# Law and regulations on doing business in Thailand for medical sector

Division of Innovative health products and services

สำนักงานคณะกรรมการอาหารและยา
Food and Drug Administration

# Consumer Health Protection System

**Goal : People have to consume quality, safety and effectiveness health products**

**MEASURE : 1. Control/Monitoring/Surveillance 2. Law enforcement 3. Risk Communication and Consumer Empowerment 4. Development of consumer health protection administrative system in provincial level**

## 3 Risk Communication and Consumer Empowerment

- Consumer Empowerment
- Product Alerts System

## 1 Pre-marketing Control

- **Licensing/Registration**
  - Product
  - Manufacturing
  - Distribution
  - Advertisement
- **Trade facilitation**
  - Outsourcing
  - Amendment
  - e-Submission
  - Reprocess
  - OSSC
  - Business Easing

## 2 Post-marketing Control

- **Import and Export** Inspection and Certification
- **Surveillance**
  - Product
  - Manufacturing
  - User
  - Advertisement
- **Laws Enforcement**
- **Vigilance Center**
- **Complaint Center**

# Laws and International Agreements

## ① Thai Laws

1. Drug Act, B.E. 2510 (1967) and Amendment No.2 (1975), No.3 (1979), No. 4 (1985) and No. 5 (1987)
2. Food Act, B.E. 2522 (1979)
3. Narcotic Act, B.E. 2522 (1979) and Amendment No.2 (1985), No.3 (1987) and No. 4 (2000)
4. The Emergency Decree on Prevention of Abuse of Volatile Substances, B.E. 2533 (1990) and Amendment No. 2 (2000)

# Laws and International Agreements

## ① Thai Laws

5. Hazardous Substance Act, B.E. 2535 (1992)

6. Medical Device Act, B.E. 2551 (2008)

7. Cosmetic Act, B.E. 2558 (2015)

8. Psychotropic Substance Act B.E. 2559 (2016)

9. Herbal Product Act B.E. 2563 (2019)


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 **pharma chemicals** or semi – processed pharma chemicals.
4. Substances intended to **affect the health, structure or function of the human or animal body**.


1. Substance can be eaten, drunk, sucked or gotten into the body either by mouth or by other means, no matter in what form, but not including medicine, psychotropic substances, narcotic under the law as the case may be.
2. Substance intended for use or to be used as ingredients in the production or food including food additive, coloring matter and flavoring


An instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article Intended by the manufacturer to be used, alone or in combination, for one or more of the specific purpose(s) of:

(a) clinical practice of medicine, medical practice, nursing and midwifery practice, dental practice, medical technology practice, physical therapy practice and veterinary practice under the laws governing the respective professions or other medical or public health practices as prescribed by Notification of the Minister;

(b) diagnosis, prevention, monitoring, treatment, alleviation or cure of human or animal disease;

(c) diagnosis, monitoring, treatment, alleviation or cure of human or animal injury;

(d) investigation, replacement, remedy, modification, or support of the anatomy or of a physiological process of human or animal body;

(e) supporting or sustaining life of human being or animals;

(f) control of conception or promotion of human or animal fertility;

(g) aid or compensation for disabled or handicapped of human or animal;,

(h) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human or animal body;

(i) disinfection or sterilization of a medical device;

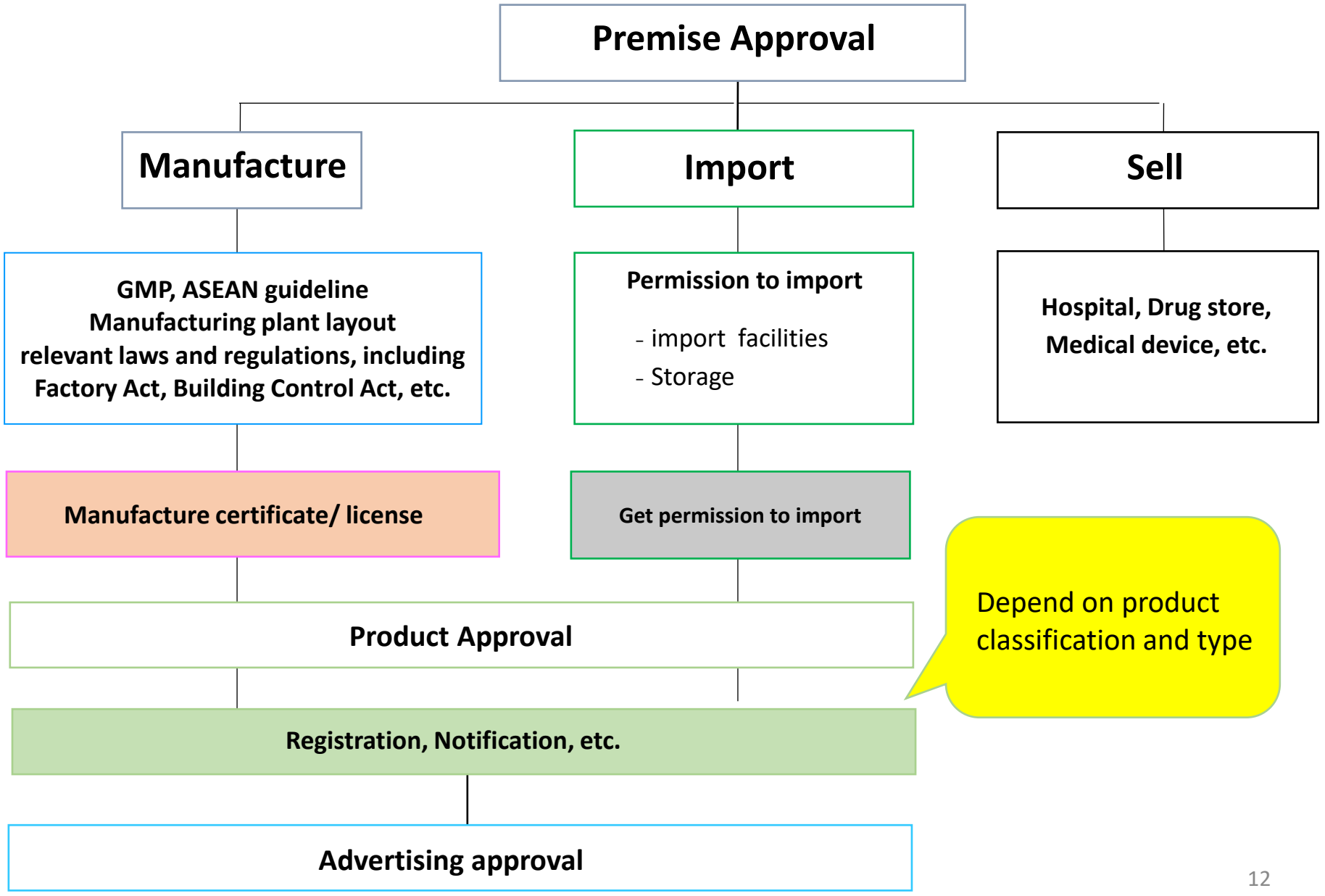

- An equipment or constituent of an instrument, apparatus, machine, product or object under (1);
- Other instrument, apparatus, implement, machine, product or object as prescribed by Notification of the Minister.
- The achievement of its primary intended action stated in (1) which occurs in or on the human or animal body must not be the result of a pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.


1. substance intended for use in applying, rubbing, massaging, sprinkling, spraying, dropping, putting on, perfuming, or acting by whatever means on external human body, and shall include the use on tooth and oral mucosa with the objective of cleaning, beautifying, or changing appearance, or deodorizing, or protecting such parts in good condition, and as well as skin treatment product, but not include adornment and dress which is an accessory for use on external body;
2. substance intended for use specifically as a mixture in producing cosmetic product;
3. other substance prescribed in the Ministerial Regulation to be cosmetic product

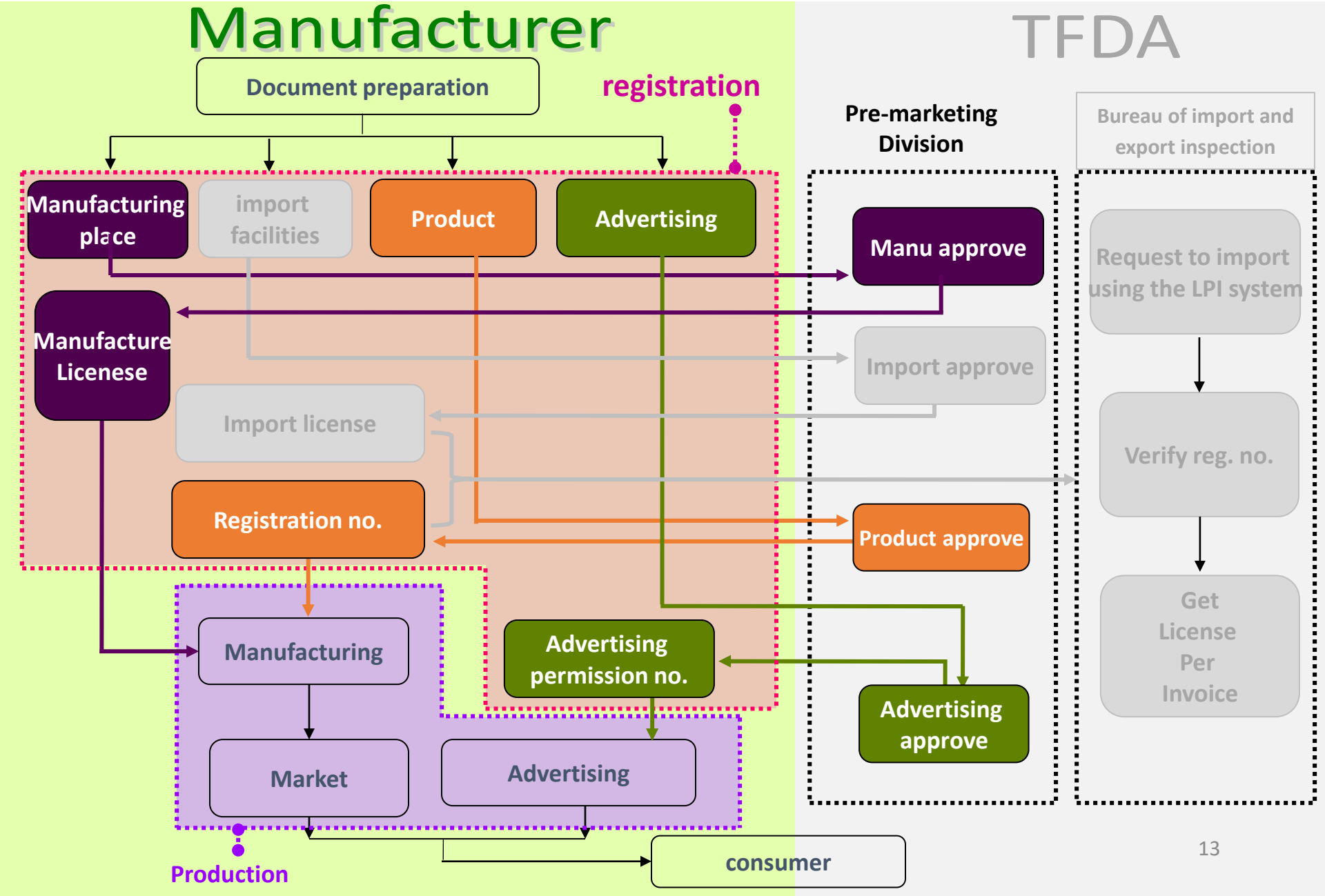
# Herbal product

- In June 2019, the Thai FDA published and implemented the Herbal Product Act which the main act **regulating herbal product including herbal/traditional medicine, herbal health supplements with health claim in Thailand**
- **National herbal policy committee** is responsible for developing strategy and policy to promote herbal product development
- **Herbal product committee for guideline development**
- The guidelines and requirements of each herbal product are not yet established. (now apply current Act of each product such as Drug Act)
- Herbal product can be approved by **registration, notification, listing** based on the level of claim and risk
- Marketing authorized holder can be anyone (not exclusive for manufacturer)

# FDA certification procedure



# Pre-marketing



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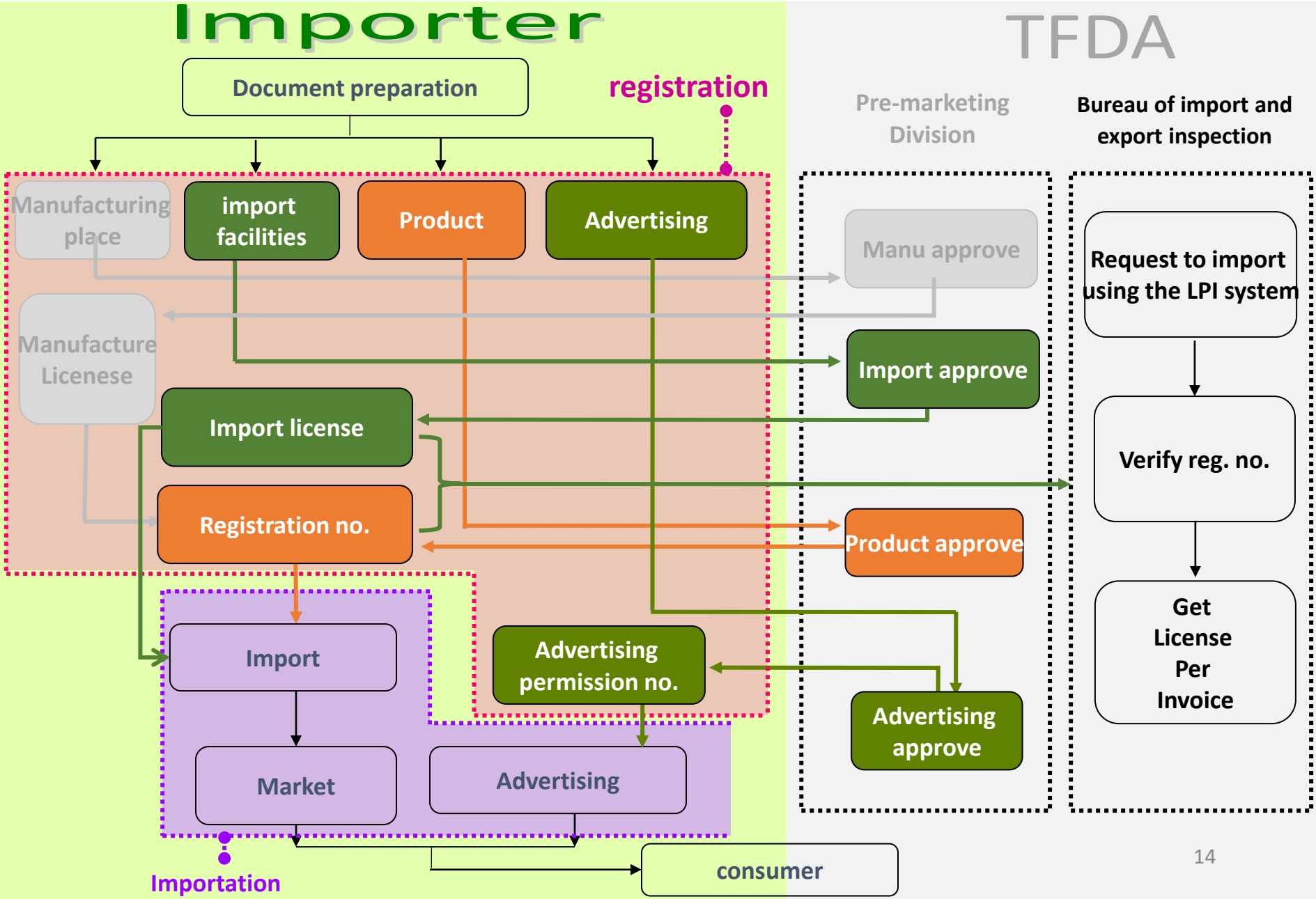


| Product Classification | Drug | Food | Medical device | Cosmetic |
|---|---|---|---|---|
| Product type | New drug<br>Generic drug<br>Biological drug<br>Traditional drug | Specially Controlled Foods<br>Standardized Foods<br>Labelled Foods<br>General Foods | Licensed medical device<br>Notified medical device<br>General medical device | - |
| Premises approval | | | | |
| ▪Manufacture | /<br>GMP/PICS<br>(Drug sample, Drug) | /<br>GMP depend on type | / | /<br>GMP (voluntary) |
| ▪Sell | / | - | /<br>HIV test, OVD, Blood bag | - |
| ▪Import | /<br>GMP/PICS<br>(Drug sample, Drug) | /<br>GMP depend on type | / | /<br>GMP (voluntary) |
| Product approval | Registration | Registration,<br>Notification,<br>None | Listing, Licensed Medical Device,<br>Notification | Notification<br>(E-submission) |
| ▪Document | **safety, efficacy, and quality** | | | |
| | ACTD/ECTD | Depend on type | Depend on type | ASEAN guideline |
| Advertising | / | / | / | - |

# What's new

Allowing cultivation and processing of **hemp** only for non-commercial uses, such as for household cooking or research and development.

**February 19, 2019** The Narcotics Act amendment (No. 7) came into effect, legalizing medical marijuana as the **first milestone of the cannabis legalization movement**.

The key regulator of cannabis-related products is the **Thai Food and Drug Administration (Thai FDA), a government agency operating under supervision of the Ministry of Public Health**. Working closely with the Narcotics Control Committee, the Thai FDA is mainly responsible for granting and administering licenses and post-marketing control, among others. Representatives of the Thai FDA also sit on most of the policymaking committees.

A protective stance towards **Thai stakeholders, now until 2024**

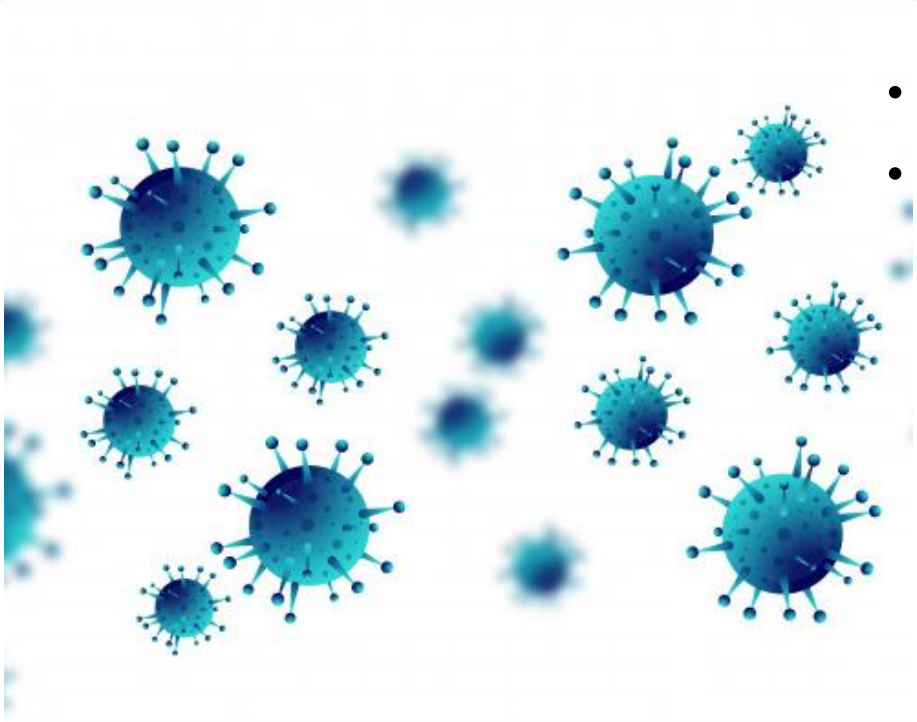
The "delisting" ministerial notification became effective, carving modern drugs, **cosmeceuticals, nutraceuticals, cosmetics, and food** containing hemp or a certain amount of CBD out of the scope of Narcotics Act

# Covid-19 Related product- Fast track approve

| Product | Requirement |
|---|---|
| Medical device<br>Surgical mask, N95, PPE, Surgical gown, Isolation gown, medical cap, medical goggles, thermometer, thermo scan, medical gloves, safety glasses, face shield, medical hood covering, leg covering, SWAB | -Manufacture License<br>-MAH<br>-Evident of sale in manufacturing country<br>-Product<br>-Certificate of free sale<br>-ISO 13485 for sterile product |
| Cosmetic<br>Hand hygiene with alcohol | - Must have ethyl alcohol, isopropyl alcohol, n-propyl alcohol, n-propanol > 70% v/v or 65% w/w |
| Hazardous substance<br>Ethyl alcohol 70% v/v<br>Sodium hypochlorite 0.5% (5000 ppm) | - Alcohol formulation must pass the Excise Department's regulations.<br>- Follow WHO guideline |

# Covid-19 Related issue - on going





- **Individual Spraying Disinfectants** such as in a tunnel, cabinet, or chamber
- **Portable Disinfectant Generator** or Disinfectant device
- **Multi-purpose** Disinfectants
- **Emergency use authorization**

# Division of Innovative health products and services

## Service

1. One stop service center (smart counter service)

2. Consultation & Training (Scientific, Guidance)

3. Approve requests that can serve at single point.

## Regulatory Sandbox

4. Promoting innovative health product

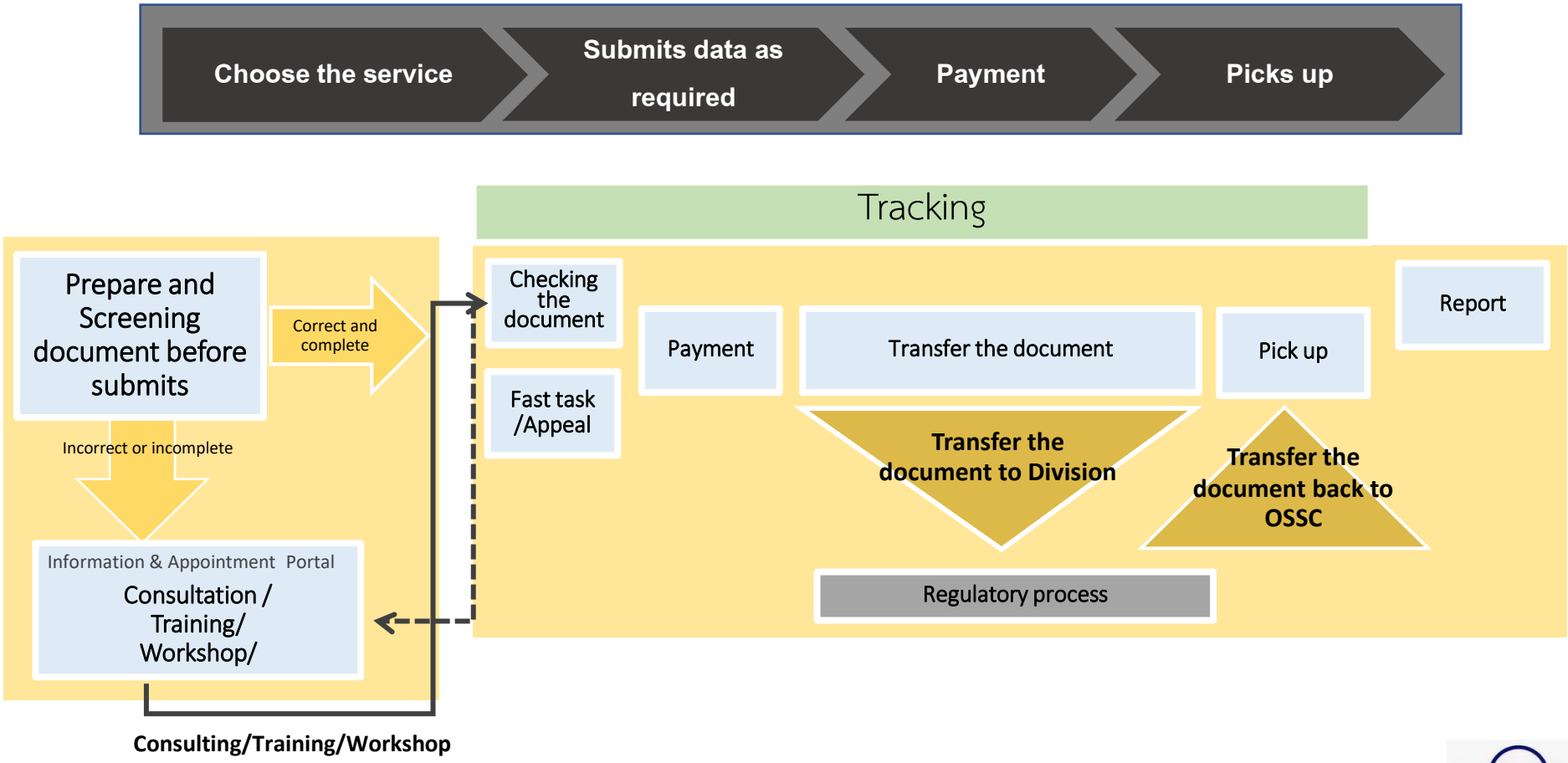
5. Provide product classification system

6. Develop innovative health product regulation model

# OSSC PROCEDURES

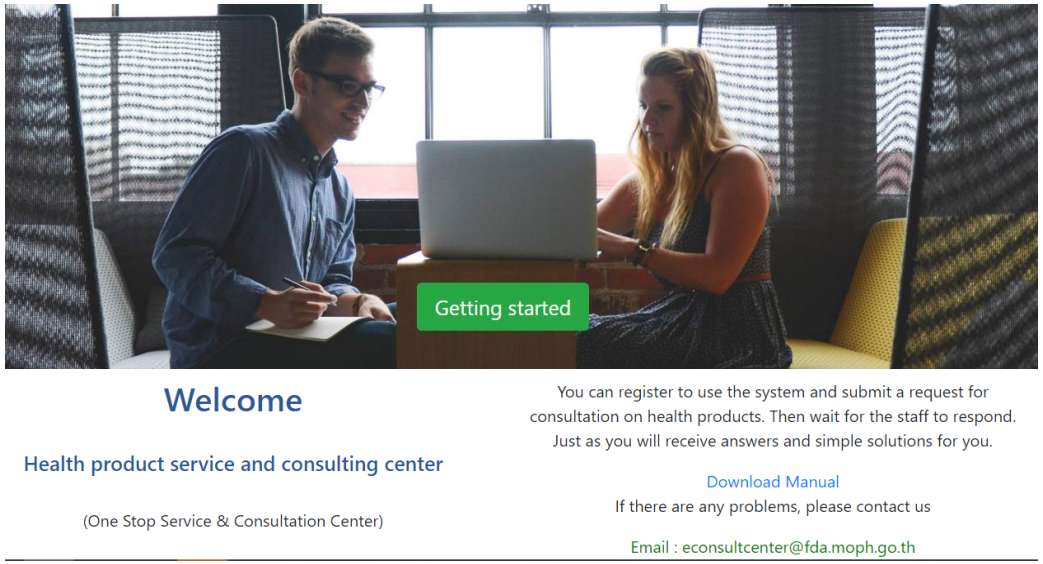
## Smart Counter Service

Submits and picks up all document, Payment, Fast task/Appeal



# Any question

- www.fda.moph.go.th
- Consultation E-service (www.thai-fda.com)




1.Registration

2.Activate account (E-mail)

3.Ask question

4.Wait for answer

# Thank You