MEDICAL DEVICES REGULATION IN THAILAND

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MEDICAL DEVICE ACT IN THAILAND

- Before 1988, using Drug Act
- Since May 1988 - Medical Device Act
- Medical Device Control Division, Food and Drug Administration was officially established in June 1990 as regulatory authority to control manufacture, import, sale and advertise medical devices in Thailand.

LAW AND REGULATION UNDER MEDICAL DEVICE ACT 1988

- Act of 82 Sections under 11 Chapters
- Ministerial Regulations(MOPH)
- Ministerial Notifications
- FDA rules

Definition of Medical Devices under the ACT(1)

1. ***Equipment, products or articles used in the clinical practice of medical doctors, dentists, nurses and midwifery, veterinarians, and other health professionals***

2. ***Equipment, products or articles that have effects on the health, the structure or any function of human or animal body***

Definition of Medical Devices under the ACT(2)

3. *Constituents, components, accessories or parts of the equipment, products or articles under 1or 2*

4. *Other equipment, products or articles notified in the Government Gazette by the Minister of MOPH as medical devices*

REMARKS: DEFINITION OF MEDICAL DEVICES

- include Medical Devices For Animal Use
- include IVD products
- include Software

CONTROL OF MEDICAL DEVICES

- Premarketing 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 approval

Medical Devices are classified into 3 groups:

- ***Licensed Medical Device***
- ***Notified Medical Device***
- ***General Medical Device***

Licensed Medical Devices

- *Condoms*
- *Surgical Gloves*
- *Examination Gloves*
- *Disposable Syringes*
- *Insulin disposable Syringes*
- *HIV test kit for diagnosis*

Notified Medical Devices

- ***Physical therapy devices***
- ***Alcohol detectors***
- ***Silicone Breast implants***
- ***Breast Enhancer external use devices***
- ***HIV test kits for research use***

General Medical Devices

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

General Medical Devices(2)

- **Certificate of Manufacturing Quality System (ISO13485,GMP) is also required for human use medical devices:**

1. **Implants**
2. **Medical devices from tissue origin**
3. **Sterile medical devices**
4. **Diagnostic/Treatment Radiation Devices**

General Medical Devices(3)

Certificate of Manufacturing Quality System (ISO13485,GMP) is also required for human use medical devices:

5. In Vitro Diagnostic Products:

- Blood group detection
- HIV/Hepatitis/HTLV infection,Anti-CMV, HPV, HLA typing
- Antihumanglobulin(Coombs' reagent)

General Medical Devices(4)

Certificate of Manufacturing Quality System (ISO13485,GMP) is also required for human use medical devices:

5. In Vitro Diagnostic Products:

- Biochemical Test: Glucose, Lipid profile, Liver function test, Uric acid, BUN, Creatinine, Pregnancy test, Narcotics, Hormones(Thyroid,Fertile), Tumor markers(AFP,CEA,PSA), Cardiac markers(CK,CK-MB,Troponin)

General Medical Devices(5)

Certificate of Manufacturing Quality System (ISO13485,GMP) is also required for human use medical devices:

6. Solution for sterilizing medical devices
7. Tooth fillings and crowning materials

Medical Devices Prohibited for Importation

- Banned in countries of manufacturing or countries of product ownership
- No FDA Certificate for custom process in case of general medical devices
- In case of suspect in efficacy or safety of medical devices and no supported technical evidence, FDA Certificate may not be issued.

Medical Devices Prohibited for Importation / Manufacture (1)

- No Product License in case of License-classed products
- No Certificate of Notification in case of Notified-classed products

Medical Devices Prohibited for Importation / Manufacture (2)

- Fake devices
- Sub-standard devices
- Deteriorated devices
- Unsafe devices which include devices which efficacy are doubtful

Control of Advertisement

- all classes of medical devices
- any means of medical device advertisement for trading purpose must be approved
- False or exaggerated **advertisement with any means** are prohibited

LABEL REQUIREMENT (1) Translated in Thai

- name, category, type of products
- name and address of importer and origin manufacturer
- name and address of manufacturer
- packing quantity
- batch or lot number

LABEL REQUIREMENT (2) Translated in Thai

- license number
- intended use
- instruction for use and storage
- warning and precaution (as required)
- expiry date (as required)
- “for single use” in case of disposable MD

Duties of Licensee and Notifier

- submit adverse effects report to FDA within 15 working days, in case of death or severe injure occurred- report within 24 hours
- submit importation and distribution report to FDA

Post-Marketing Control of Medical Devices

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

Network of Control

- Provincial FDA operated by provincial health office
- Inspection at FDA port situated among all region
- Network of Expertise, Lab/Test Agency, Standard organization, etc

One Stop Service Center in Thai FDA

- Pre-marketing service for all FDA responsible health products: medical device, drug,food, cosmetic, hazardous substances
- Pre-advertisement approval
- Issuing Certificates, complaint service, etc

FUTURE TREND?!