
- Drug,
- Medical devices
- Health products,
- Cosmetics,
- Narcotic and psychotropic drugs,
-Toxic from food and pharmaceutical products;

Challenges

- Language barrier
- Implementation ACTD/ACTR
- Reliance mechanism
- Overload Paper–Based application
- Timely assessment drug application
- Assessor’s education background
- New drug Evaluation capability
- Biologic product
- Emergency Use Authorisation migrating to the regular Authorized

Limitations

- Limited human Resource
- Limited expertise on assessment the New Chemical Entity (NCE) and Biological product
- Limited expertise for GMP inspection
- Limited capacity to test all kinds of medical products
- Limited budget to do sampling and quality test of pharmaceutical product in the market
- Limited expertise for analyze ADR and AEFI


Thank
you