The Biological Product Registration Requirements of Thailand

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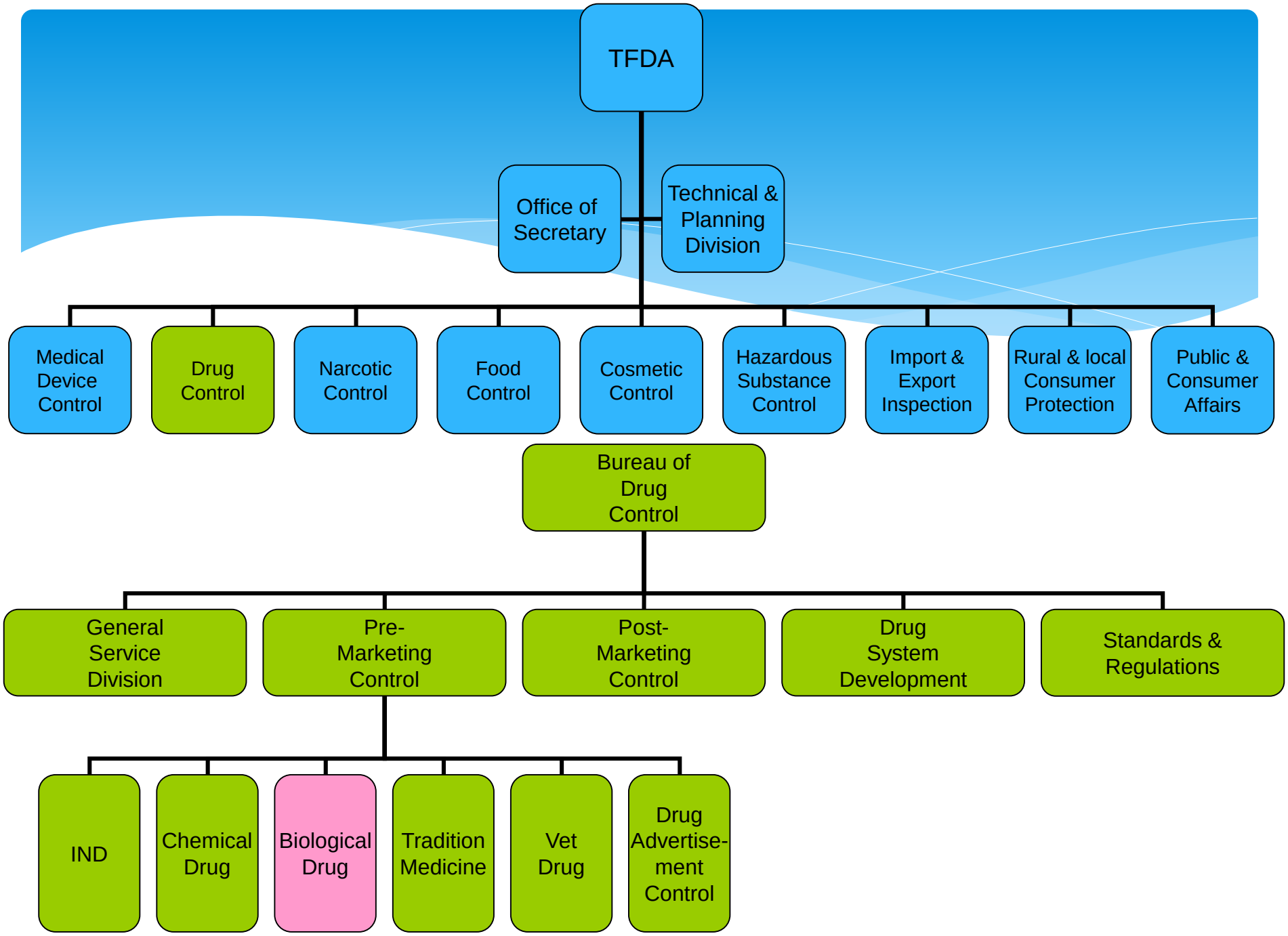
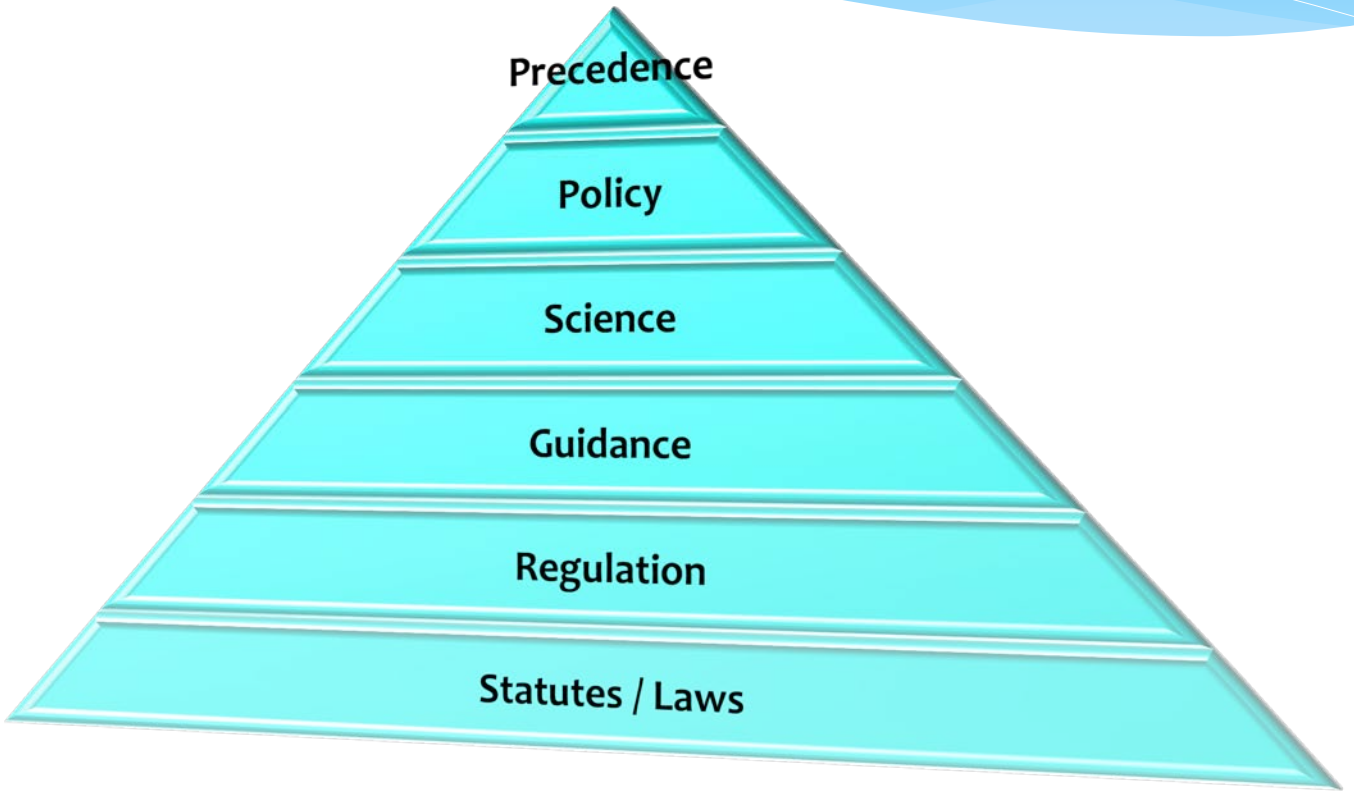
GBC 2016, Korea (29 June 2016)

Outline

- Legal Basis and classification of medicines for registration
- Standards, Requirements and Recommendations
- Conclusions


TFDA
Office of Secretary
Technical & Planning Division
Medical Device Control
Drug Control
Narcotic Control
Food Control
Cosmetic Control
Hazardous Substance Control
Import & Export Inspection
Rural & local Consumer Protection
Public & Consumer Affairs
Bureau of Drug Control
General Service Division
Pre-Marketing Control
Post-Marketing Control
Drug System Development
Standards & Regulations
IND
Chemical Drug
Biological Drug
Tradition Medicine
Vet Drug
Drug Advertise-ment Control

Building Blocks of Decision-Making



Regulatory System of Medicinal Products in Thailand

* **Drug Act B.E. 2510 (1967)** and its four **amendments**

  2nd Revision **B.E.2518 (1975)**

  3rd Revision **B.E.2522 (1979)**

  4th Revision **B.E.2527 (1984)**

  5th Revision **B.E.2530 (1987)**

Regulatory System of Medicinal Products in Thailand (Cont.)

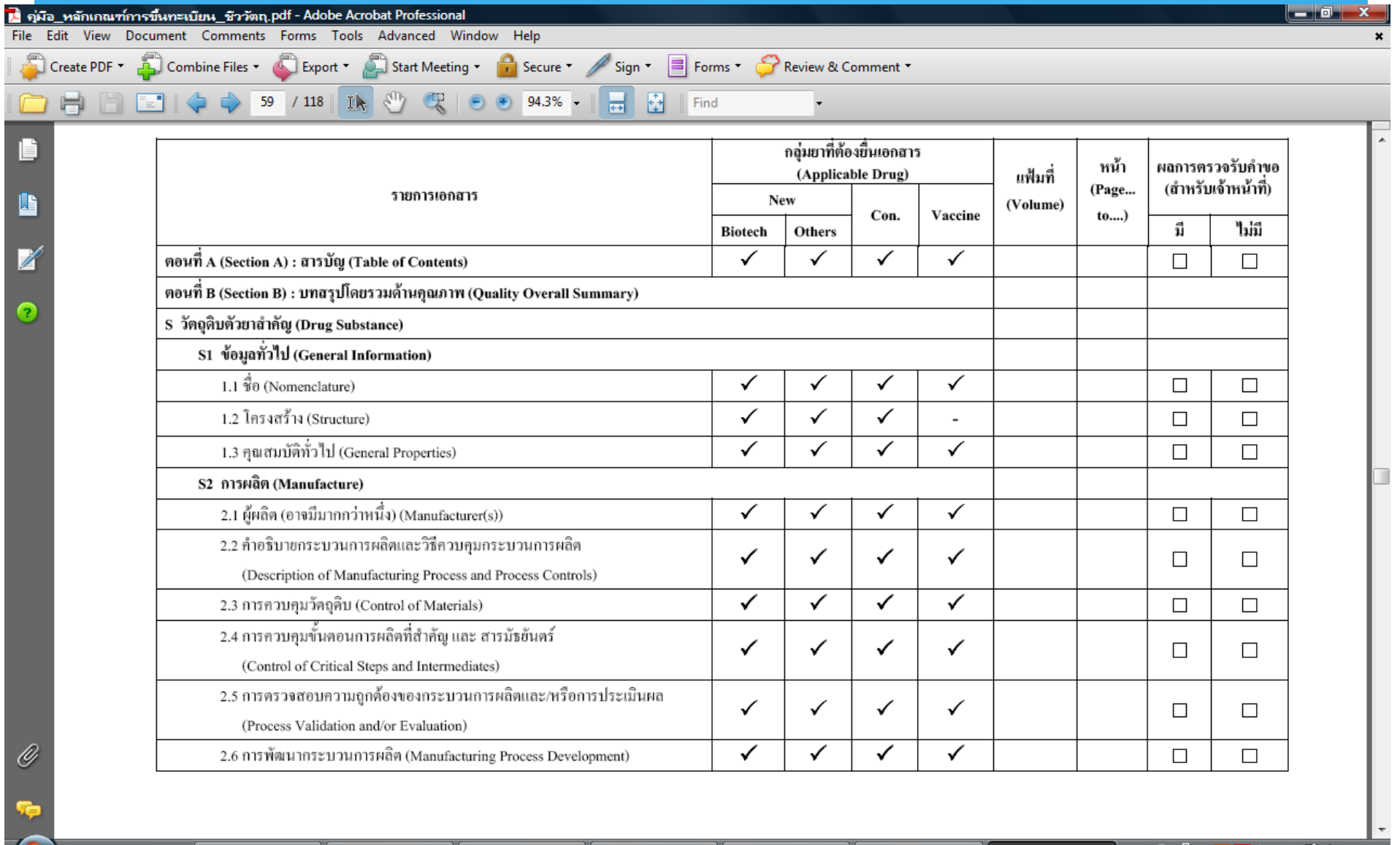
* Empowers TFDA as National Regulatory Authority
* Encompasses legal framework to regulate **Medicinal Products for both human and veterinary** use in Thailand to meet consistent and reliable standard of assured Quality, Safety and Efficacy

Current Control

For examples :

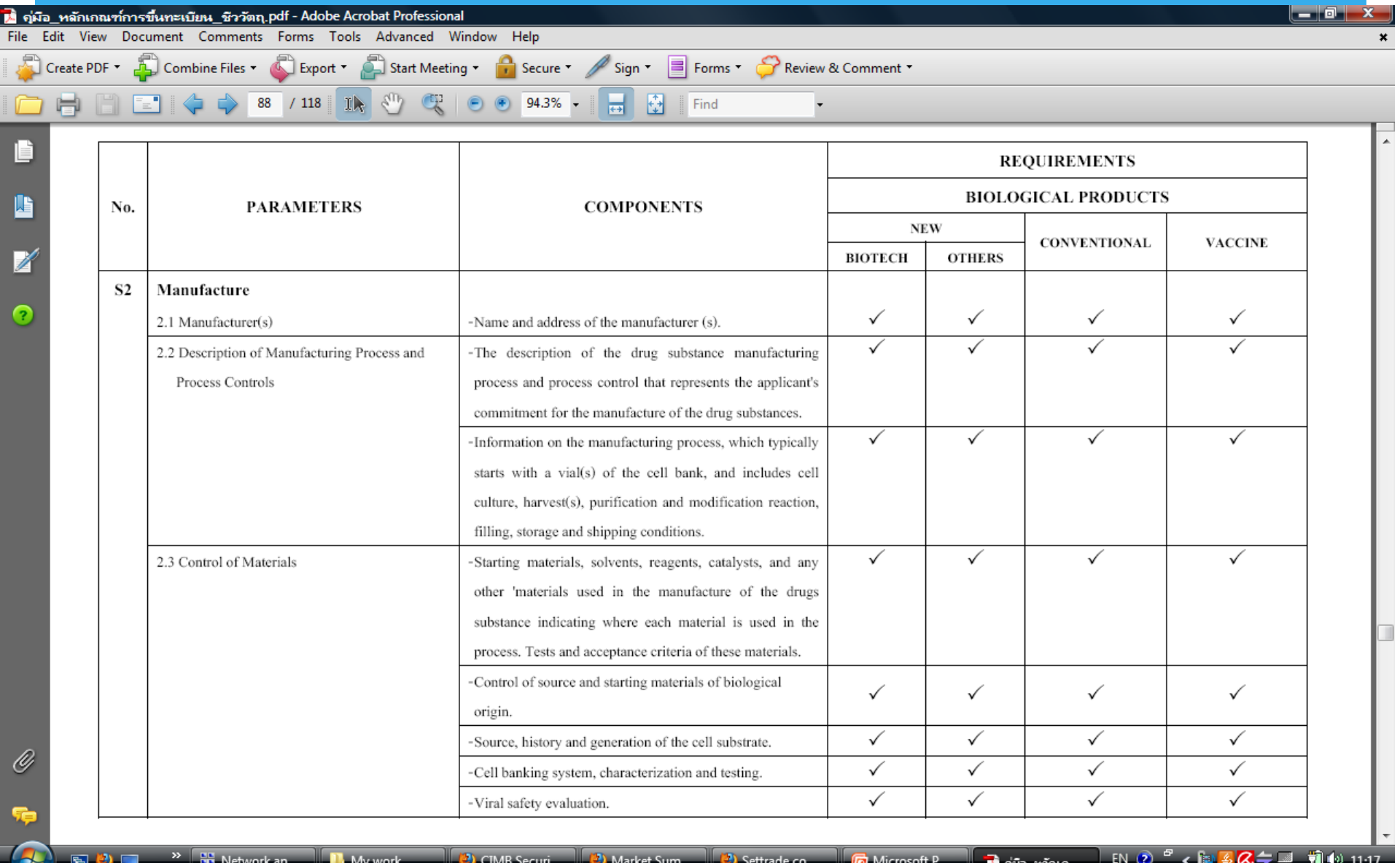
* Ministerial regulation : Lot release control (Thai)
* Ministerial regulation : GMP for Biological products (Thai)
* TFDA announcement : Biosimilar products registration (Thai)
* ACTD/ACTR for ASEAN Harmonization (Thai, Eng)

ACTD/ACTR



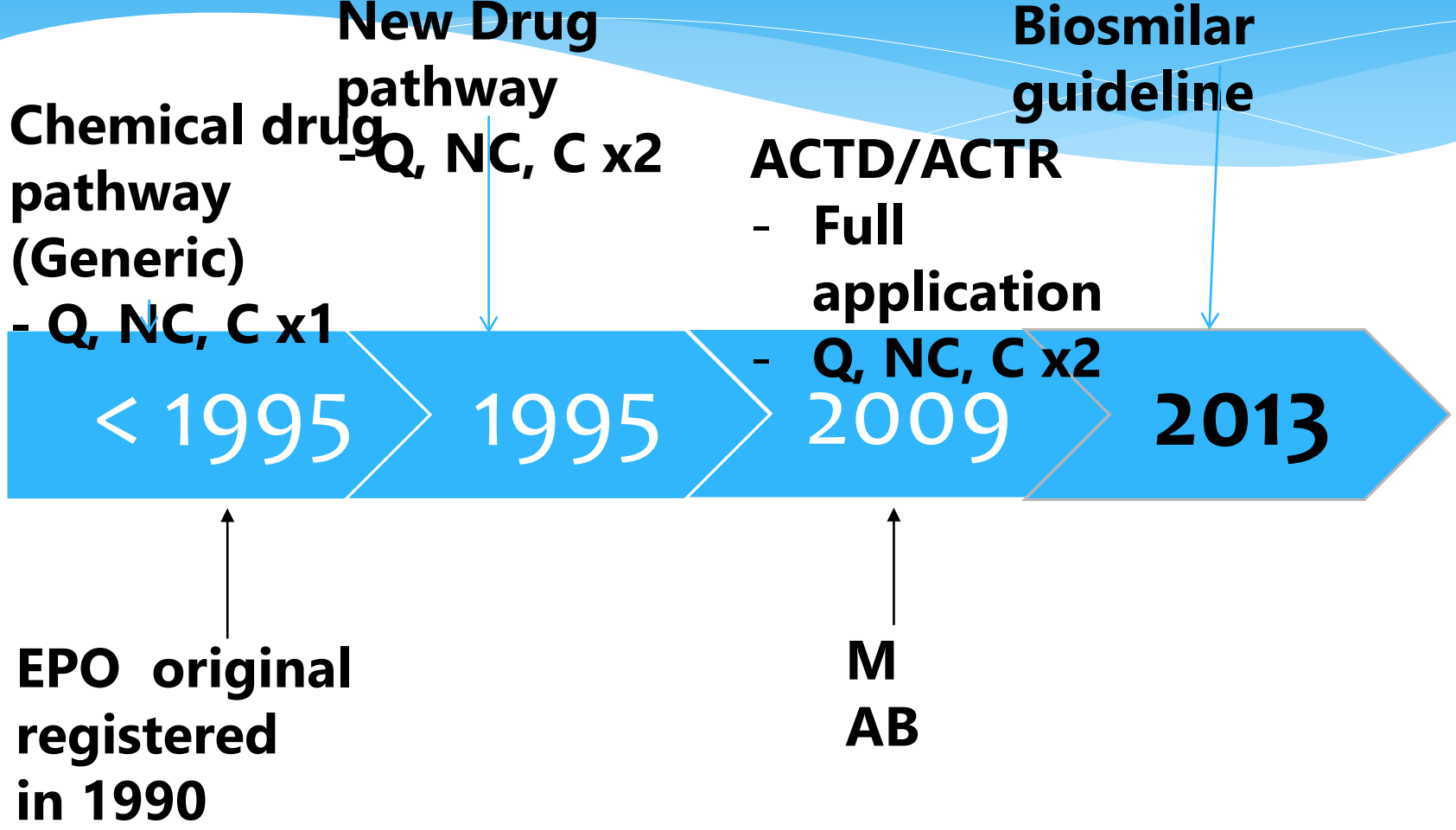
รายการเอกสาร	กลุ่มยาที่ต้องยื่นเอกสาร (Applicable Drug)				แฟ้มที่ (Volume)	หน้า (Page... to....)	ผลการตรวจรับคำขอ (สำหรับเจ้าหน้าที่)	
	New		Con.	Vaccine				
	Biotech	Others					มี	ไม่มี
ตอนที่ A (Section A) : สารบัญ (Table of Contents)	✓	✓	✓	✓			☐	☐
ตอนที่ B (Section B) : บทสรุปโดยรวมด้านคุณภาพ (Quality Overall Summary)								
S วัตถุดิบตัวยาสำคัญ (Drug Substance)								
S1 ข้อมูลทั่วไป (General Information)								
1.1 ชื่อ (Nomenclature)	✓	✓	✓	✓			☐	☐
1.2 โครงสร้าง (Structure)	✓	✓	✓	-			☐	☐
1.3 คุณสมบัติทั่วไป (General Properties)	✓	✓	✓	✓			☐	☐
S2 การผลิต (Manufacture)								
2.1 ผู้ผลิต (อาจมีมากกว่าหนึ่ง) (Manufacturer(s))	✓	✓	✓	✓			☐	☐
2.2 คำอธิบายกระบวนการผลิตและวิธีควบคุมกระบวนการผลิต (Description of Manufacturing Process and Process Controls)	✓	✓	✓	✓			☐	☐
2.3 การควบคุมวัตถุดิบ (Control of Materials)	✓	✓	✓	✓			☐	☐
2.4 การควบคุมขั้นตอนการผลิตที่สำคัญ และ สารมัธยันตร์ (Control of Critical Steps and Intermediates)	✓	✓	✓	✓			☐	☐
2.5 การตรวจสอบความถูกต้องของกระบวนการผลิตและ/หรือการประเมินผล (Process Validation and/or Evaluation)	✓	✓	✓	✓			☐	☐
2.6 การพัฒนากระบวนการผลิต (Manufacturing Process Development)	✓	✓	✓	✓			☐	☐

ACTD/ACTR



No.	PARAMETERS	COMPONENTS	REQUIREMENTS			
			BIOLOGICAL PRODUCTS			
			NEW		CONVENTIONAL	VACCINE
			BIOTECH	OTHERS		
S2	**Manufacture**					
	2.1 Manufacturer(s)	-Name and address of the manufacturer (s).	✓	✓	✓	✓
	2.2 Description of Manufacturing Process and Process Controls	-The description of the drug substance manufacturing process and process control that represents the applicant's commitment for the manufacture of the drug substances.	✓	✓	✓	✓
		-Information on the manufacturing process, which typically starts with a vial(s) of the cell bank, and includes cell culture, harvest(s), purification and modification reaction, filling, storage and shipping conditions.	✓	✓	✓	✓
	2.3 Control of Materials	-Starting materials, solvents, reagents, catalysts, and any other 'materials used in the manufacture of the drugs substance indicating where each material is used in the process. Tests and acceptance criteria of these materials.	✓	✓	✓	✓
		-Control of source and starting materials of biological origin.	✓	✓	✓	✓
		-Source, history and generation of the cell substrate.	✓	✓	✓	✓
		-Cell banking system, characterization and testing.	✓	✓	✓	✓
		-Viral safety evaluation.	✓	✓	✓	✓

Development of registration pathway



Regulatory Control System in Thailand

- Pre-marketing Control System shall include:

  - IND approval

    - Clinical trails must be conducted using the biological product submitted for registration

    - Clinical trials must have been approved by the NRA* (TFDA; import permit for investigation products)

  - Registration

Regulatory Control System in Thailand

- Post-marketing Control System shall include:

  - GMP Compliance

  - Lot release

  - Surveillance of Quality related issues, Safety related issues or Effectiveness monitoring

Registration

* **Prerequisite of registration**
* Section 12 of Drug Act A.C.1967 forbids any person from manufacturing , selling or importing modern medicinal product unless he/she obtains license from TFDA

Registration

- **Legal compliance**

-Section 79 of Drug Act A.C.1967 defines that any authorized license holder (manufacturer or importer) who wishes to manufacture or import medicinal products into Thailand shall obtain marketing authorization approval/ credential certificate of drug registration from TFDA prior to manufacture or import any medicinal

Terminology of Biological Products in Thailand

* Biological Products mean the products are manufactured by these methods ;
  * Growth of strains of microorganisms and eukaryotic cells
  * Extraction of substances from biological tissues including human, animal, and plant tissues (allergens)
  * Recombinant DNA or rDNA techniques
  * Hybridoma techniques
  * Propagation of microorganisms in embryo or animals
  * Derived from blood and plasma
* So biological products include a wide range of

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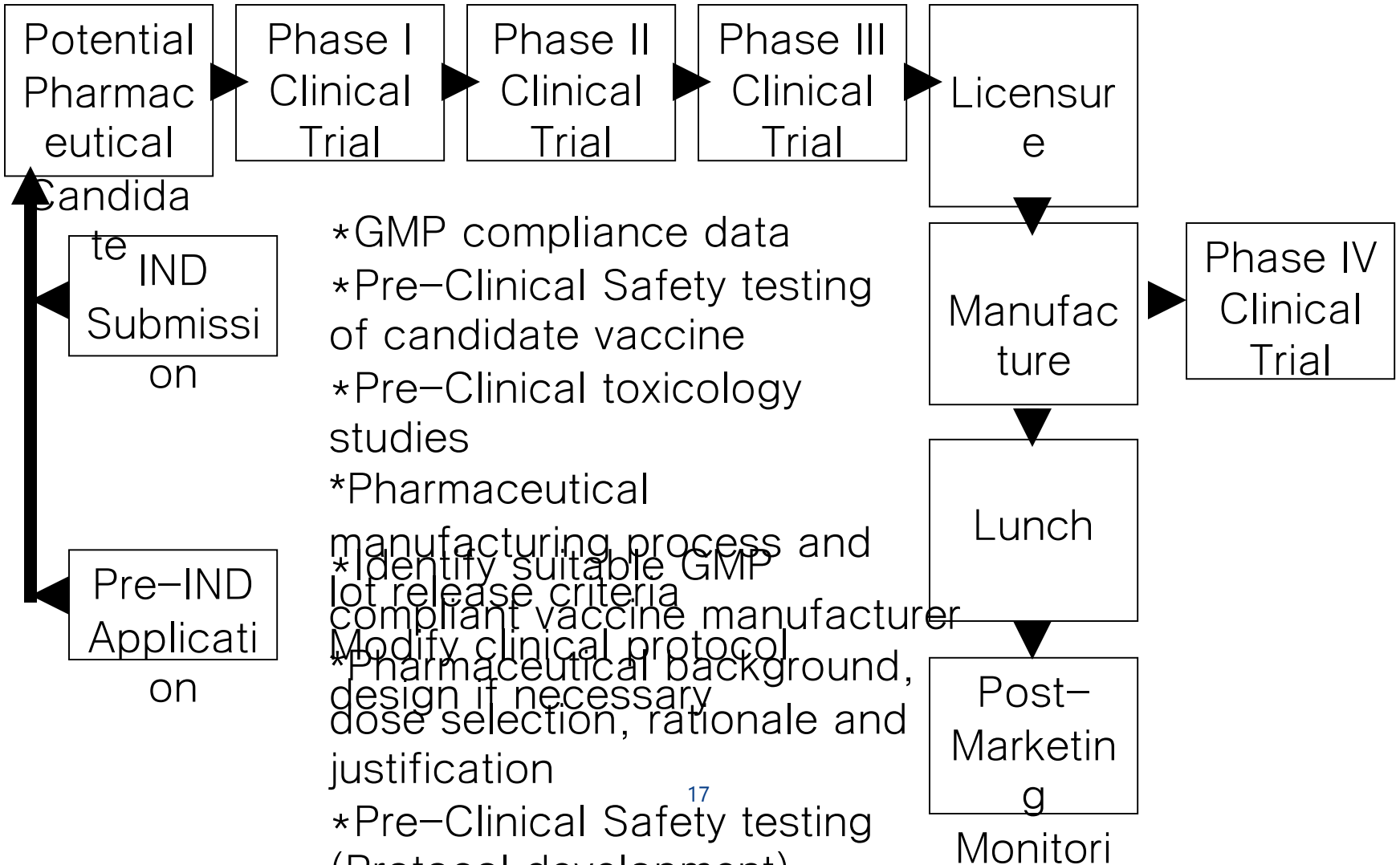
Stage of New Drug Licensure



Current regulatory framework in Thailand

* Development stages (not fully regulated)
* Authorizing clinical trials
* Licensing stages
  * 1. Manufacturing license
  * 2. Product registration
  * 3. Lot release
* Post-Licensure stage, Product S]surveillance, Manufacturing

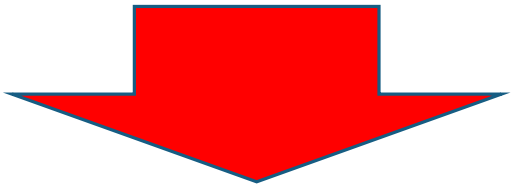
BIOLOGICAL PRODUCTS

GMP,
Manufacturing process,
Quality control test,
Specification,
Packaging,
Stability, Etc.

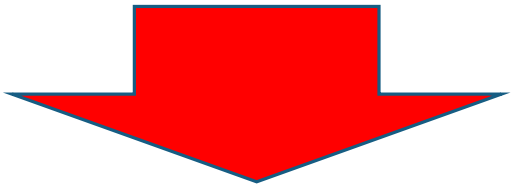
Pharmacology,
Pharmacokinetics,
Toxicology,
Etc.

Clinical efficacy (Ph. I,II,III) ,
Clinical safety,
Biopharmaceutical study,
Human PK/PD,
Etc.

BIOSIMILAR

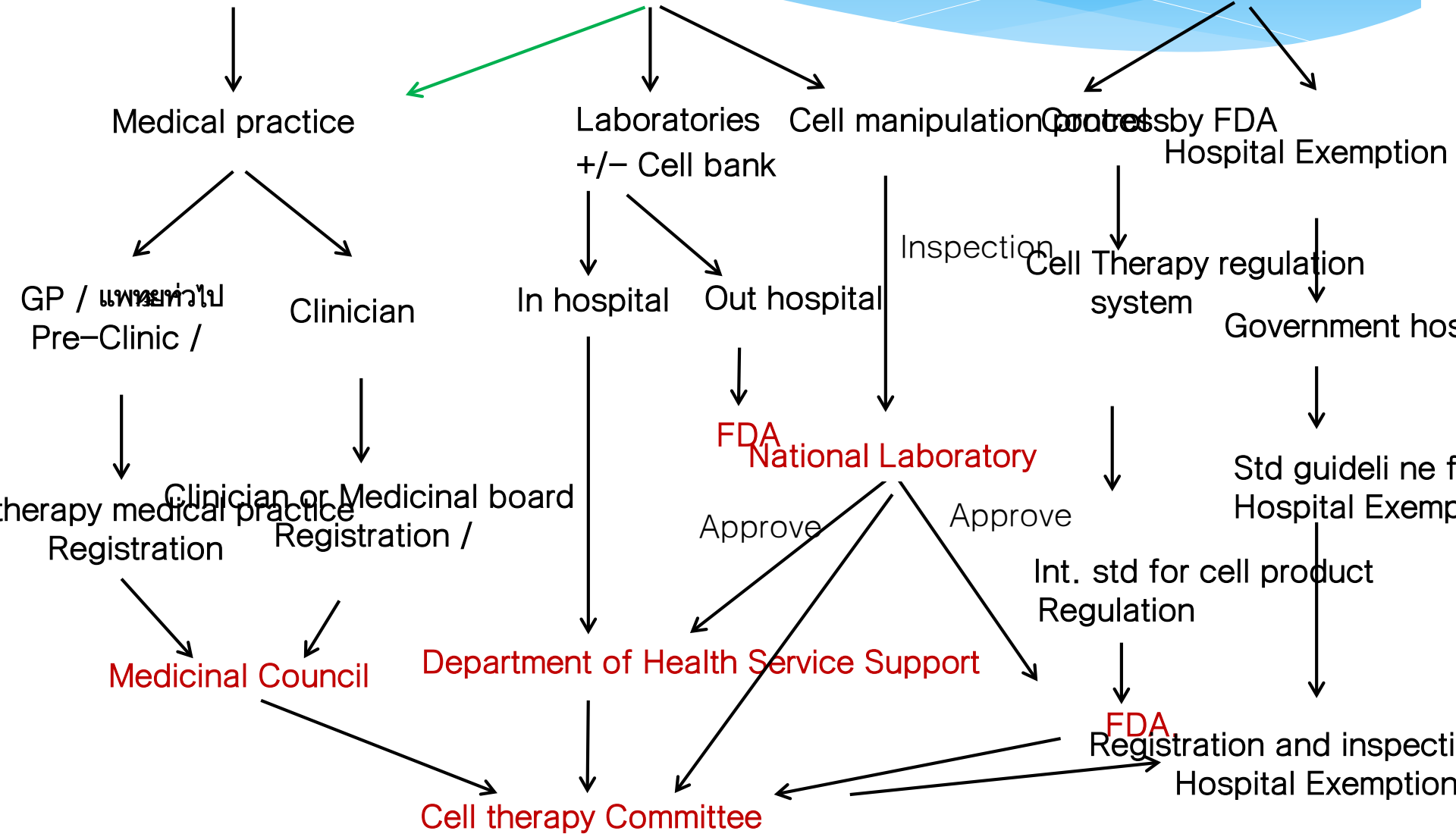


CELL PRODUCT



Cell therapy regulation in Thailand (Dra

1. Cell therapy, which is used in a medical practice.
2. Cell therapy, which is used as a drug.
3. Cell therapy, which is a



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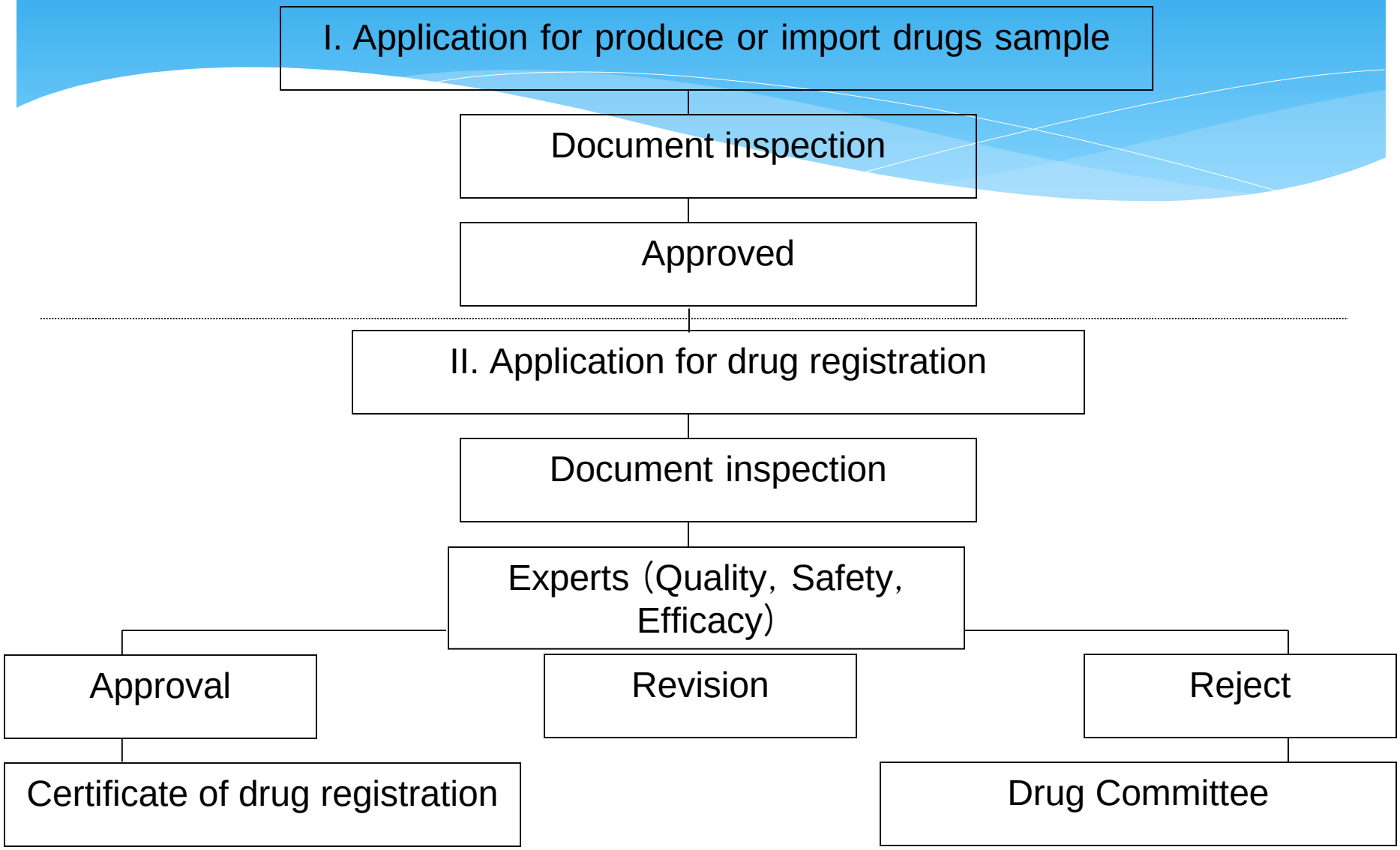
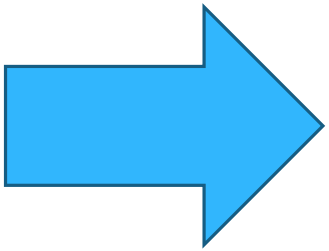
Registration Procedure



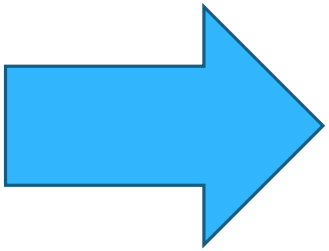
Timelines

* New biological product
* Biosimilar product
* Vaccine
* Cell products



320 working days

* Fast track review



Life saving drug, Emergency, Outbreak

Ocassions

* Drafting : The Cell therapy products registration guideline
* Revising : Drug Act
* Re-evaluation : EPO (on going)

ขอบคุณ

고맙습니다

Thank you