REGULATIONS of MEDICAL DEVICES IN THAILAND

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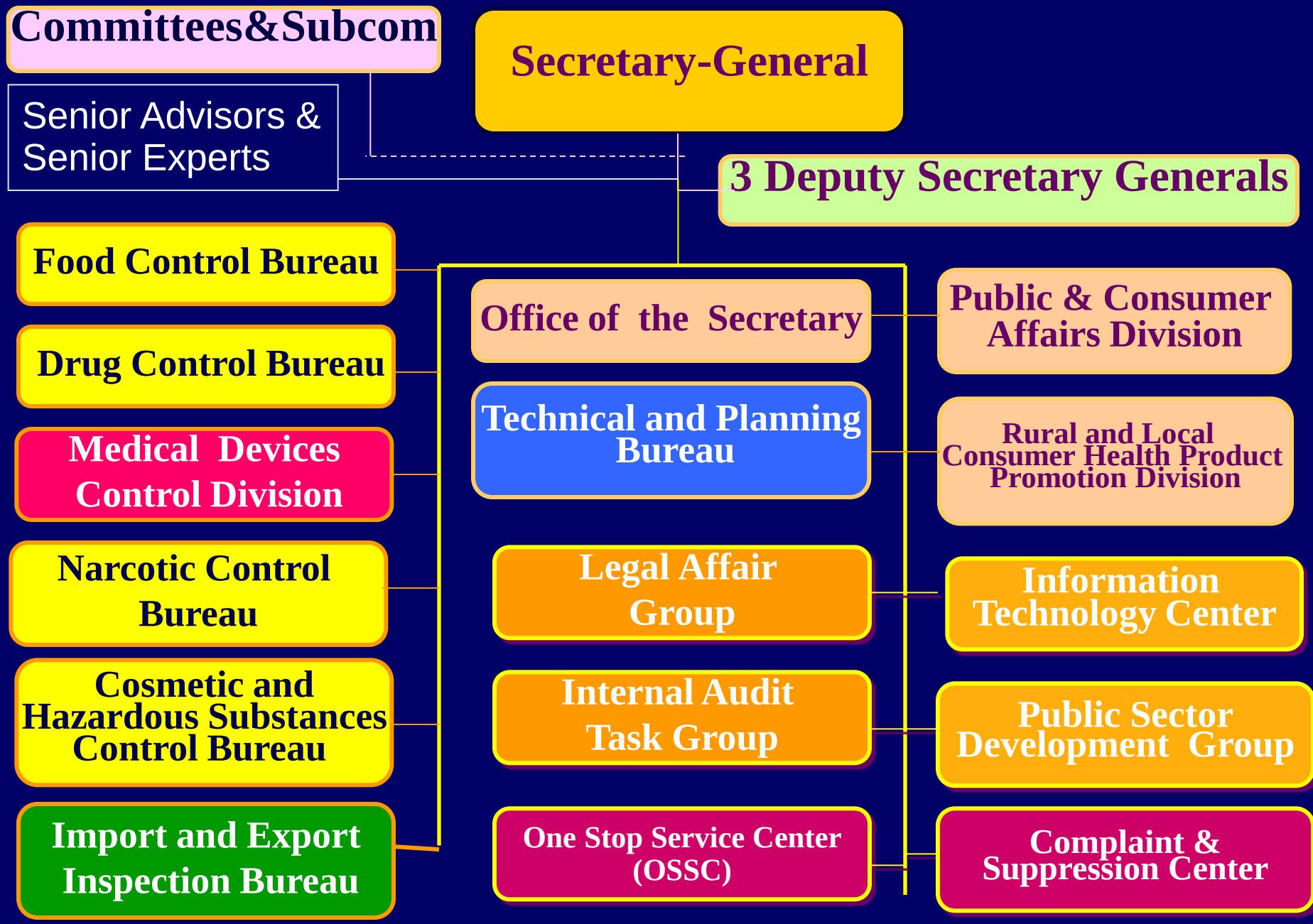
สำนักงานคณะกรรมการอาหารและยา
Food and Drug Administration

Thai FDA

Infra-structure of Food and Drug Administration



VALUE

"PROTECT"

- P People Centric
- R Reliability
- O Ongoing Learning
- T Team work
- E Ethic
- C Competency
- T Transparency

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Mission

1) Regulate, monitor and promote for the availability of safe and good quality health products.
2) Promote the consumer knowledge, understanding and the correct behavior in consumption of health products.
3) Support entrepreneurs to get more competitive opportunities for further increase value of the national economy.
4) Develop organization management to the excellence

Products in Control of Thai FDA

- Food, Drugs, Psychotropic Substances, Narcotics, Volatile Substances
- Medical Devices
- Cosmetics
- Hazardous substances for household use

MEDICAL DEVICE ACT IN THAILAND

- **Before 1988, using Drug Act**

- **Since May 1988 - Medical Device Act 1988**

- **Medical Device Control Division, Food and Drug Administration was officially established in June 1990 as regulatory authority to control manufacturing, importing, selling and advertising of medical devices in Thailand.**

- **Medical Device Act 2008 *** + Draft Amendment**

DEFINITION OF MEDICAL DEVICES (1)

- include Medical Devices

  For Animal Use

- include IVD products

- include Software

DEFINITION OF MEDICAL DEVICES (2)

- include accessories, components or parts of medical devices

- include any products announced by the Minister to be medical devices

Conditions to be classified as Medical Devices

The medical devices must not achieve its primary intended action in or on the human or animal body by **pharmacological**, **immunological** or **metabolic means**, but which may be assisted in its intended function by such means.

CONTROL OF MEDICAL DEVICES

- Pre-market approval
- **Control at port by FDA inspectors with close relation with custom officers**
- **Postmarketing surveillance and vigilance**
- **Advertisement control**
- **Communication of risk information to the public**

Premarketing premise approval (1)

1. Establishment Registration:

- Manufacturing Registration
- Importing Registration

2. Selling License for announced medical devices

Premarketing product approval (2)

Medical Devices are controlled into 3 levels:

- ***License required Medical Devices***

- ***Notification required Medical Devices***

- ***General Medical Devices***

Premarketing approval (at present)

1. *Licensed medical devices* → *Licensing* ← *CSDT*
2. *Notified Medical Devices* → *Notification* ← *CSDT*
3. *General Medical Devices* → *FDA Cert. for custom process*

General Medical Devices

- *Devices not on the list of License required medical devices and Notification required medical devices*
- *Majorities are general medical devices*

Licensed Medical Devices

- *Condoms*
- *Surgical Gloves*
- *HIV test kit for diagnosis purpose*
- *Corrective and Cosmetic Contact Lens*
- *Blood Bags both empty and containing anticoagulants or additive solutions*
- *etc*

Notified Medical Devices

- *Physical Therapy Devices*
- *Alcohol Detectors*
- *Silicone Breast Implants*
- *Breast Enhancer External Use devices*
- *Urine Screening Test for Methamphetamine*
- *Ophthalmic Viscoelastic devices*
- *etc*

Post-Marketing Control of Medical Devices

- premise regular inspection
- product sampling check, recalling system
- cease production, importation and distribution
- AE reporting and vigilance system
- law enforcement
- public education and awareness

One Stop Service Center in Thai FDA

- Pre-marketing service for all FDA responsible health products: medical device, drug, food, cosmetic, hazardous substances (except narcotic and psychotropic drugs)
- Pre-advertisement approval
- Issuing Certificates, etc

One Stop Complaint and Suppression Center in Thai FDA

- All complaint Post-marketing services for all FDA responsible health products
- Post-advertisement control/monitoring
- Suppression and Law enforcement done by Post market team of related health products

Network of Control (1)

- **Provincial FDA operated by provincial health offices**

- **Inspection at FDA port situated among all region and work closely with Custom Department**

Network of Control (2)

- **Network of Expertise, Health Professional**
- **Network of Lab/Test Agency and Standard organization**
- **Network of Consumer Police Agency, etc**

Important Notes (1)

Reclassification and Control Level of Medical Devices based on Risk Factor

- **Medical devices (Non IVD)**
- **IVD devices**

Thai FDA Notification relating to Risk Classification of Medical Devices

- Thai FDA Notification relating to Risk Classification of Non IVD Medical Devices (April 2015)
- Thai FDA Notification relating to Risk Classification of IVD Medical Devices (April 2015)

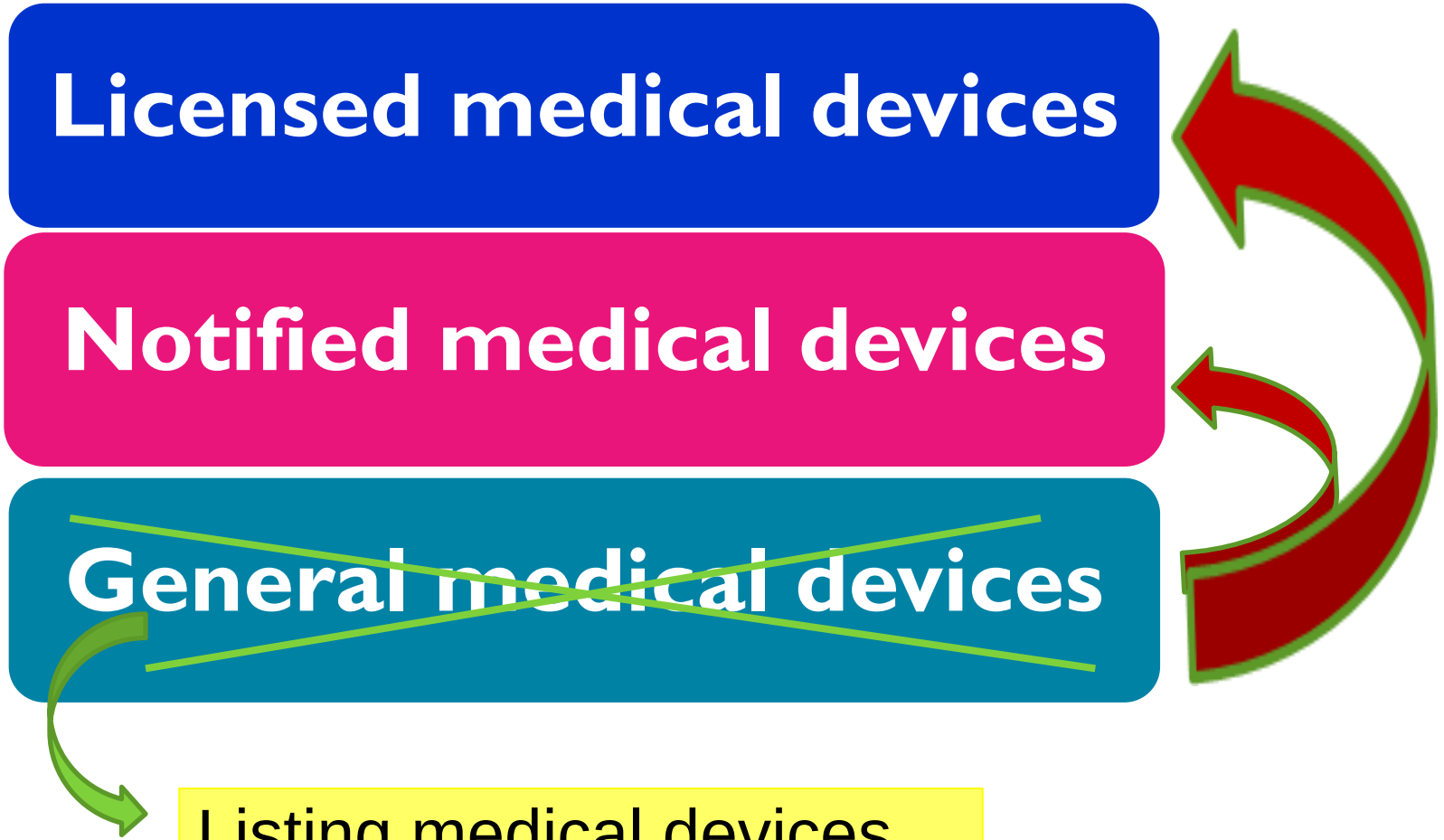
Risk Classification of Medical Devices

Annex 2 Non IVD medical devices	Annex 3 IVD medical devices
(16 Rules) Class A Low risk Class B Low-moderate risk Class C Moderate-high risk Class D High risk	(7 Rules) Class A **Low Individual Risk and Low Public Health Risk** Class B **Moderate Individual Risk and/or Low Public Health Risk** Class C **High Individual Risk and/or Moderate Public Health Risk** Class D **High Individual Risk and High Public Health Risk**

Premarketing approval Future

1. *License required medical devices* → *High Risk*
2. *Notification required Medical Devices* → *Moderate Risk*
3. *Listing Medical Devices* → *Low Risk*

RECLASSIFICATION



Important Notes (2)

National Single Window/ License

per invoice

Duties of Importers

- Input product database for all items that are still active or planned to be sold in Thailand
- Training organized by Thai FDA has been provided.

Important Notes (3)

ASEAN Medical Device Directive Agreement (AMDD)

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Transposition to Law and/or regulations

Implementation of CSDT requirements for license required medical devices and notification required medical devices

- Ministerial Regulations and FDA Notifications on Application and Issuing of Manufacturing/Importing Medical Device Products Licenses and Notifications dated 28 May 2012

--- CSDT Requirements

Near Implementation

1. Detail requirements for industries on

Adverse Events Reporting System

- Information required
- AER Form
- Time frame on reporting

Near Implementation

2. Detail requirements for industries on FSCA Reporting System

- **Information required**
- **FSCA Form**
- **Time frame on reporting**

In Process of Drafting and Finalization

Good Distribution Practice

(GDP)

SUMMARY of FUTURE TRENDS/ACTIONS

- Amendment of Medical Device Act 2008
- Upcoming products to be controlled
- Drafting new regulations
- GDP, Quality Management System Requirements
- e-listing of low risk medical devices
- Registration of moderate and high risk medical devices
- Roadmaps for implementation and enforcement, etc