

The background features a dark blue field filled with numerous small, glowing particles in shades of blue and red. Some particles form faint, curved lines or trails, creating a sense of movement and depth, similar to a starfield or a microscopic view of particles.

**Baker
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Legal & Regulatory Pathways in Thailand's Medical Sector

5 March 2026

Agenda

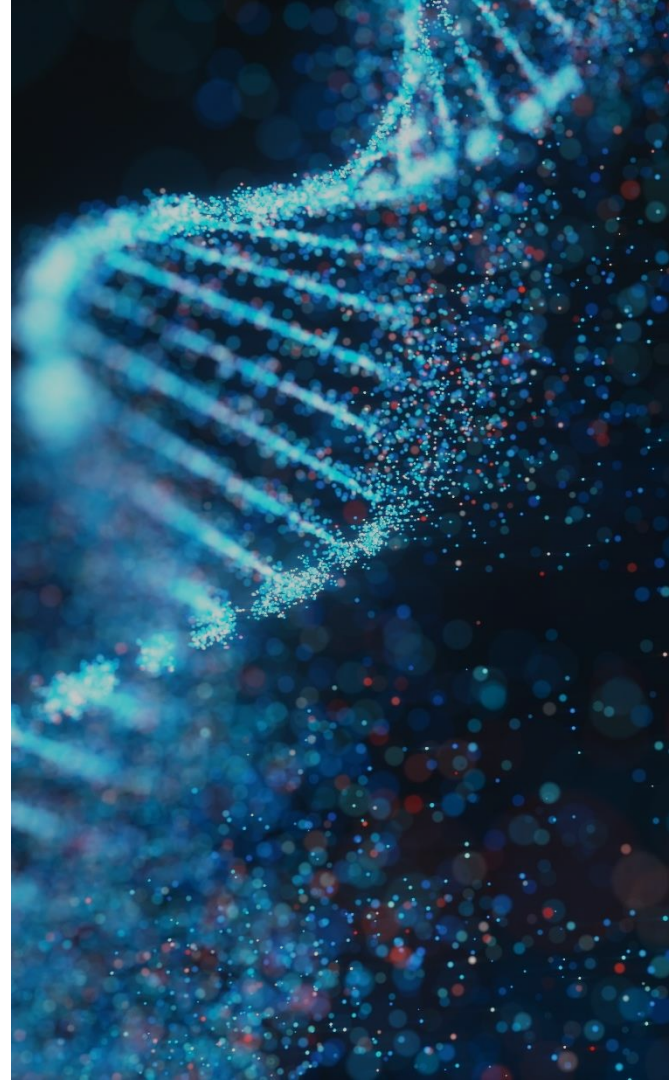
- 01** Thailand's Medical Regulatory Framework

- 02** Product Approval & Registration Pathways

- 03** International Alignment & ASEAN Context

- 04** Market Entry, Importation & Legal Setup

- 05** Key Legal Risks & Strategic Takeaways



Speakers



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Thailand's Medical Regulatory Framework



Food and Drug Administration, Ministry of Public Health

To regulate and ensure the safety, quality, and standards of foods, drugs, and health products to protect consumers.



Drug Act B.E. 2510 (1967)

A substance or product intended for use in the diagnosis, treatment, relief, or prevention of disease in humans or animals, or intended to affect the structure or function of the body; including APIs and medicinal products such as pharmaceuticals, biologics, ATMPs, household drugs, and veterinary drugs.



Medical Device Act B.E. 2551 (2008)

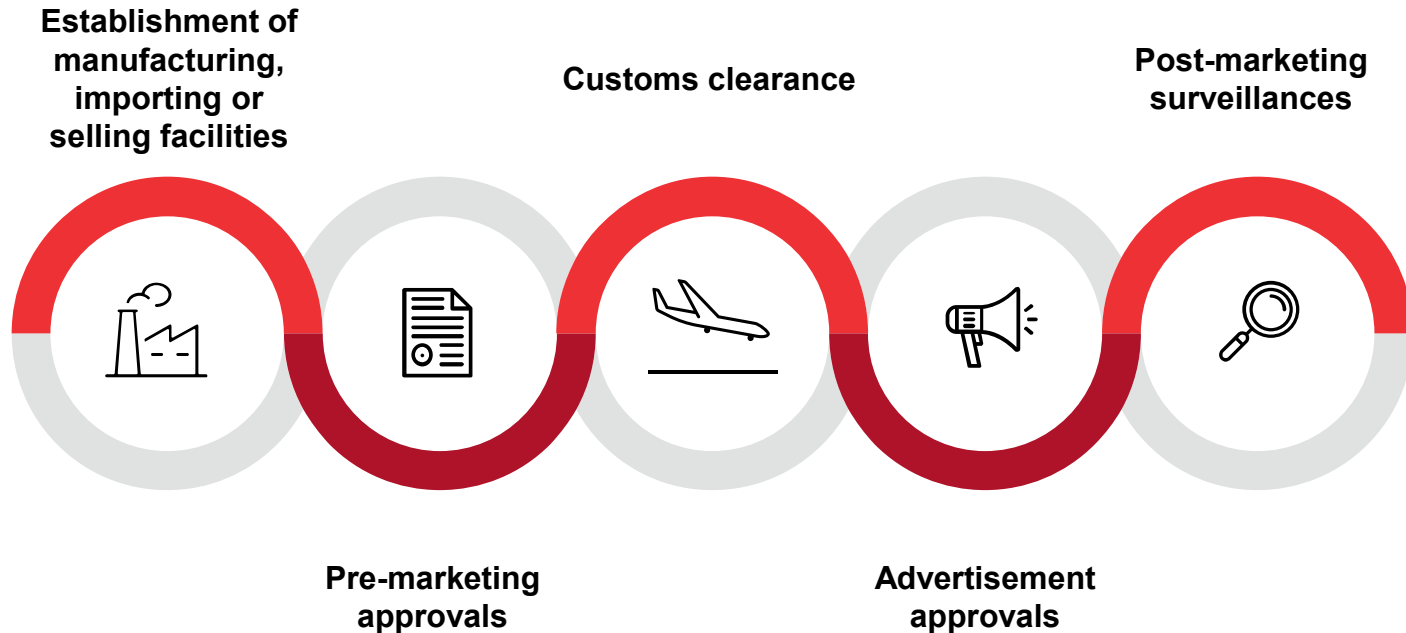
A medical device is an instrument, material, or software used for diagnosis, treatment, prevention, or relief of disease, without primary pharmacological action.



Regulatory and enforcement trends for foreign importers

Strict product classifications, rigorous registration dossiers, alignment of manufacturing standards, tighter advertising controls, intensified post-marketing surveillance

Market Entry, Importation & Legal Setup



Product Approval & Registration Pathways

How products are regulated by category and risk class

Drugs are classified based on control levels i.e. specially controlled drugs, dangerous drugs, drugs that are not specially controlled or dangerous drugs, household drugs.

Medical device are regulated through risk-based system i.e. Class I, Class II, Class III and Class IV.

Registration pathways

- Normal registration pathway
- Regulatory alliance pathway

Common delays and bottlenecks

- Different product classification
- Different manufacturing standards
- Insufficient documents for registrations

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International Alignment & ASEAN Context



International

Stringent Regulatory Authority
e.g. WHO, EMA, US FDA, Health
Canada, TGA Australia, PMDA Japan



ASEAN

Medical device i.e. HSA Singapore
and MDA Malaysia (pilot test)

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