Medical Device Regulation in Thailand

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Medical Device Act , 1988

Objective :

Quality consumer safety standards for marketable devices

organization : Medical Device Control Division, FDA, MOPH

3 Main activities

1. Premarketing Control

2. Postmarketing Control

3. Vigilance system

Premarketing Control

-Assessment = Safety, Performance

- Advertisement
- Certificate for Exportation

Postmarketing Control

- Surveillance
  - products - quality
  - advertisement
- Complaints

Vigilance System

- Adverse reactions

- Annual reports of production, importation and sale

Definition:
Medical Device

1.) Equipment, products or articles

(a) used in the medical professions of the clinical practice of both human being or animal

(b) effecting the health, structure, or functions of the human being or animal body

Definition (Continue)

2.) Constituents, components, accessories or parts of them (1)

3.) Other equipment, products or articles prescribed by the Minister as medical devices by publication in the Government Gazette

Classification

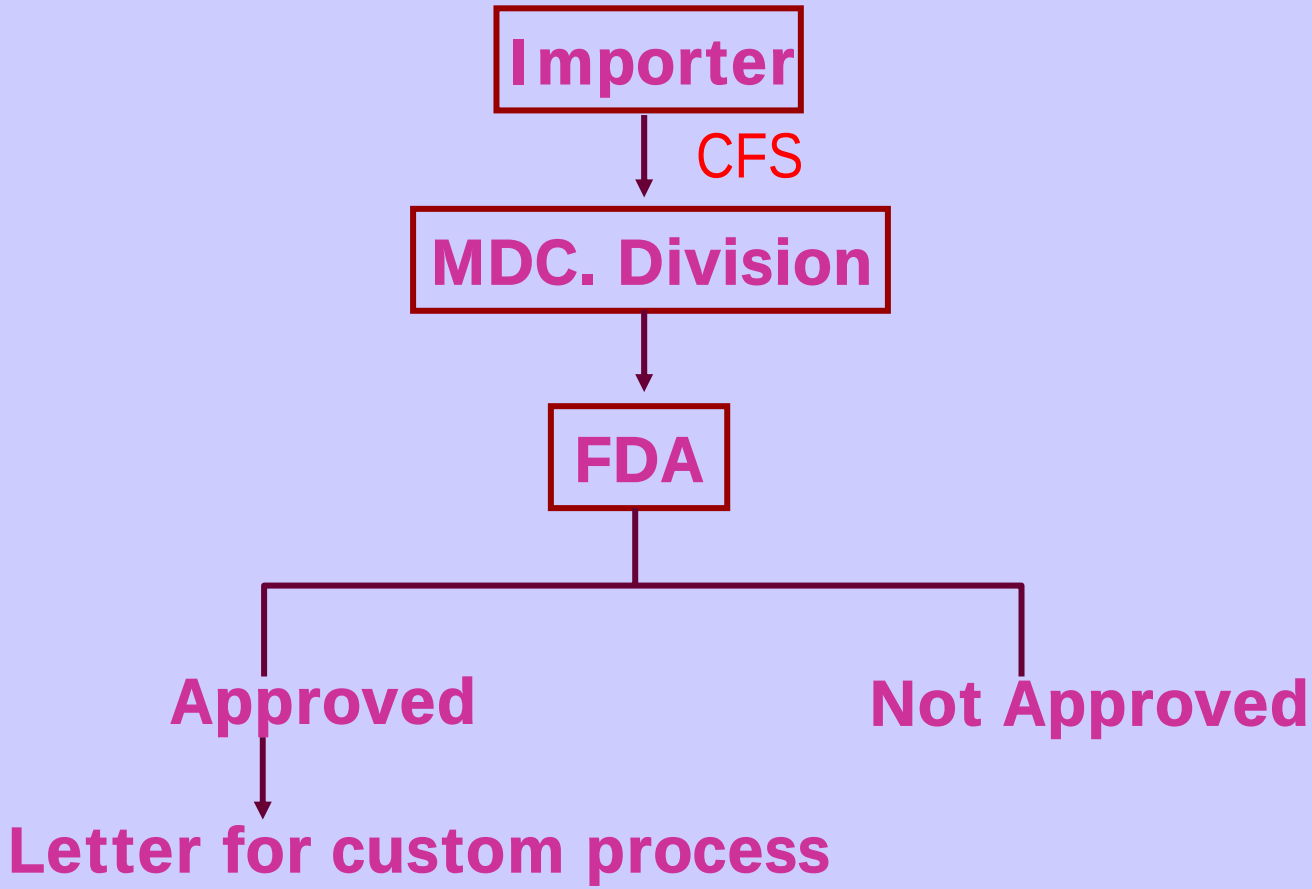
1. General Medical Devices : least control
2. Notification Medical Devices : tighter control
3. License or Pre-market Approval of Medical Devices : require most strict control

Requirement for Verification

General Medical Devices:

- Submit CFS only for Imported products
- Comply with the Notice of MOPH No.6 (BE.2532/AD.1989)

Verification Process



- All medical devices exempted from license and notification

Requirement for Notification

Medical Device Notification

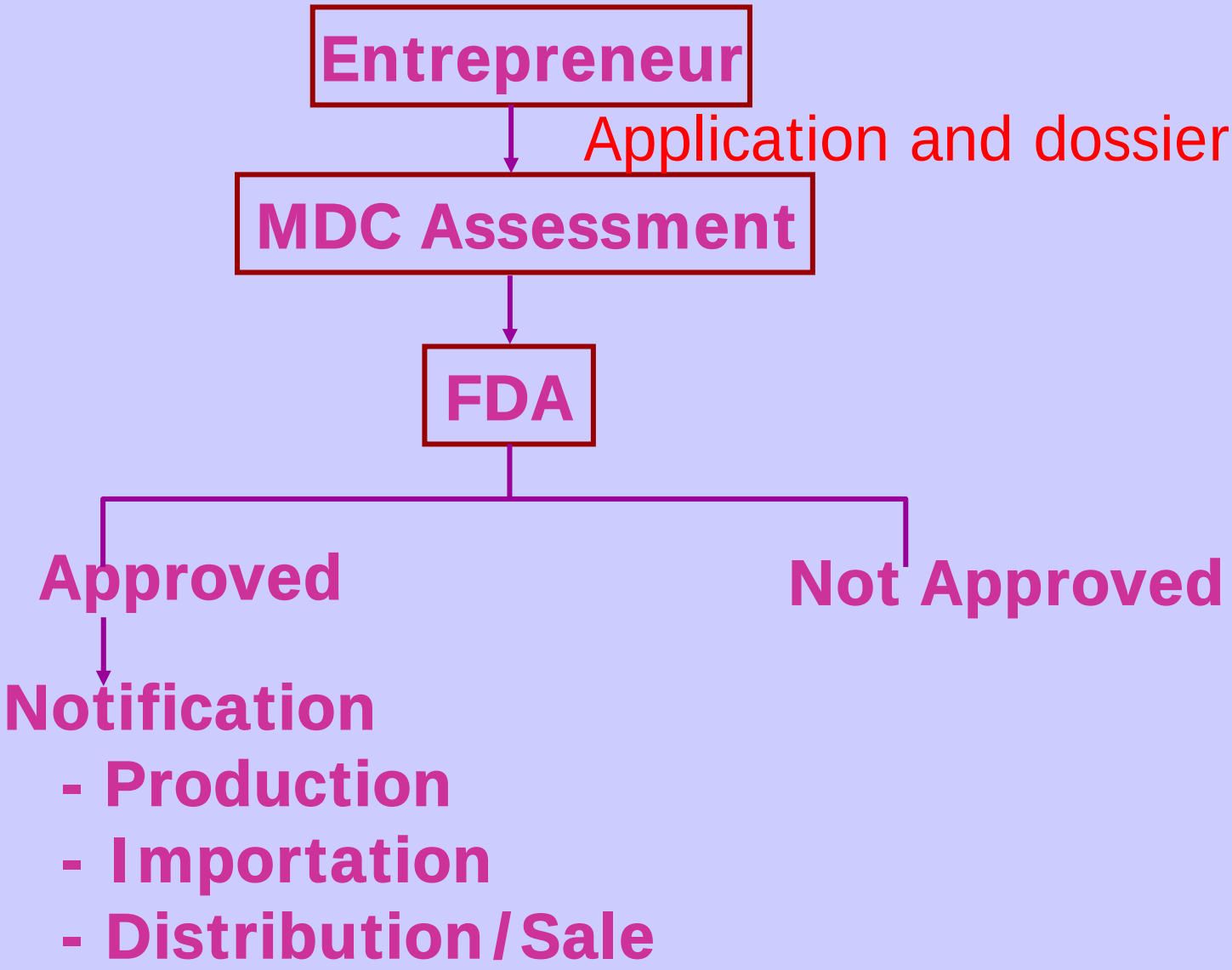
- notify details of medical device
- comply with the Ministerial Regulation No.4-5

Notification types - Production, Importation

Distribution/Sale -HIV test kits

Dossier - Similar to License Medical Device except Manufacturing information and Test report of DMS

Notification Process



PRODUCTS

1) HIV Test Kit- (for investigation/ research use)
   (Notice of MOPH No.18 : BE2538/AD1994)
2) Physical Therapy Products-
   (Notice of MOPH No. 19 : BE2539/AD1995)
3) Alcohol Detector-
   (Notice of MOPH No.22 : BE2540/AD1996)
4) Silicone Breast Implant-
   (Notice of MOPH No.23 : BE2540/AD1996)

Requirement for License

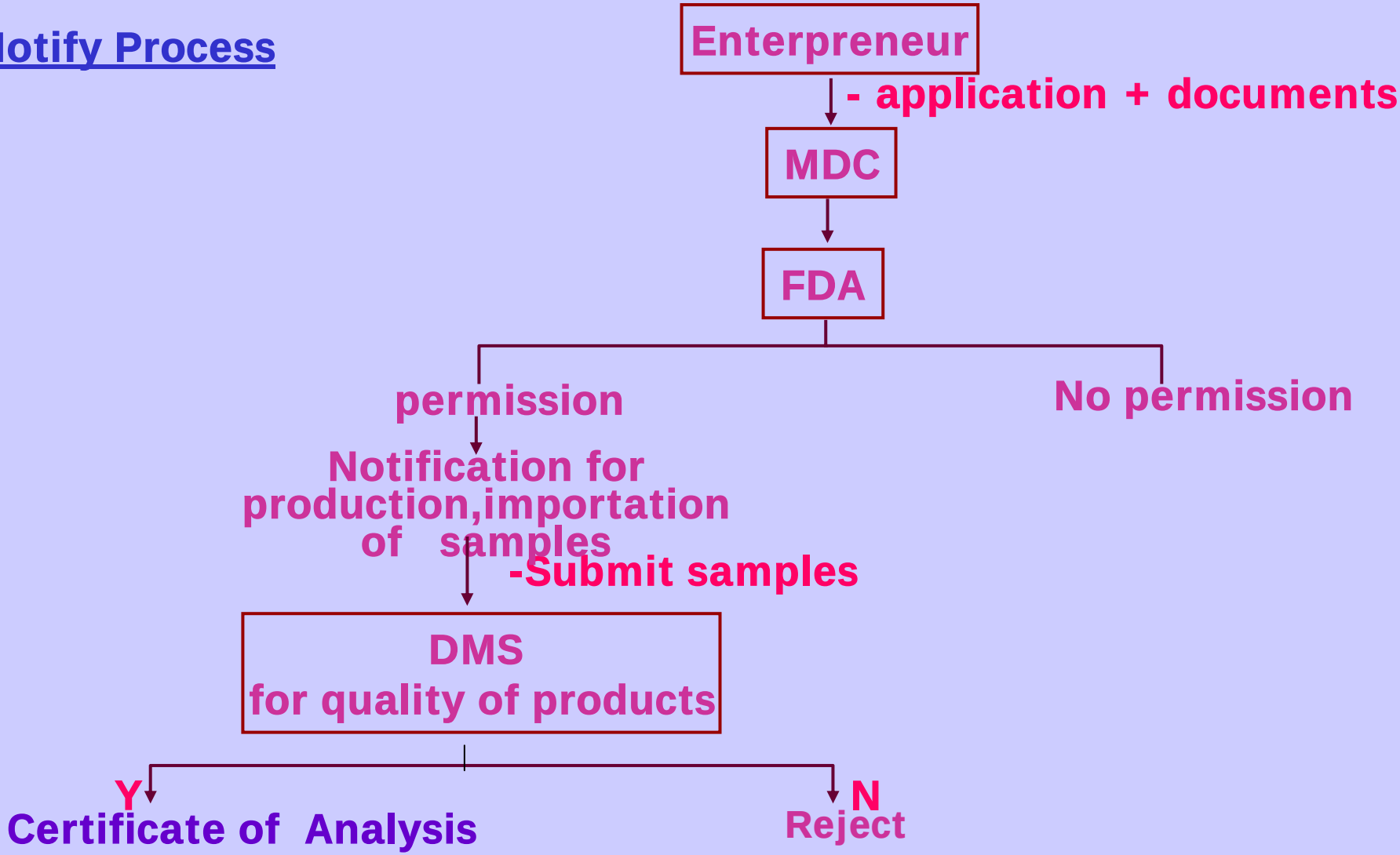
- Get approval for licenses

- Comply with the Ministerial Regulation

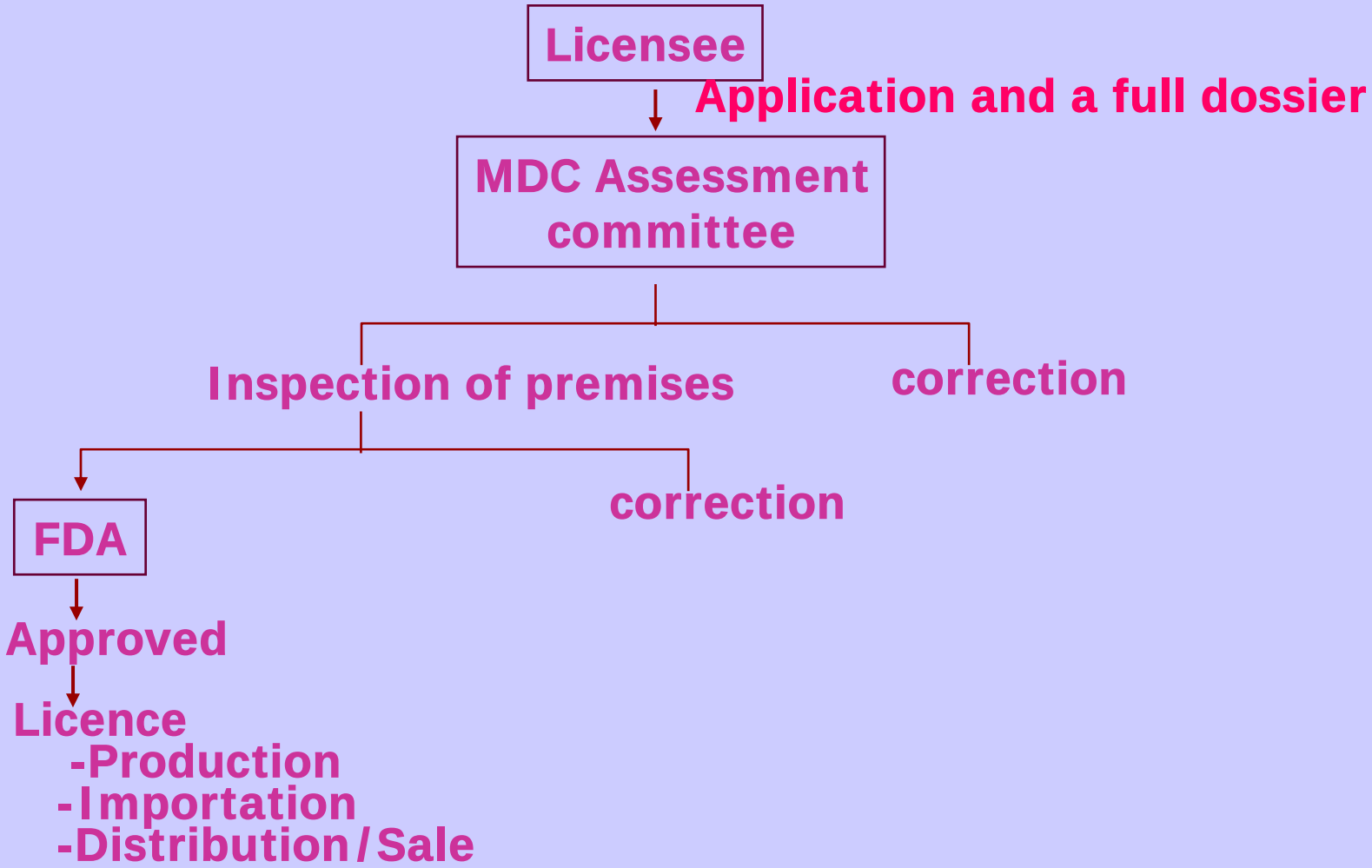
No.1-3 and No.5-6

Granting License Process: 2 steps

Notify Process



Licensing process



Medical Device Licensing and Notification

1. To be announced by the Minister of Public Health

2. Documents to be submitted with Application form

2.1 Premises & Warehouse

(a) location map and adjacent structures

(b) correct-scale interior construction plan

2.2 Licensee and/or business operator

(a) ID Card copy, photograph

(b) residential document

(c) health certificate

(d) business documents

3.Product Documentation

(a) The name, category and type of medical device
(b) The characteristics of the medical device
(c) Packaging
(d) The type and quantity of components
(e) Operating procedure*
(f) Indication and use
(g) Instruction for use
(h) Storage, shelf life (if any)
(i) Standard, quality, inspection or analytical procedure
(j) Testing result from authority Laboratory
(k) The name and address of the producer or the importer
(l) Label and Insertion
(m) Sample/Catalog
(n) Other related documents; ex. CFS**, Toxicity Data etc.

* only for the Licensing of the medical device
** only for the importer.

4.MD for sale shall have Thai labeling on its container or packaging bearing the following information:

(a) Name, category, and type of medical device
(b) Name and premises of the producer and importer
(c) Content
(d) Lot no. of production
(e) License No./Notification No.
(f) Indication of use; instruction for use and storage/maintenance of medical device
(g) The word "**for single use**" for disposable medical device
(h) Warning and Precautions for handling the medical device
(i) Expiration date (if any)
(j) Other information as prescribed by the Minister of Public Health

License types

Production, Importation

Distribution/Sale

1. Production / Importation license - 5 years
2. Distribution / Sale license - 1 year
   (only for HIV Test Kit)

PRODUCTS

1) Condoms-
(Notice of MOPH No.11,28: BE2535/AD1992,BE2545/AD2002)

2) Examination Gloves-
(Notice of MOPH No.13: BE2537/AD1994)

3) Surgical Gloves-
(Notice of MOPH No.14: BE2537/AD1994)

4) Disposable Hypodermic Syringes-
(Notice of MOPH No.15: BE2537/AD1994)

5) Disposable Insulin Syringes-
(Notice of MOPH No.16: BE2537/AD1994)

6) HIV Test Kit- (for diagnostic use)
(Notice of MOPH No.18: BE2538/AD1995)

Future Trends

1. The near future :

Implement the new act!

2. The current act :

Amend some parts and announce more notices.

THANK YOU FOR YOUR ATTENTION!