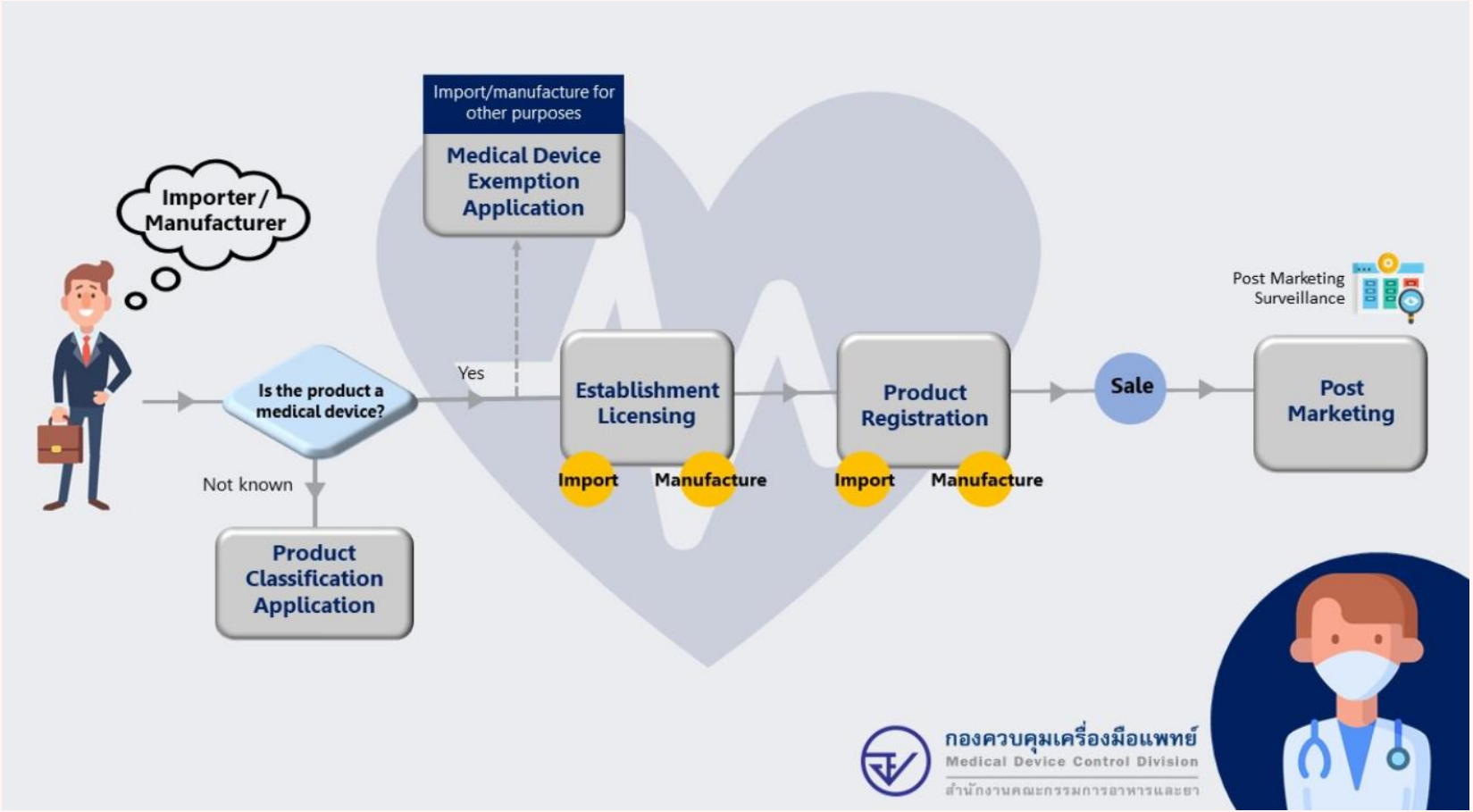
UPDATE ON MEDICAL DEVICE REGULATION IN THAILAND

ASEAN MEDICAL DEVICE COMMITTEE (AMDC) MEETING AND ITS RELATED EVENTS

11th – 14th September 2023


Importer / Manufacturer
Is the product a medical device?
Yes
Not known
Import/manufacture for other purposes
Medical Device Exemption Application
Product Classification Application
Establishment Licensing
Import
Manufacture
Product Registration
Import
Manufacture
Sale
Post Marketing
Post Marketing Surveillance
กองควบคุมเครื่องมือแพทย์
Medical Device Control Division
สำนักงานคณะกรรมการอาหารและยา

Product Registration

1. PARTIAL CSDT Submit only partial documents during transition period (15 Feb 2021 – 14 Feb 2024)

2. FULL CSDT

- Full Evaluation Pathway
- Concise Pathway: CLASS 2-4 Medical Devices registered and marketed for more than 1 year

Therapeutic Goods Administration: **TGA**

Health Canada: **HC**

European Union Notified Bodies: **EU NB**

Japan Ministry of Health Labour and Welfare: **MHLW**

US Food and Drug Administration: **US FDA**

WHO Prequalification of in Vitro Diagnostics (IVD)

- Thai FDA-HSA Reliance pathway since 2019: CLASS 2-4 Medical Devices that approved from HSA

THANK YOU