REGULATORY REQUIREMENTS FOR MEDICAL DEVICES IN THAILAND

Yuwadee Patanawong

FDA THALAND

5 November 2012

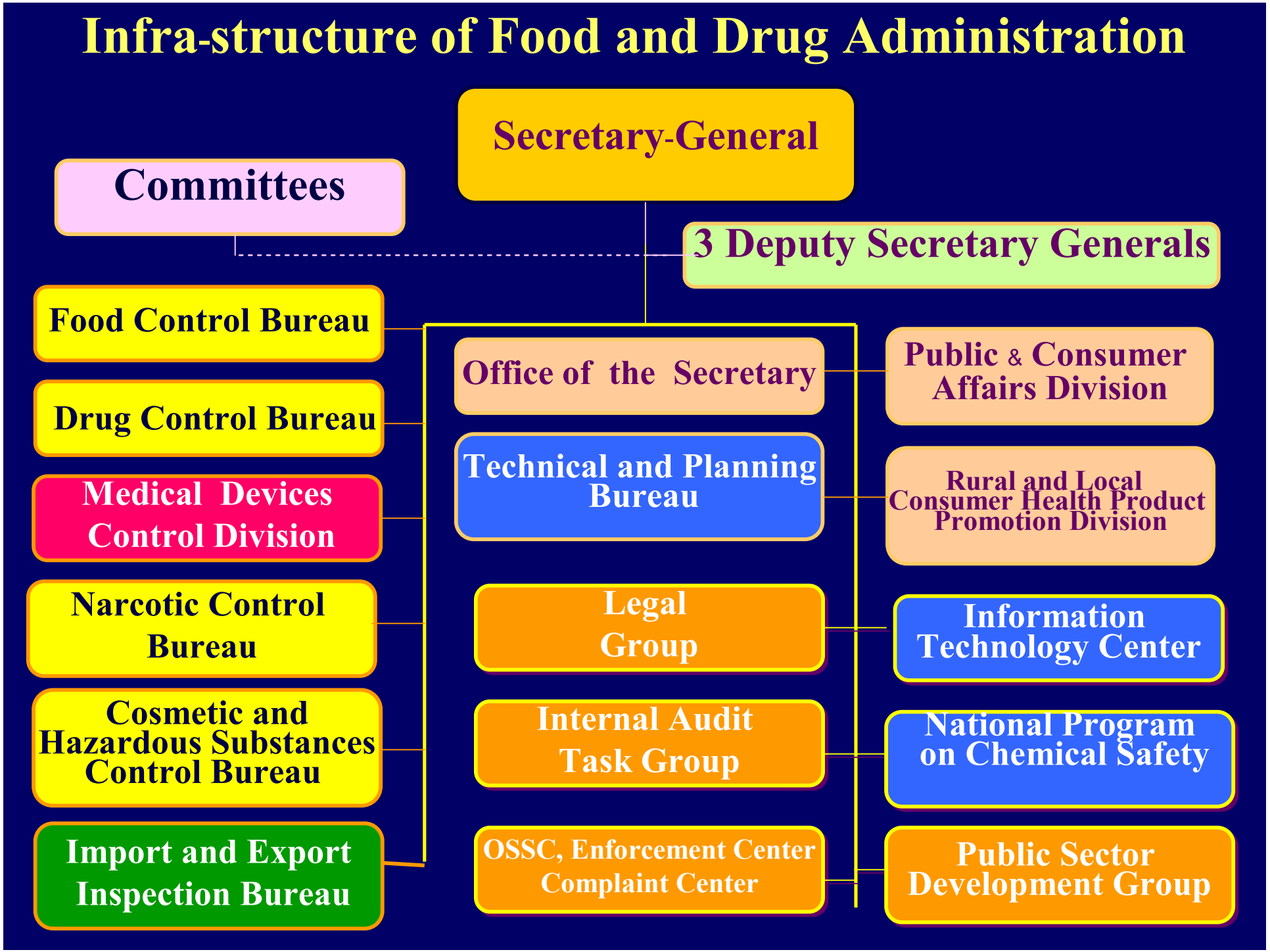

สำนักงานคณะกรรมการอาหารและยา
Food and Drug Administration

Thai FDA

Products in Control of Thai FDA

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

Infra-structure of Food and Drug Administration



THAI FDA VISION

" Excellent organization to protect public health and promote the use of health products which are safe, cost-effective and in good quality, leading to healthy society."

THAI FDA VALUE

“PROTECT”

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

MEDICAL DEVICE ACT IN THAILAND

- Before 1988, using Drug Act
- Since May 1988 - **Medical Device Act 1988 (effective date: 6 March 2008)**
- **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.

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 Device s

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 some medical devices

Premarketing product approval (2)

Medical Devices are classified into 3 groups:

- ***Licensed Medical Devices***
- ***Notified Medical Devices***
- ***General Medical Devices***

Premarketing approval

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

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 Center in Thai FDA and Adhoc Post-market Team

- Post-marketing service for all FDA responsible health products
- Post-advertisement control/monitoring
- Law enforcement

Network of Control

- Provincial FDA operated by provincial health offices
- Inspection at FDA port situated among all region and work closely with Custom Department
- Network of Expertise, Lab/Test Agency, Standard organization, Health Professional Associations, etc

Licensed Medical Devices

- *Condoms*
- *Surgical Gloves (being reclassified)*
- *Examination Gloves (being reclassified)*
- *HIV test kit for diagnosis*
- *Corrective and Cosmetic Contact Lens*

Notified Medical Devices

- *Physical Therapy Devices*
- *Alcohol Detectors*
- *Silicone Breast Implants*
- *Breast Enhancer External Use devices*

General Medical Devices

- *Devices not on the list of Licensed medical device and Notified medical device*
- *Majorities are general medical devices*

Important REGULATIONS Update

2011-2012 (1)

- **Ministerial Notification: Requirements on Recording and Reporting of manufacturing/importing/selling of medical devices dated 7 June 2011**

Important REGULATIONS Update

2011-2012 (2)

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

--- CSDT Requirements

FUTURE PRIORITY PLANS (1)

Reclassification and Control Level of Medical Devices based on Risk Factor

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

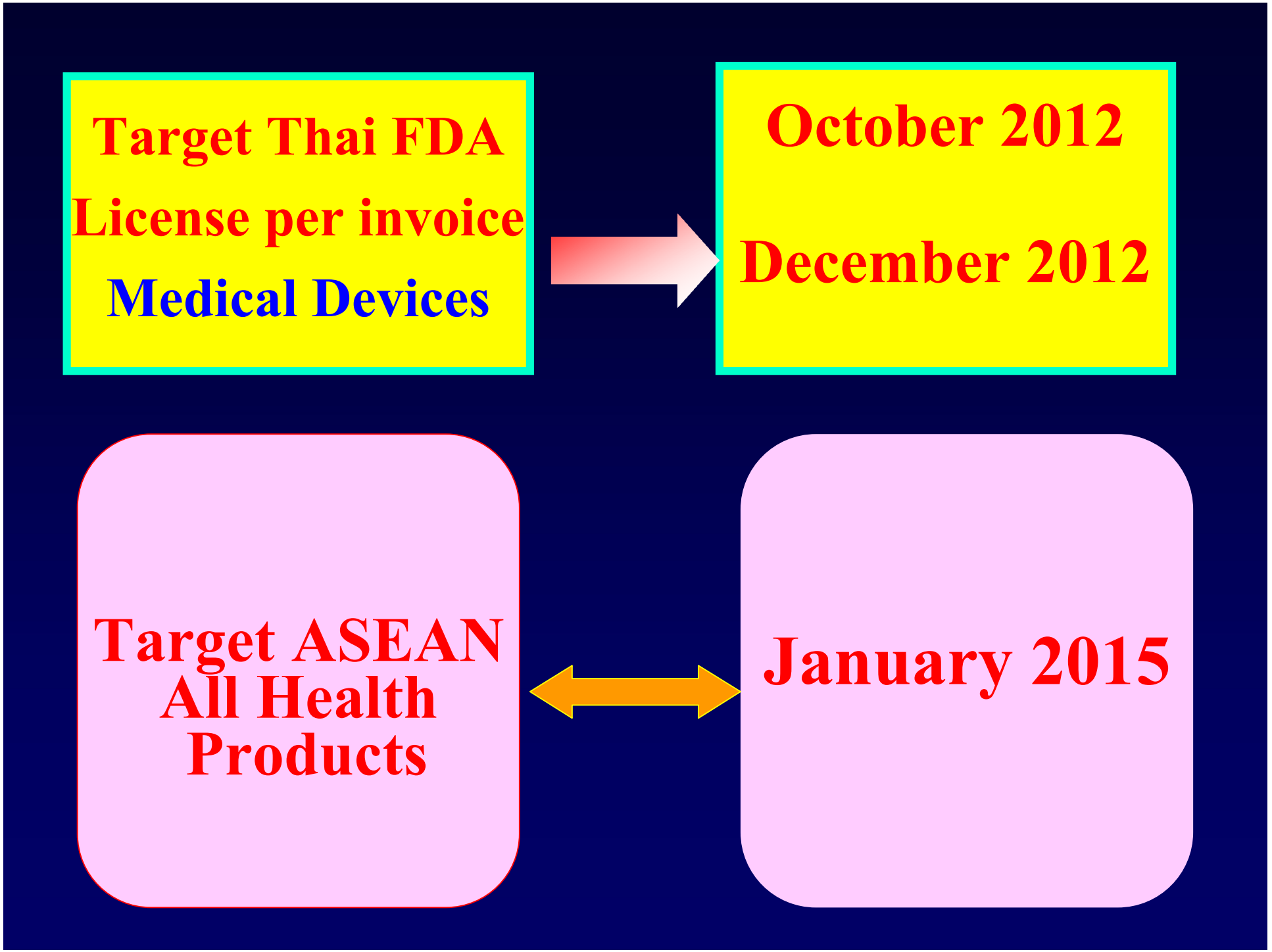
Premarketing approval

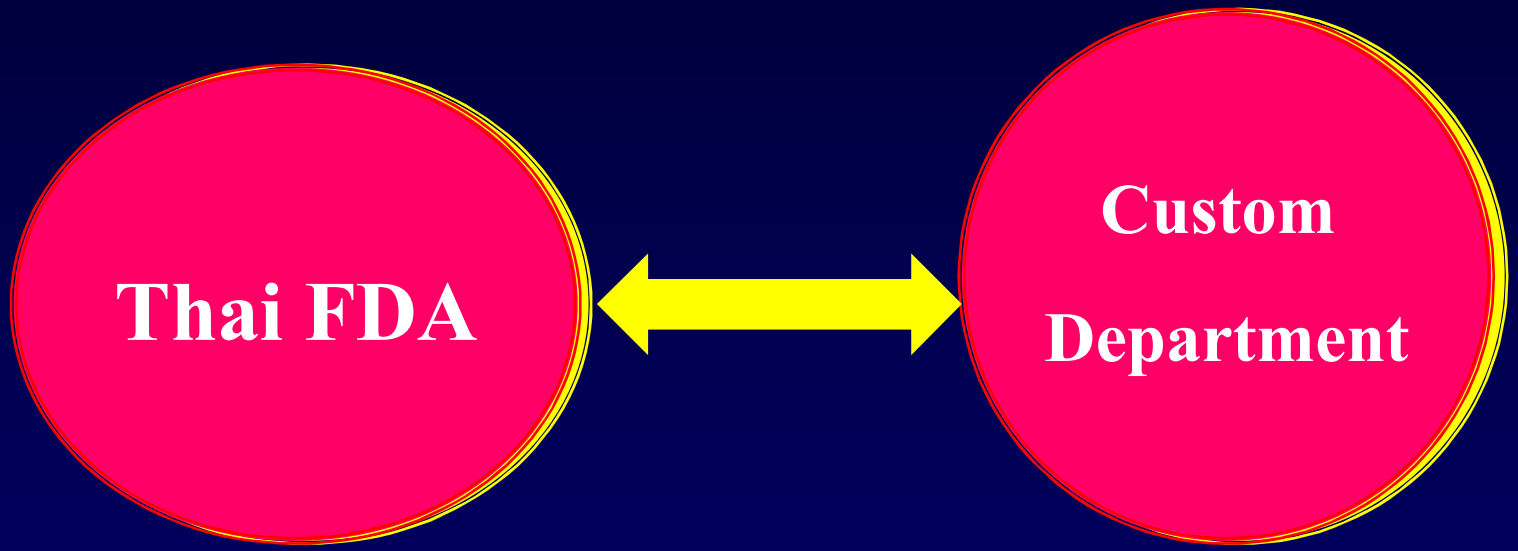
1. *Licensed medical devices* → *High Risk*
2. *Notified Medical Devices* → *Moderate Risk*
3. *General Medical Devices* → *Low Risk*

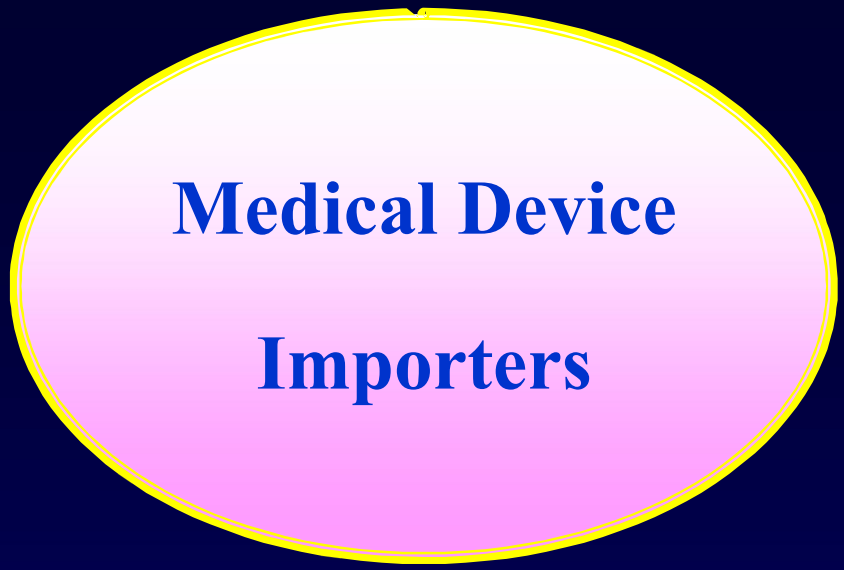
FUTURE PRIORITY PLANS (2)

National Single Window/ License

per invoice


Target Thai FDA
License per invoice
Medical Devices
October 2012
December 2012
Target ASEAN
All Health
Products
January 2015


Thai FDA
Custom
Department



ID Number

Database

Database Importers

Importer (Company) Registration Number	ID code

Database Medical Devices (1)

Product License No	Product Notification No
FDA Import Permit Letter for General Medical Devices No	

Database Medical Devices (2)

Custom (HS) Code	Product Code
City and Country of Origin/ Manufacturers	

Duties of Importers

- input product database for all items that are still active or planned to be sold in Thailand
- pilot implementation
- full scale implementation

FUTURE PRIORITY PLANS (3)

ASEAN Medical Device Directive

and AEC 2015

FUTURE PRIORITY PLANS (4)

Continue to draft or amend regulations e.g.

- **Ministerial Notification No. 34, 19 July 2006 " Medical Devices to be prohibited for import and sale "**

- **FDA rule 2007, 28 February 2007 " Principles on Certification required for import approval of medical devices "**

FUTURE PRIORITY PLANS (5)

Outsource Program