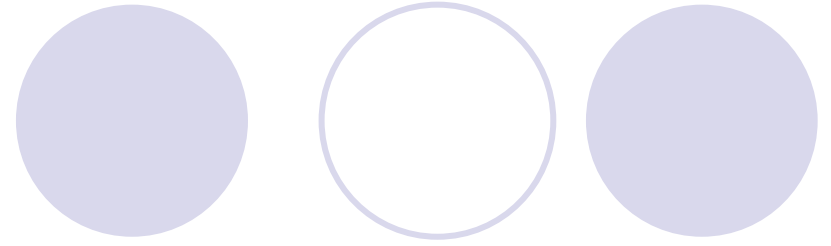
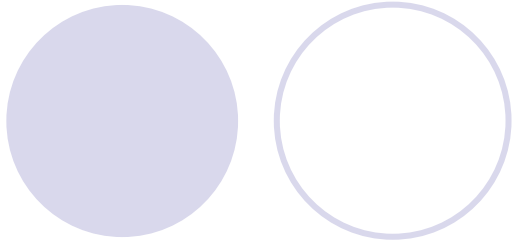


DRUG CONTROL AND REGISTRATION



SIRIPORN CHAWANON
Pharmacist, professional level
Drug Control Division
Thai Food and Drug Administration



OUTLINE

- Drug Control System
- The Organization of Drug Control Division
- Drug Licensing and Registration
- Drug Registration system
- Safety Monitoring Program

DRUG CONTROL SYSTEM

MINISTRY OF PUBLIC HEALTH

FOOD AND DRUG ADMINISTRATION (FDA)

DEPARTMENT OF MEDICAL SCIENCES

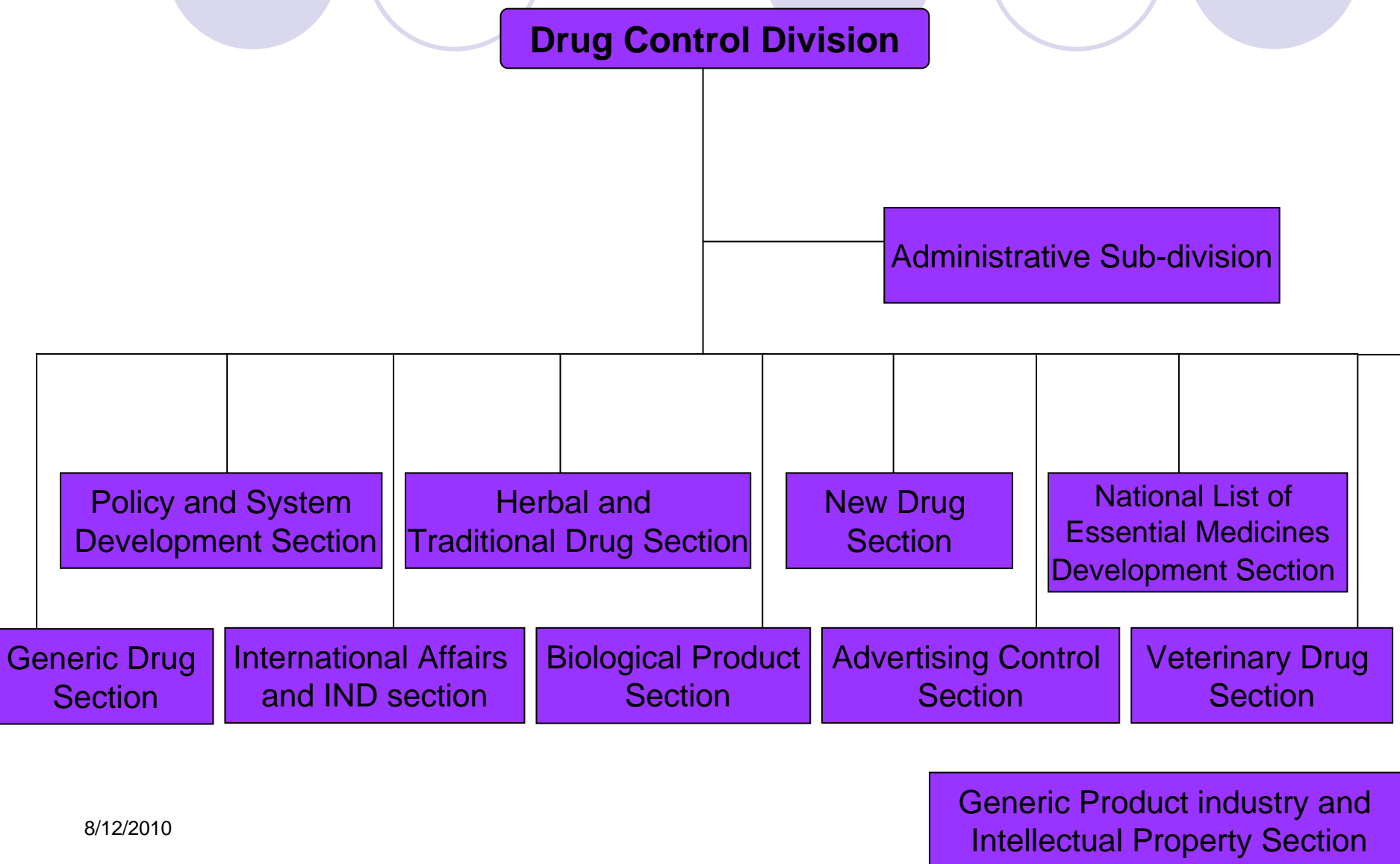
PROVINCIAL HEALTH OFFICES

THAI FDA

- **PRE-MARKETING:** LICENSING
DRUG REGISTRATION
- **POST-MARKETING:** INSPECTION
SURVEILLANCE
ADR MONITORING



The Organization Chart of Drug Control Division

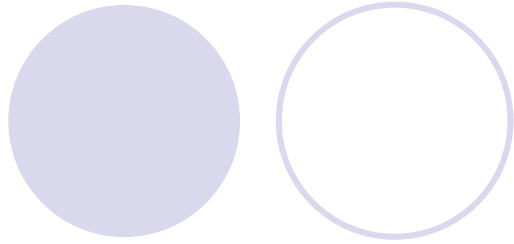


Thai Regulatory System

The legislative basis of this system is the Drug Act BE 2510 (1967) and amendments

Thai Regulatory System

- **The Drug Act provides that decisions of the Secretary-General, FDA, be made with advice of a Drug Board made up of principal relevant Departmental Directors General in the MoPH as well as representatives from related organizations, plus five to nine drug experts.**
- **The Drug Board meets monthly and may give recommendations or opinions on licensing and registration decisions such as approved, withdraw or suspend the licenses.**



Licensing

The drug Act requires that persons who wish to sell, produce, or import drugs into Thailand have to obtain a license from the FDA.



Registration

- **Qualified person: Authorized licensees**
- **To ensure efficacy safety and quality of drugs**
- **Upon receipt of Drug Registration Certificate, the drug can be lawfully marketed.**

DRUG REGISTRATION AND APPROVAL

New Drugs and New Generic Drugs

(for human uses)



New Drug Section

Generic Drugs (for human uses)



Generic Drug Section

Biological Products

(for human or veterinary uses)



Biological Product Section

Veterinary Drugs



Veterinary and Pharmaceutical chemicals Section

(not include Biological Products and Traditional and Herbal Drugs)

Traditional and Herbal Drugs



Traditional and Herbal Medicine Section

(for human or veterinary uses)

DRUG REGISTRATION PROCESS



Applicants: Only authorized licensees are qualified to apply for product registration.



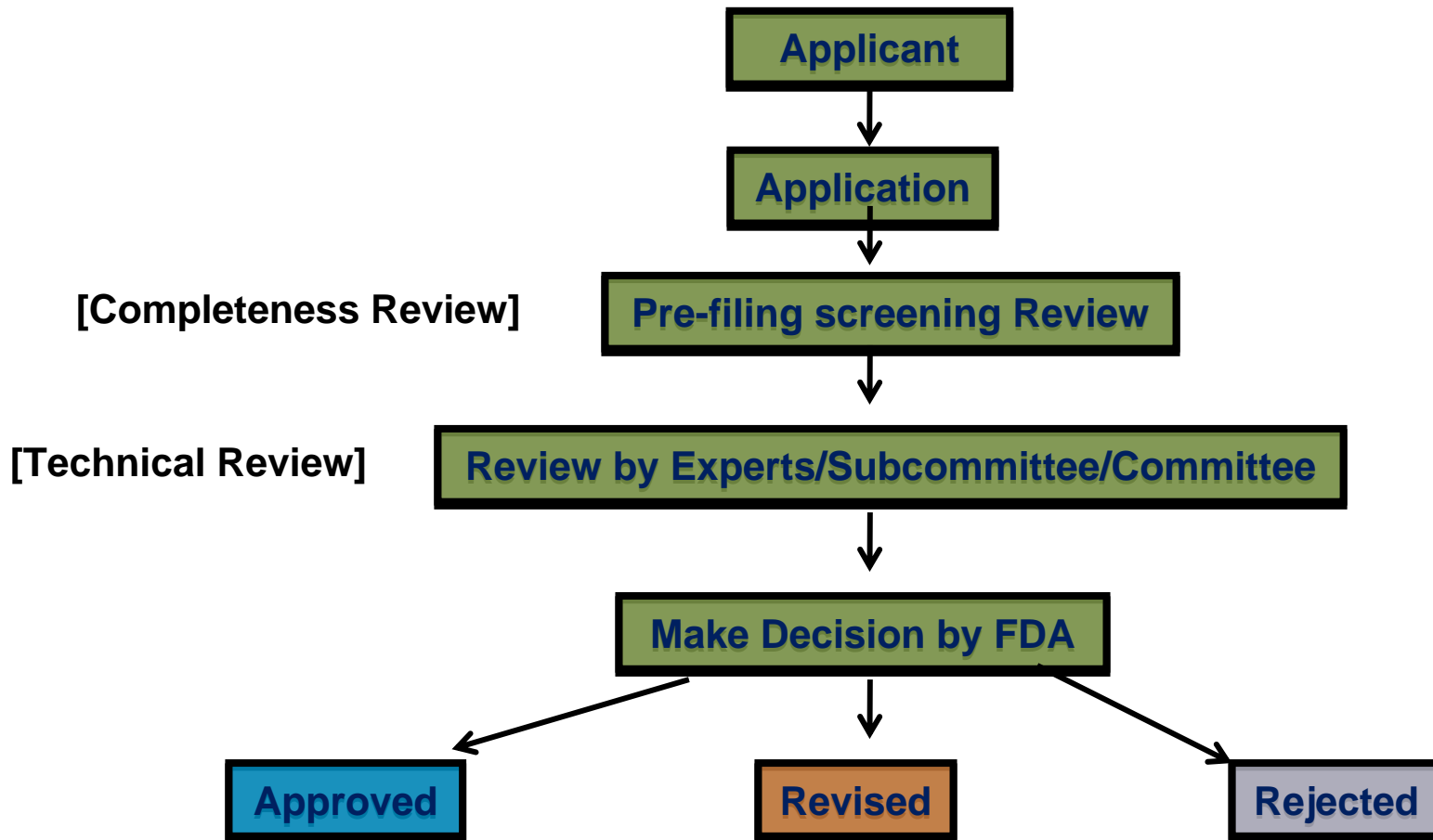
Manufacturing plants :GMP compliance

2 steps:

Step 1: Application for permission to manufacture or import of drug samples – One Stop Service Center

Step 2: Application for product registration approval

Flow Chart of Drug Review Process



Thai FDA Classified modern medicine into 3 categories :

- **New drugs**
- **New generic drugs:** Pharmaceutical products with the same active ingredients, doses and dosage forms as those of new compounds (new drugs) registered after 1992 but manufactured by different manufacturers
- **Generic drugs.**

Thai FDA Classified modern medicine into 3 categories :

- **New drugs:** registrations is the most stringent of all require a complete set of product dossiers
- **Generic drugs.** The registrations require basically dossiers on product manufacturing and quality control together with product information.
- **New generic drugs:** In addition to the required dossiers for generic submission, the new generic registrations require dossiers of bioequivalence studies as well as literature documents for supporting safety and efficacy

ASEAN HARMONIZATION PRODUCT i.e.

- **ACTR , ACTD**
- **4 Technical Guidelines**
 - (1) Analytical Validation guideline**
 - (2) BA/BE Studies guideline**
 - (3) Process Validation guideline**
 - (4) Stability Study**



Process of New Drug Registration

Track 1 : Standard Review

210 - 280 working days

Track 2 : Accelerated or Priority Review

(Drugs for public health problems / life threatening)

100-130 working days



Process of New Generic Drug Registration

Track 1 : Standard Review

110 working days

Track 2 : Accelerated or Priority Review

(Drugs for public health problems / life threatening)

70 working days



New Drug Registration (ASEAN Harmonization)

ASEAN Common Technical Dossiers (ACTD)

Documents to be submitted 4 Parts

Part 1: Administrative Data and Product Information

Part 2: Quality Document

Part 3: Nonclinical Document

Part 4: Clinical Document

New Drug Registration System

Step I

New Drug

**Experts/Subcommittee
Approval**

Conditional approval

SMP & Limited distribution (2 yrs)

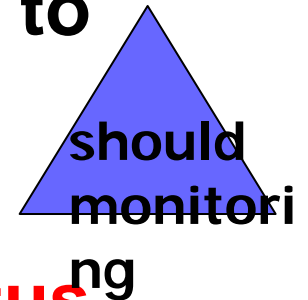
Unconditional approval

Step II

Voluntary Spontaneous ADR Reporting System

Conditional Approval

- Safety Monitoring Program (SMP) will be conducted for approx. 2 years.
- Drug packages must bear labeling to show conditional approval status.



- Triangle shows monitoring status.
- Specially-control drug
- Limited distribution only through medical institutes or hospitals



Why SMP?

Objectives:

- **To confirm the drug safety in Thai patients**
- **To generate earlier safety signals and gather more safety information of new drugs before granting and unconditional approval.**
- **To more rigorously control the usage of new drugs**



Why SMP? (2)

Objectives:

- **To encourage physicians, pharmacist and other health professionals to have more concerns on the safety of new drugs and their usage.**

What Have Been Currently Done ?

- Capacity building on drug evaluation and registration in order to be prepared for ASEAN Pharmaceutical Harmonization and WHO assessment of regulatory system.
- Collaboration and communication links with other NRAs in order to strengthen professional competence and exchange information (MOU with TGA, US FDA Regulator Training Program for vaccine)
- BE study submitted for registration should be conducted in compliance with the ICH GCP as well as GLP standard.

What Have Been Currently Done ?

- Encourage current and new domestic manufacturer to upgrade their quality standard.
- The proposed revision of Drug Act is expected to bring about better drug regulatory implications
- One Stop Service Center has been established for submitted applications which can be processed and approved within a short time period.

What Have Been Currently Done ?

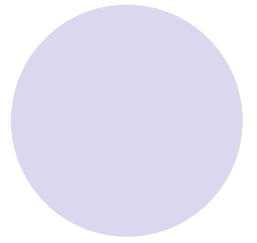
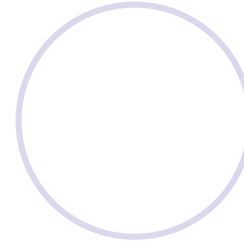
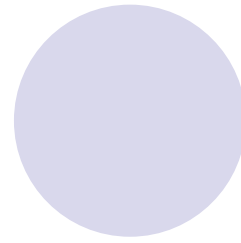
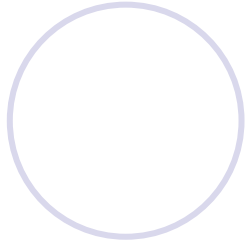
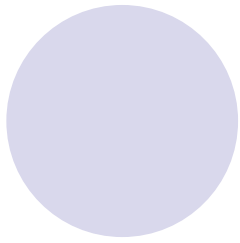
- Maintain a balance between ensuring a product is safe, efficacious and of good quality and not delaying public access to the products. by Clearly separate the tracks of registration submission into standard review and priority review and Reduce the timelines for each steps were announced.

The proposed policies to promote the accessibility of the medicine, which can solve the public health's problem

1. The fast track pathway for the emergent medicine, such as, *neoplastic, H.I.V.*, antituberculous drug, antiviral vaccine, can reduce the consideration period from 280 working days to 130 working days.
2. Thailand's MoPH issued a compulsory license for HIV drug (EFFAVIRENZE, lopinavir/ritonavir) and drug for other diseases with public health consequences such as cancer or other chronic diseases (letrozole Imatinib errotinib docetaxel clonidogrel)

The proposed policies to promote the accessibility of the medicine, which can solve the public health's problem

3. The personnel's efficiency should be more developed and improve competence
4. the ASEAN Economic Ministers signed the ASEAN Sectoral Mutual Recognition Arrangement (MRA) for Good Manufacturing Practice (GMP).



**THANK YOU FOR YOUR
ATTENTION**

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