Laws and Regulations of Doing Business in Thailand : Pharmaceutical and Medical Devices

Mrs. Sitanun Poonpolsub
Director of International Affairs Division
International Affairs Division
Thai Food and Drug Administration

THAILAND BOARD OF INVESTMENT

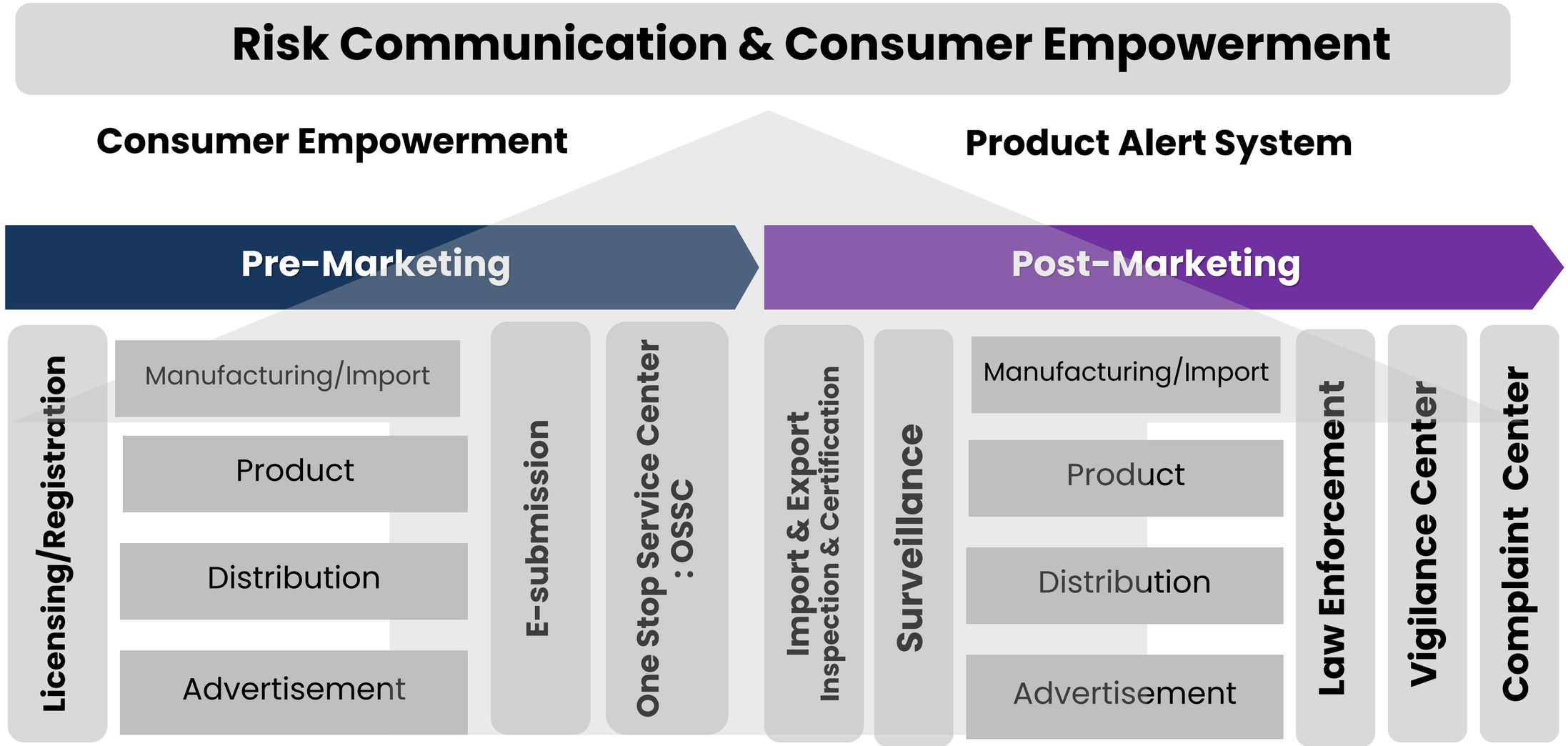
Seminar Program :
Business and Investment Opportunities in Medical Sector in Thailand

Our Responsibilities

- Drugs
- Foods
- Cosmetics
- Hazardous Substances
- Volatile Substances
- Narcotics
- Psychotropic Substances
- Medical Devices
- Herbal Products

Thai Food and Drug Administration (Thai FDA)

Framework of Thai FDA's Responsibilities



Outlines

❶ Pharmaceutical

1.1 Law and Regulation

- Definitions
- ACTD & ACTR

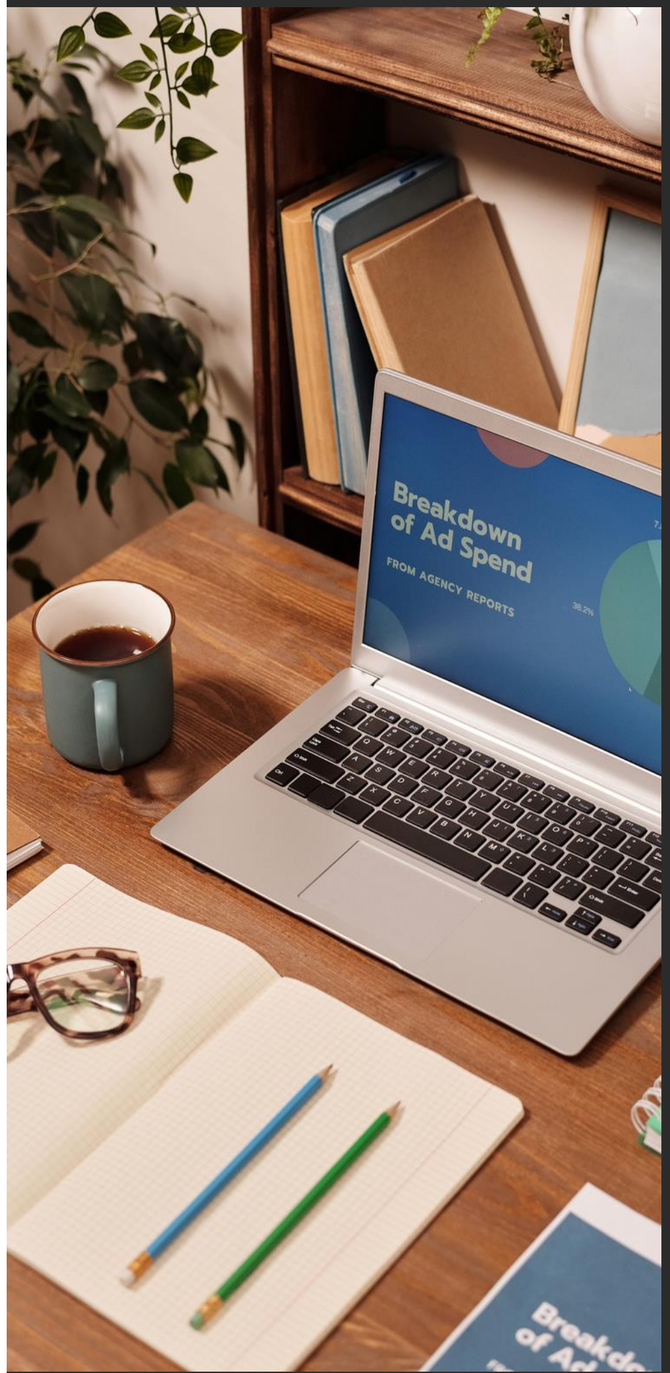
1.2 Placing Pharmaceutical in Thailand Market

❷ Medical Devices

2.1 Law and Regulation

- Definitions
- Common Submission Dossier Template: CSDT

2.2 Placing Medical Device in Thailand Market



Outlines

❶ Pharmaceutical

1.1 Law and Regulation

- Definitions
- ACTD & ACTR

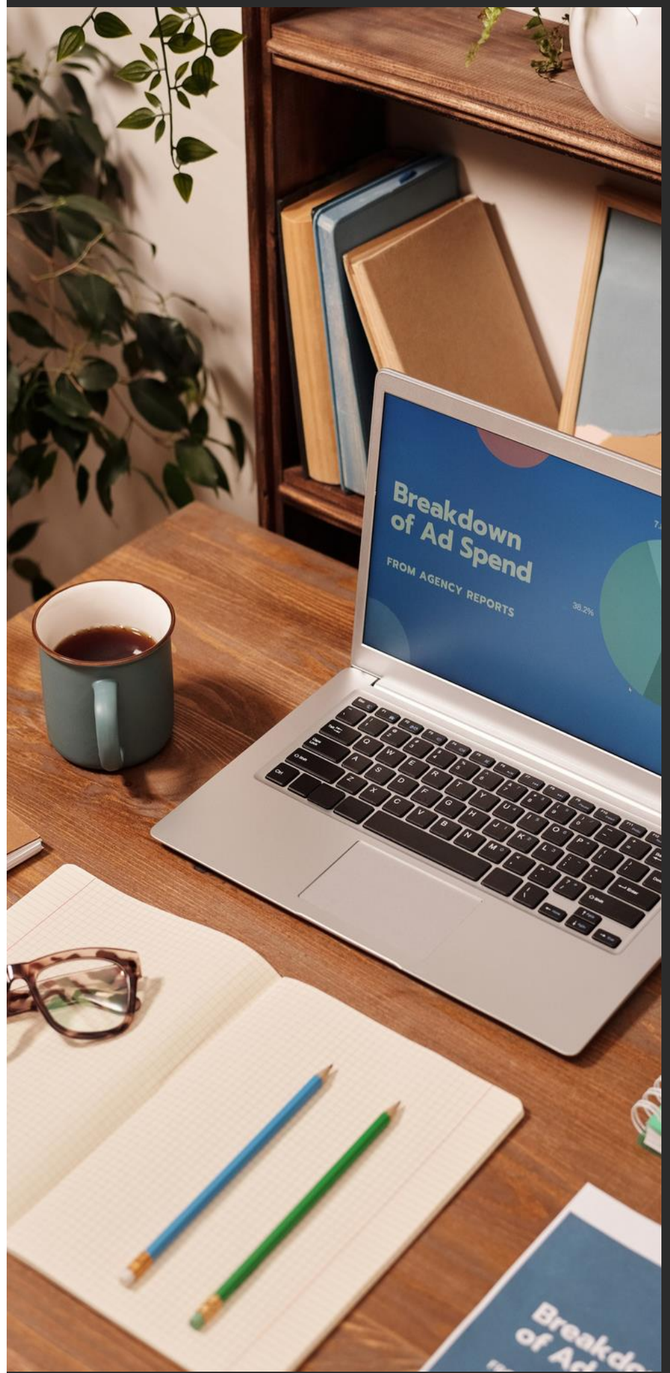
1.2 Placing Pharmaceutical in Thailand Market

❷ Medical Devices

2.1 Law and Regulation

- Definitions
- Common Submission Dossier Template: CSDT

2.2 Placing Medical Device in Thailand Market



Regulation of Medicinal Products

Current Laws and Regulations :

- Drug Act B.E. 2510 (1967)
- Drug Act (2nd Revision) B.E. 2518 (1975)
- Drug Act (3rd Revision) B.E. 2522 (1979)
- Drug Act (4th Revision) B.E. 2527 (1984)
- Drug Act (5th Revision) B.E. 2530 (1987)
- Drug Act (6th Revision) B.E. 2562 (2019)
- Ministerial Regulation on Drug Registration B.E. 2555 (2012)

Medicines Regulation Division

Standards and Regulations

Pre-Marketing

Post-Marketing

- **Licensing**
  - License to Manufacture
  - License to Sell
  - License to Import
- **Registration**
- **Advertising Control**

Definitions ??

“Drugs” means

1. Substances recognized by pharmacopoeias notified by the Minister;
2. Substances intended for use in the diagnosis, treatment, relief, cure or prevention of human or animal disease or illness;
3. Substances which are pharmaceutical chemicals or semi-processed pharmaceutical chemicals;
4. Substances intended to affect the health, structure or function of the human or animal body;

Substances under 1 2 or 4 shall **not include:**

a) those intended for use in agriculture or industry as notified by the Minister,
b) those intended for use as food for human, sport device, medical apparatus, cosmetics or device for use in the practice of healing arts or practice of medicine and a component thereof,
c) those intended for use in science laboratory for research, analysis or verification of disease which is not directly done to human body;

Modern Drug Registration

1. New Drugs

2. New Generic Drugs

3. Generic Drugs

4. Biological Products

5. Veterinary Products

Definition “New Drugs” ??

- New Chemical Entities (NCE)
- New Indication (NI)
- New Combination (NCO)
- New Delivery System (ND)
- New Route of Administration (NR)
- New Dosage Form (NDOS)
- New Strength (NS)

Definition “Generic Drugs” ??

- Same active ingredient(s)
- Same dosage form
- Same strength
- Same route of administration
- Same conditions of use
- Compared to reference drugs
  (New Drugs in Thailand which registered after 1991)

ASEAN Harmonization on Pharmaceutical Registration

ASEAN Common Technical Requirement (ACTR)

ASEAN Common Technical Dossier (ACTD)

Drug Registration Process

STEP 1

The permission to import/manufacture drug samples

STEP 2

Application for Product Registration Approval

STEP 2

Application for Product Registration Approval

- **New Drug Registration**
  - Standard Review
  - Priority Review
  - Abridge Review
- **ASEAN harmonization on Pharmaceutical Registration** (ACTD, ACTR)
- **Priority Review** for Life-Threatening Medicines and Medicines in Urgent need for Public Health Problems
- **Abridged Evaluation of New Drugs** using reference drug regulatory authority assessment

STEP 2

Application for Product Registration Approval

Applicant*

↓ Prepare Dossier (ASEAN Harmonization)

Submit Application (E-submission)

↓

[Completeness Review] Dossier Screening Review

- Review of Completeness 1-2 days
- Correction 15 days

↓

[Technical Review] Review by Experts/Sub-Committee

↓

Make Decision by FDA

Advertising Control

Drug Act
Section 88 – 80

Regulate the promotion of Medicinal Products.

- **Advertisement** must be truthful and must not be exaggerated.
- **Advertisements** and others **promotional** material **must be** approved by the FDA before dissemination.

Timeline for Drug Registration

Type of Drugs	Working Days	Abridge Evaluation* (Working Days)
• **New Drugs**	**220**	**180**
• **New Drugs** (Priority Review)	**200**	**150**
• **New Biological Products**	**220**	**200**
• **New Biological Products** (Priority Review)	**200**	**180**
• **Vaccines**	**280**	**250**
• **Vaccines** (Priority Review)	**200**	**180**
• **Generic Drugs**	**135**	-

***Conditions**: Drug which have been approved by one of the following benchmark/reference agencies includes US FDA, EMA (EU: Centralized Procedure), MHRA UK, TGA Australia, Swiss Medic, Health Canada (Canada), PMDA (Japan).

Fees for Pharmaceutical Registration and Applications

Type	Application (Completeness Review) (THB)	Assessment (Technical Review) (THB)		
Drug Samples for Clinical Trial				
Manufacture	**1,000**	**4,000** (Clinical Trial)	**1,000** (BE)	**4,000** (Others)
Import or Order	**1,000**	**4,000**		
Drug Samples for Registration				
Manufacture	**300**	**-**		
Import or Order	**300**	**-**		

Type	Application (Completeness Review) (THB)	Assessment (Technical Review) (THB)	Certificate (THB)
Drug Registration			
New Drugs	**2,500**	**155,000/182,500** (NCE)	**2,000**
New Generic Drugs	**1,000**	**94,000**	**2,000**
Generic Drugs	**1,000**	**59,000**	**2,000**

Data as of 27 Jun 2022

Fees for Pharmaceutical Registration and Applications

Type	**Application** (Completeness Review) (THB)	**Assessment** (Technical Review) (THB)	**Certificate** (THB)
Biological Products			
- New	**2,500**	**155,000/182,500**(NCE) **/196,500**(Biosimilar)	**2,000**
- Vaccine	**2,500**	**182,500**	**2,000**
Veterinary Products			
- New Veterinary Products	**2,500**	**155,000/ 182,500**(NCE)/ **395,000**(NCE 1st apply in Thailand to address problems of diseases in ASEAN)	**2,000**
- Veterinary Products	**1,000**	**39,000** (Standard and analytical Method in line with MOPH announcement) **/49,000**	**2,000**
- Veterinary Biological Products (i.e. Vaccine)	**1,000**	**123,000**	**2,000**

Data as of 27 Jun 2022

Outlines

1 Pharmaceutical

1.1 Law and Regulation

- Definitions
- ACTD & ACTR

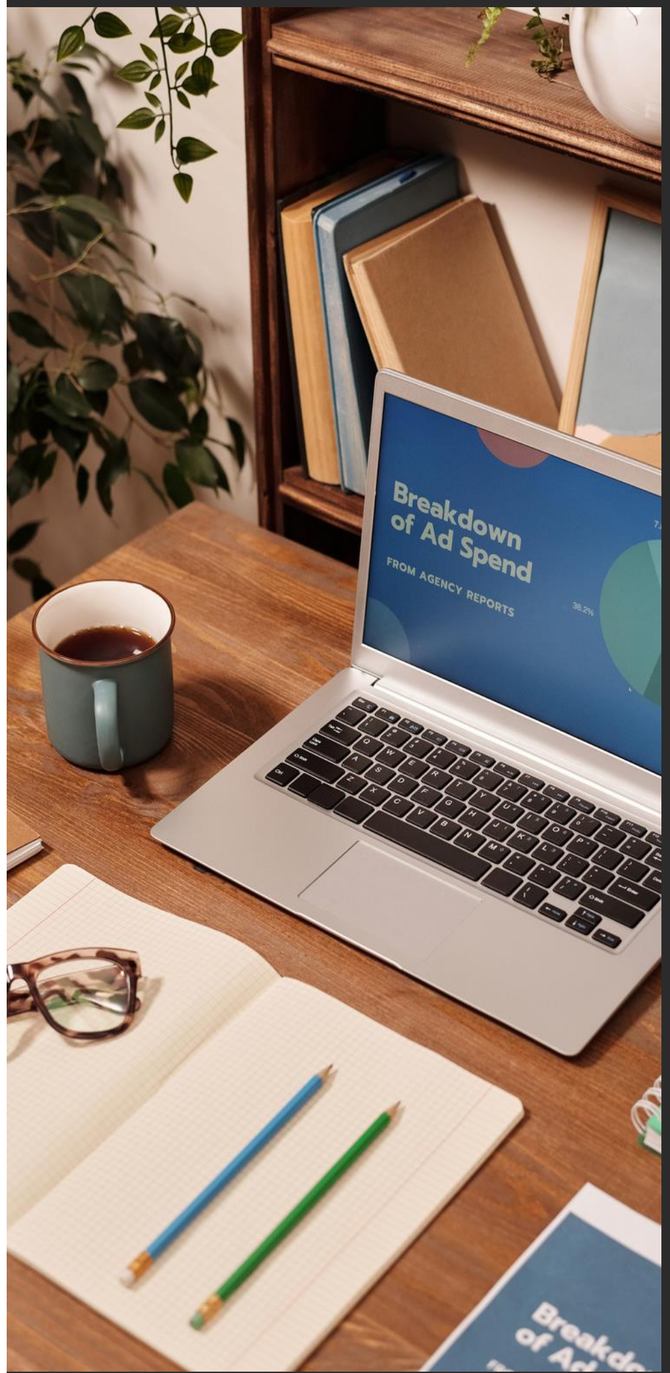
1.2 Placing Pharmaceutical in Thailand Market

2 Medical Devices

2.1 Law and Regulation

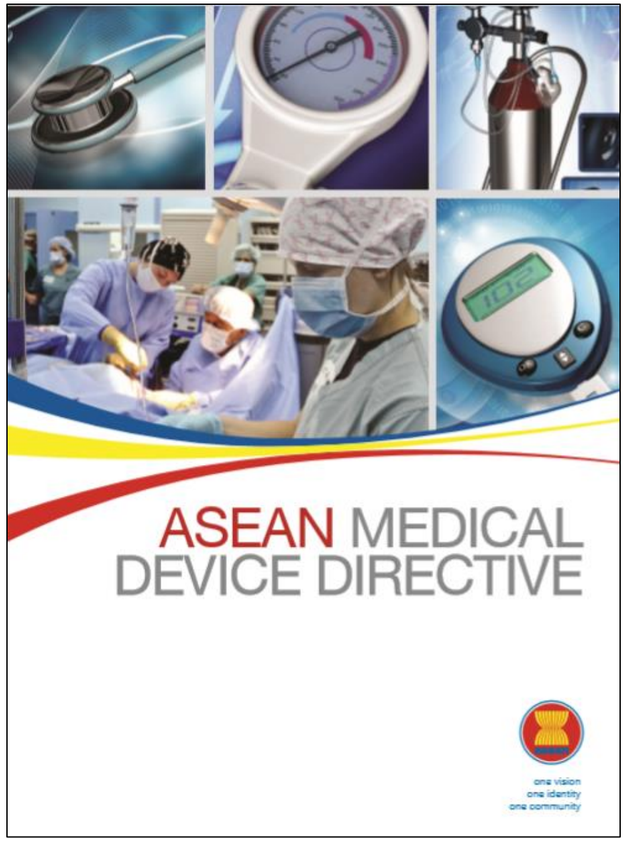
- Definitions
- Common Submission Dossier Template: CSDT

2.2 Placing Medical Device in Thailand Market



Medical Device Regulation in Thailand

- Thailand submitted Instrument of Ratification on 19th January 2021
- Legislation are aligned with AMDD



ASEAN AGREEMENT ON MEDICAL DEVICE DIRECTIVE

What is Medical Devices ??

- Definition of a Medical Device in accordance with The Medical Device Act, 2019

1. any instrument, apparatus, machine, implant, in vitro reagent that used inside or outside laboratory, material, software or related article intended by the manufacturer or product owner to be used in humans or animals, alone or combination **for the specific purpose(s) of**

(A)
Diagnosis, prevention, monitoring, treatment or alleviation of human or **animal** diseases

(B)
Diagnosis, monitoring, treatment of or compensation for an injury in human or **animal**

(C)
Investigation, replacement, modification, or support of the anatomy or of a physiological process in human or **animal**

(D)
Supporting or sustaining life of human or **animal**

(E)
Control of conception or aid in the reproduction of human or **animal**

(F)
Aiding or compensation for the disability of human or **animal**

(G)
Providing information for medical diagnostic purposes by means of in vitro examination of specimens derived from human or **animal**

(H)
Disinfection of medical devices

What is Medical Devices ??

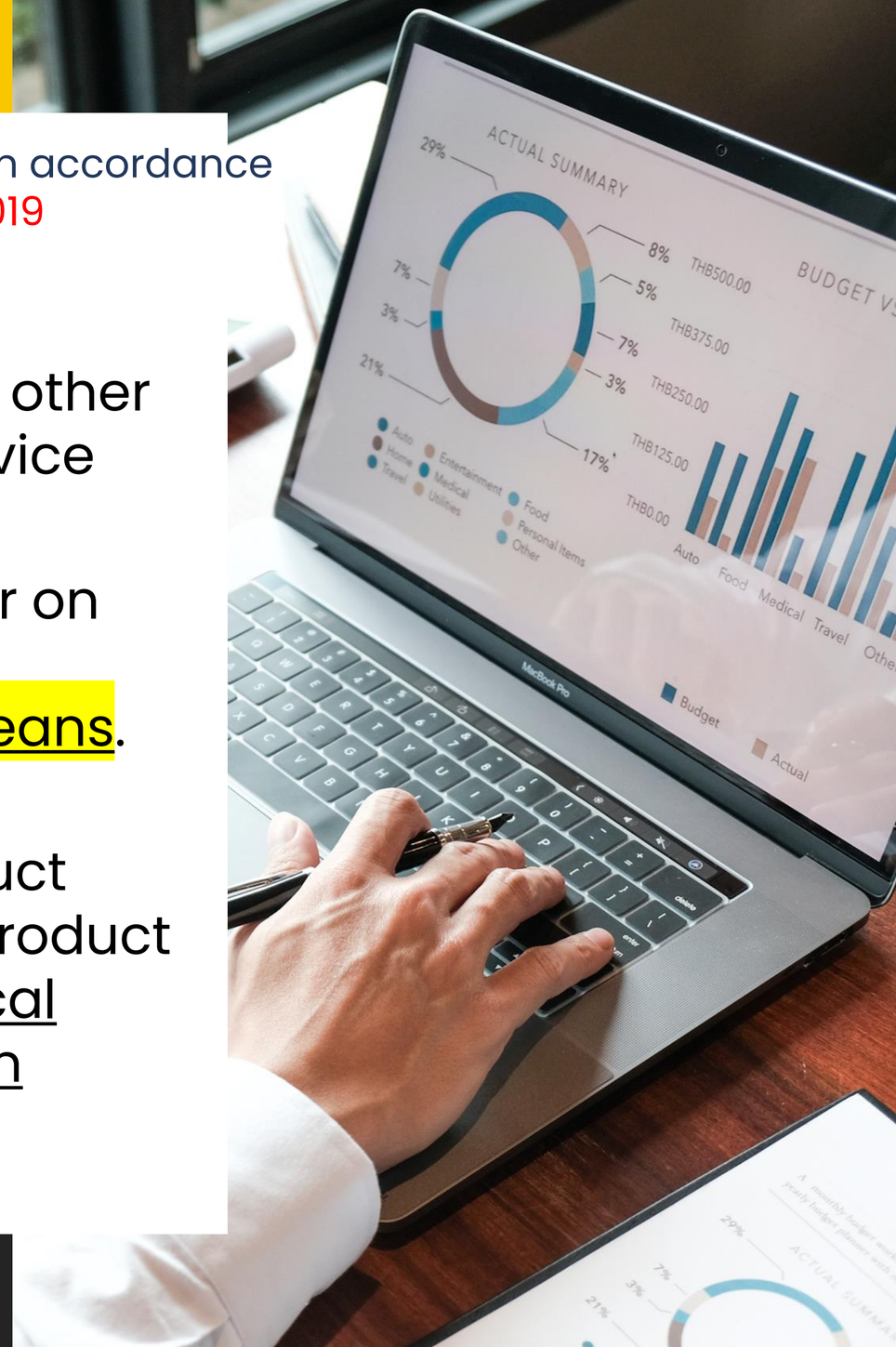
- Definition of a Medical Device in accordance with The Medical Device Act, 2019

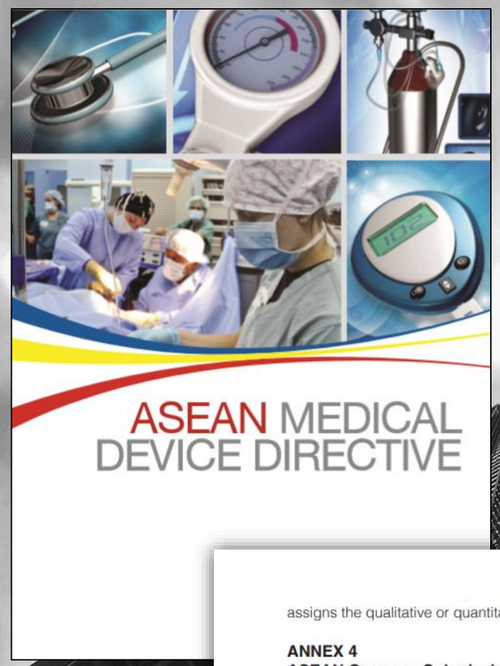
❷ Accessories pursuant to ❶

❸ Instruments, apparatus, machines, products or other articles declared by the Minister as medical device

Achievement of the purposes according to ❶ in or on human or animal bodies must not intend by pharmacological, immunological or metabolic means.

"Accessory" means the article, apparatus or product that is intended specially by its manufacturer or product owner to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended purpose





assigns the qualitative or quantitative value.

ANNEX 4
ASEAN Common Submission Dossier Template

1. INTRODUCTION

The Common Submission Dossier Template (CSDT) should reduce the differences in documentation formats that presently exist in different ASEAN jurisdictions. The adoption of the CSDT in ASEAN should minimise the preparation of multiple dossiers, arranged in different formats but with essentially the same contents, for regulatory submission to different Regulatory Authorities.

2. SCOPE

This CSDT is intended to apply to all medical devices. For IVD medical devices, the Regulatory Authority of the Member State may choose to adopt this CSDT or prescribe another format for regulatory submissions to that Member States. The depth and detail of the information contained in the CSDT will depend on:

- the classification of the subject medical device;
- the complexity of the subject medical device.

The format of the CSDT recommended herein is based upon the goal of both regulators and product owners to strive for the least burdensome means to demonstrate conformity to the Essential Principles for all classes of medical devices.

Where there are sections not applicable to the medical device, the reason for the non-applicability should be provided under the section heading. Requirements for post-market vigilance or adverse event reporting are outside the scope of this document.

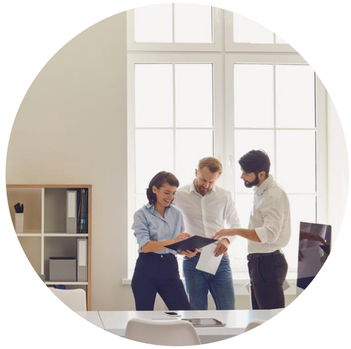
3. EXECUTIVE SUMMARY

An executive summary shall be provided with the common submission dossier template, which shall include the following information:

Common Submission Dossier Template (CSDT)

Annex 4

- **Document format** to demonstrate conformity to the essential principles of safety and performance (EPSP) for all classes of medical devices.
- **Summary of Technical Documentation** (STED) by IMDRF (International Medical Device Regulatory Forum).



ASEAN MEDICAL DEVICE DIRECTIVE

asean

Annex 1
Essential Principles of Safety and Performance of Medical Devices

General Requirements

1. Medical devices shall be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with the use of the medical device for its intended purpose constitute acceptable risks when weighed against the intended benefits to the patient and are compatible with a high level of protection of health and safety.

2. The solutions adopted by the product owner for the design and manufacture of the medical devices shall conform to safety principles, taking account of the generally acknowledged state of the art. In selecting an appropriate solution for the design and manufacture of a medical device so as to minimise any risks associated with the use of the medical device , the product owner shall apply the following principles:
   - identify any hazard and associated risk arising from the use of the medical device for its intended purpose, and any foreseeable misuse of the medical device,
   - eliminate or reduce risks as far as reasonably practicable through inherently safe design and manufacture,
   - if appropriate, ensure that adequate protective measures are taken, including alarms if necessary, in relation to any risk that cannot be eliminated, and
   - inform users of any residual risks.

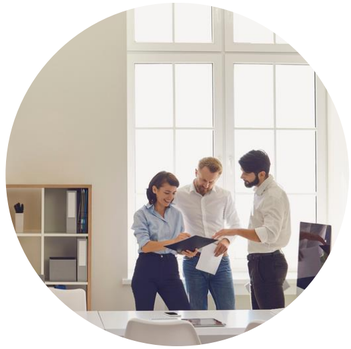
3. Medical devices shall achieve the performance intended by the product owner and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device.

Essential Principles of Safety and Performances (EPSP) of Medical Devices

Annex 1

❶
General Requirements: **1-7**

❷
Design and Manufacturing Requirements: **8-19**



Product Registration

2

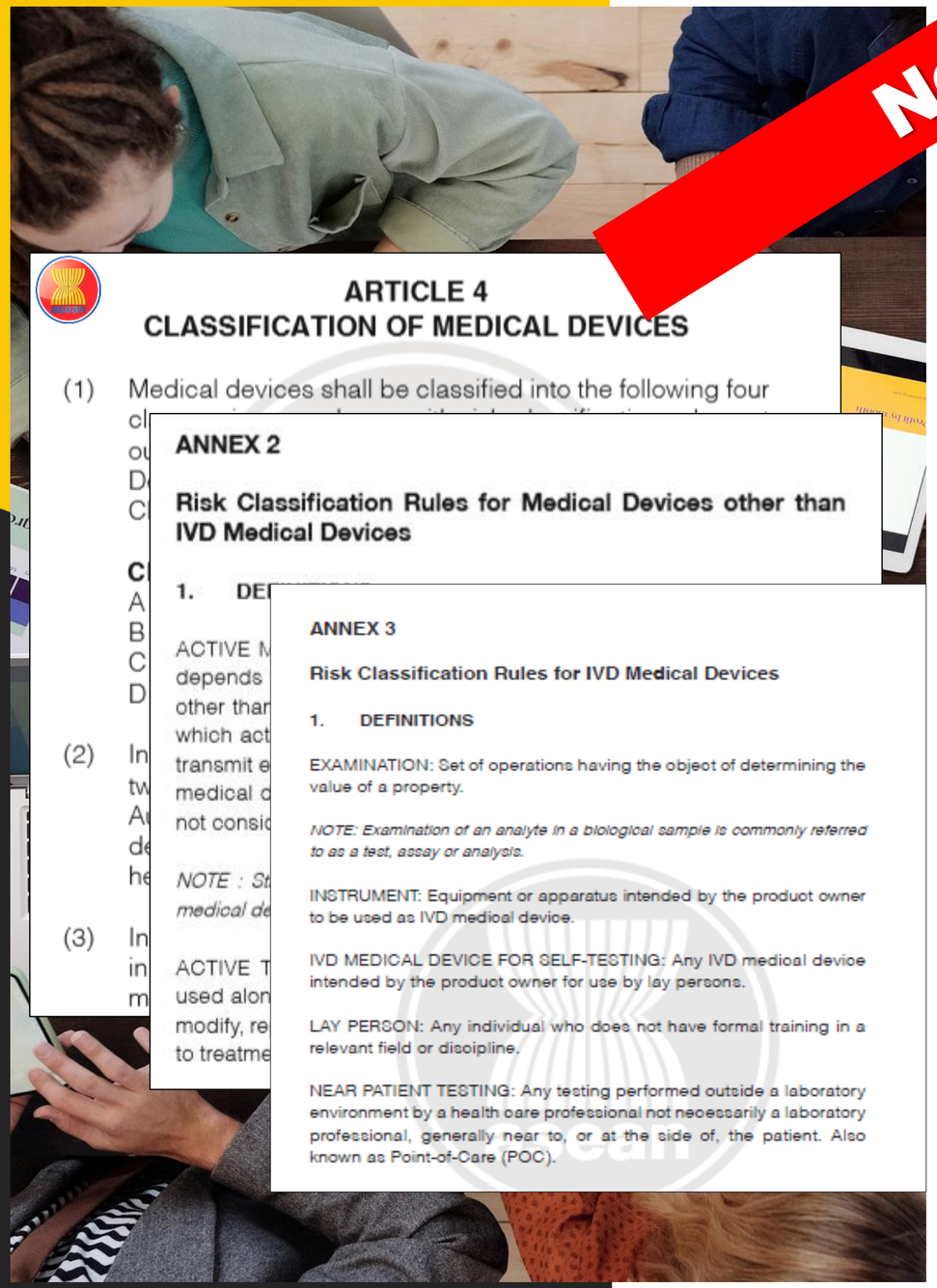
Placing Medical Device in Thailand Market

1

Establishment Licensing

3

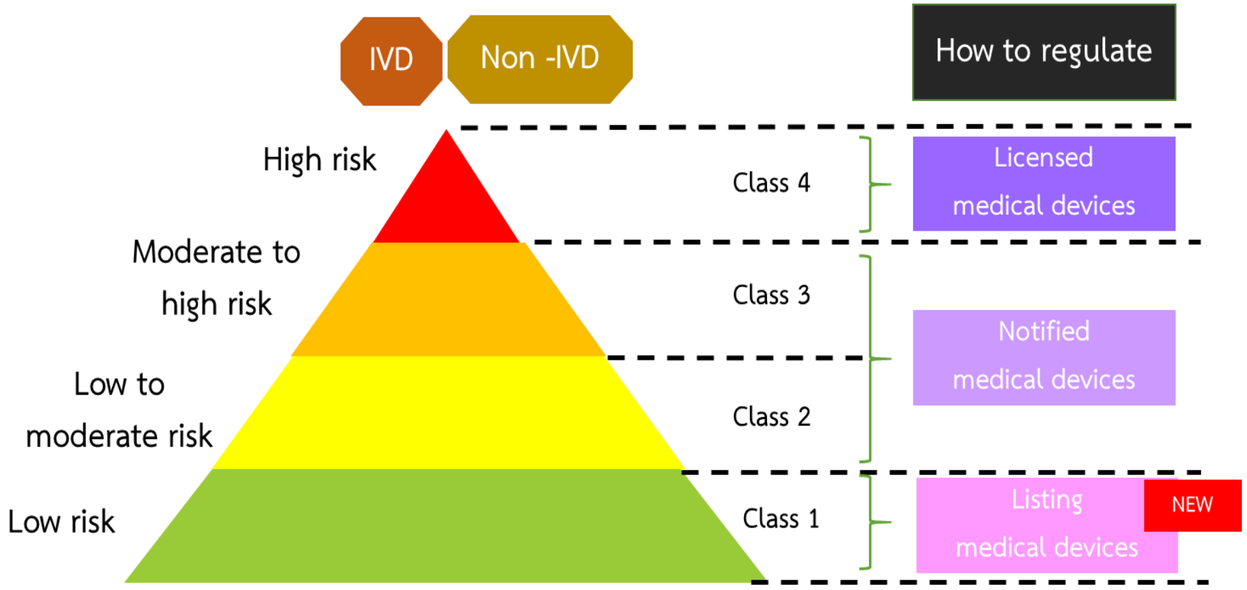
Post-market Obligations



New

Medical Devices Regulation

- The new regulations are aligned with ASEAN Medical Device Directive (AMDD): **Article 4**, **Annex 2** and **Annex 3**



New regulation are risk-based classification since 15 February and 17 March 2021.

Medical Device Regulation

Medical Device Submission Process

Full Submission

Class 1-4 + Animal MD

Medical Devices according to Notification of MOPH

Partial Submission

Partial 2: Class 2-4

Notified : 150 Calendar Days
Licensed : 200 Calendar Days

Fast track

Medical Devices Related to COVID-19 Situation

Approval Duration:

Certificates	Full submission (Calendar Days)		
	Auto Approval + Post Audit	External Expert review	Internal review
Listing	✓	-	-
Notified	–	250	200
Licensed	–	250	200

Data as of 27 Jun 2022

Timeline: Facilitation for Medical Device Submission CLASS 2 - 4

Submission date	Regulation	
	Voluntary	Partial 2
Now	Full Submission CSDT for Class 2-4	The importing license expires after Feb 14, 2022 or the establishment license for manufacture expires after Dec 31, 2021 with proof of sale documents or
Feb 14, 2024	Full CSDT	

Note: This regulation is not for the renewal

Data as of 27 Jun 2022

Fees for Medical Device Registration and Applications

Type	Application Fee (THB)	Screening Fee (THB)	Assessment Fee (THB)	Certificate (THB)	Sum (THB)
1. Listing					
• Manufacture	**500**	**300**	–	**1,000**	**1,800**
• Import	**500**	**600**	–	**2,000**	**3,100**
2. Notified					
• Manufacture	**1,000**	–	**30,400**	**5,000**	**36,400**
• Import	**1,000**	–	**38,000**	**10,000**	**49,000**
3. Licensed					
• Manufacture	**1,000**	–	**42,400**	**10,000**	**53,400**
• Import	**1,000**	–	**53,000**	**20,000**	**74,000**

Data as of 27 Jun 2022

Exemption of some Advertising Approval

Direct advertising to healthcare professional are **exempted from approval**

Effective date on 2nd November 2020

Do not require approval

- Trade name or
- Trademark or
- Trade logo

Effective date on 5th November 2020

Contact Us

Medicines Regulation Division
Food and Drug Administration,
Ministry of Public health
Tel. 0-2590-7171, 0-2590-7160
Fax. 0-2590-7170, 0-2591-8390, 0-2591-8489
E-mail : drug@fda.moph.go.th

Medical Device Control Division
Food and Drug Administration,
Ministry of Public health
Tel. 02 591 8480, 02 590 7625
Fax. 02 591 8445
E-mail : mdcd1988@fda.moph.go.th

OSSC

One Stop Service Center

Call Center 1556
(Mon-Fri
8.30 am – 4.30 pm)

LINE official : @OSSC_FDA
E-mail :
OSSC@fda.moph.go.th

Thank You

International Affairs Division
Thai Food and Drug Administration

International Affairs Division,
Food and Drug Administration,
Ministry of Public health
Tel. 02 590 7286, 02 590 7021
Fax. 02 591 8475
E-mail : interfda@fda.moph.go.th