OVERVIEW OF MALAYSIA MEDICAL DEVICE REGULATORY PROGRAM

23rd AHWP MEETING
KUALA LUMPUR, MALAYSIA

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OVERVIEW MEDICAL DEVICE REGULATION IN MALAYSIA

OBJECTIVE FOR REGULATORY CONTROL OF MEDICAL DEVICE

- **Ensure public health & safety**
  - Provide assurance for quality, safety, performance
  - Prevent defective & unsafe medical devices
  - Timely access to beneficial medical devices

- **Facilitate medical devices trade & industry**
  - Rules-based environment for medical devices industry
  - Facilitate trade & export

Medical Device AUTHORITY MALAYSIA

MEDICAL DEVICE REGULATION: HARMONISATION

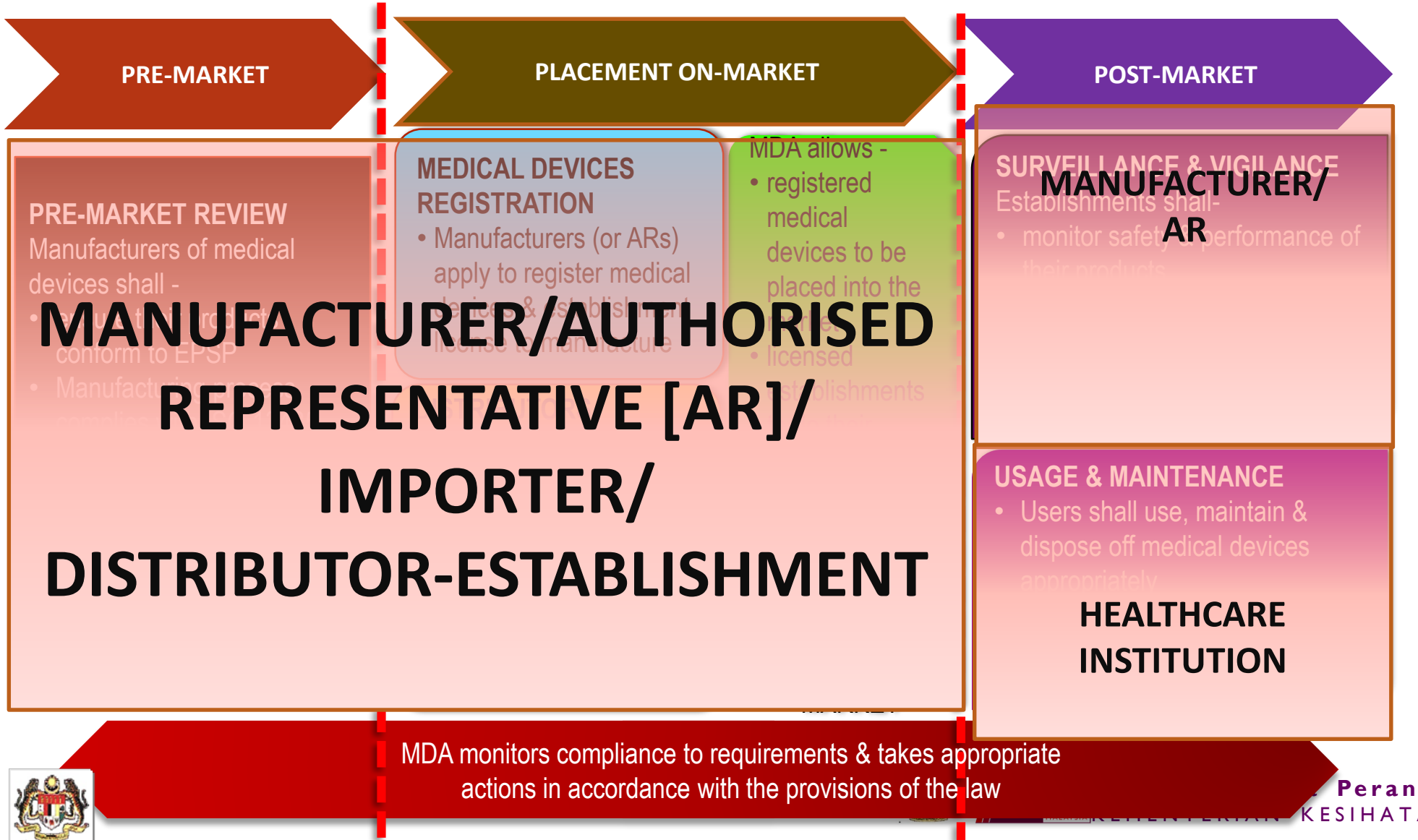
WHO Regulatory model

- Definition of medical device
- Risk Based Classification
- Essential Principles of Safety & Performance of Medical Device (EPSP)
- Common Submission Dossier Template (CSDT)

is based on GHTF.

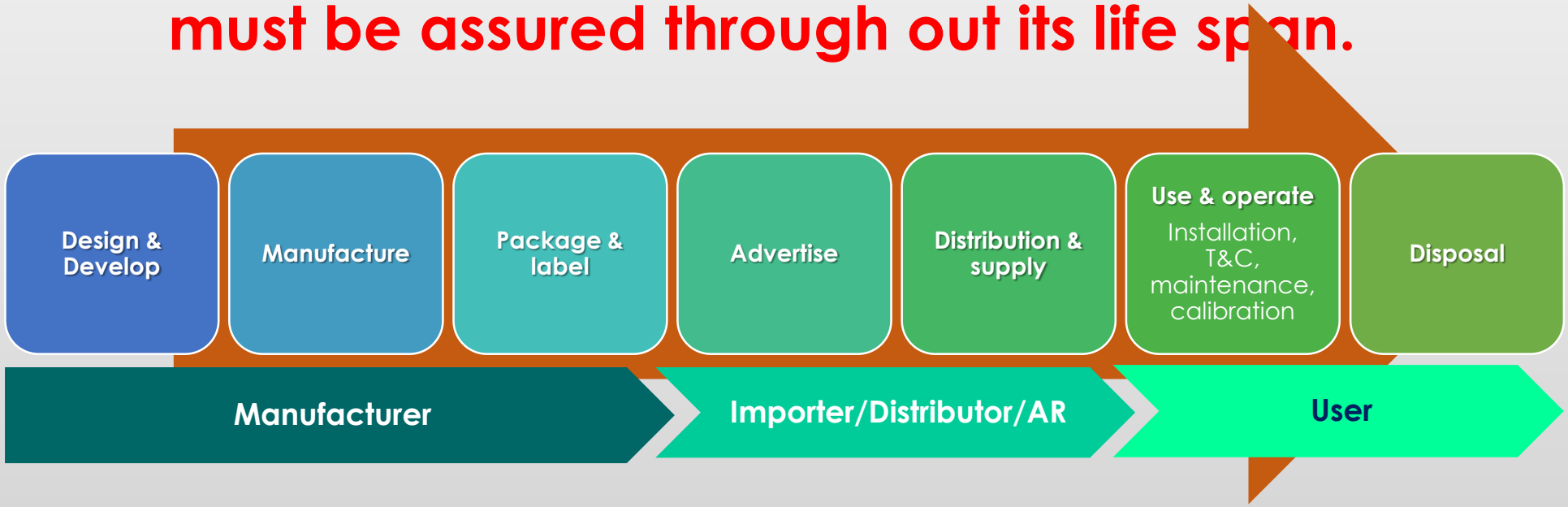
ASEAN Medical Device Directive (AMDD)

THE REGULATORY FRAMEWORK



MEDICAL DEVICES REGULATORY FRAMEWORK IN MALAYSIA:

The safety and performance of medical device must be assured through out its life span.



PARTICIPANTS IN ENSURING THE SAFETY OF MEDICAL DEVICE

Medical Device AUTHORITY MALAYSIA

MEDICAL DEVICE ACT 2012 (ACT 737) & SUBSIDIARY LEGISLATIONS

PRE-MARKET | **PLACEMENT ON-MARKET** | **POST-MARKET**

CONFORMITY ASSESSMENT
Manufacturers of medical devices shall -
- ensure their products conform to EPSP
- establish appropriate quality system for manufacturing their products
- collect evidence of conformity

CAB verifies evidence of conformity

MEDICAL DEVICE REGISTRATION
- Manufacturers (or LARs) apply to register medical devices & establishment license

ESTABLISHMENT LICENSING
Importers/distributors shall -
- ensure compliance to GDP & advertising requirements
- apply for establishment license to import/distribute medical devices

SURVEILLANCE & VIGILANCE
Establishments shall -
- monitor safety & performance of products
- carry out post-market obligations, eg complaint handling, FSCA, recall

USAGE & MAINTENANCE
- Users shall use, maintain & dispose off medical devices appropriately
- Users shall apply for permit to use/operate designated medical devices

MDA monitors compliance to requirements & takes appropriate actions in accordance with the provisions of the law

Medical Device AUTHORITY MALAYSIA

STRUCTURE OF MEDICAL DEVICE REGULATORY SYSTEM

- **Medical Device Act 2012 (Act 737)**
  To regulate medical devices, the industry and to provide for matters thereto
- **Medical Device Authority Act 2012 (Act 738)**
  To provide for the establishment of the Medical Device Authority with powers to control and regulate medical device, its industries and activities, and to enforce the medical device laws, and for related matters
- **Medical Device Regulation 2012**
  Prescribes requirements for registration, licensing and conformity assessment of medical devices

New Upcoming Regulation:

- **Medical Device (Duties And Obligations Of Licensees Or Permit Holders And General Duties) Regulations 201x**
  - Post-market Surveillance And Vigilance
  - Usage, Operation, Installation, Test, Commission, Maintenance and Disposal Of Medical Devices
- **Medical Device (Advertisement) Regulations 201x**
- **Medical Device (Designated Medical Device Permit) Regulations 201x**

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MEDICAL DEVICE AUTHORITY

http://www.mdb.gov.my

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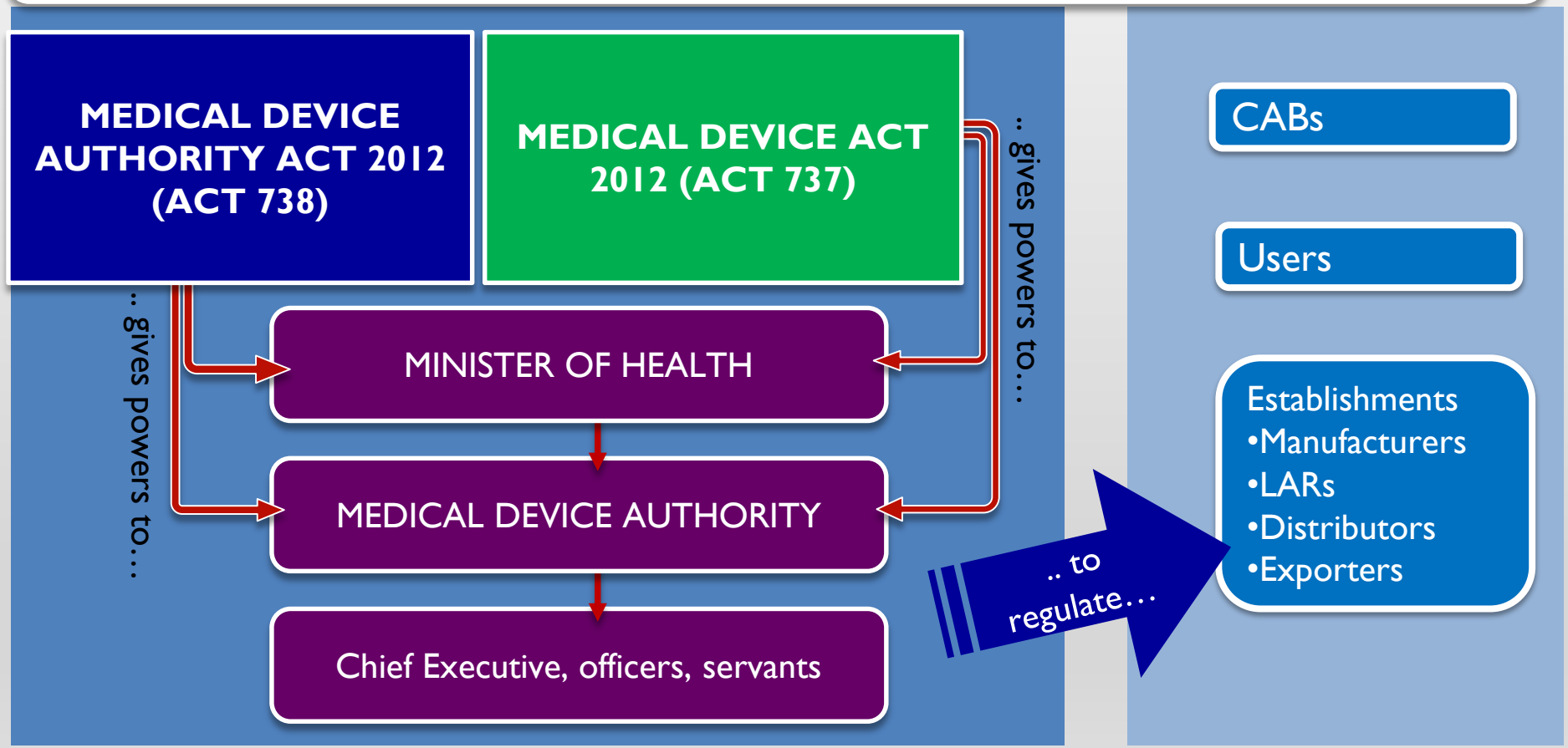
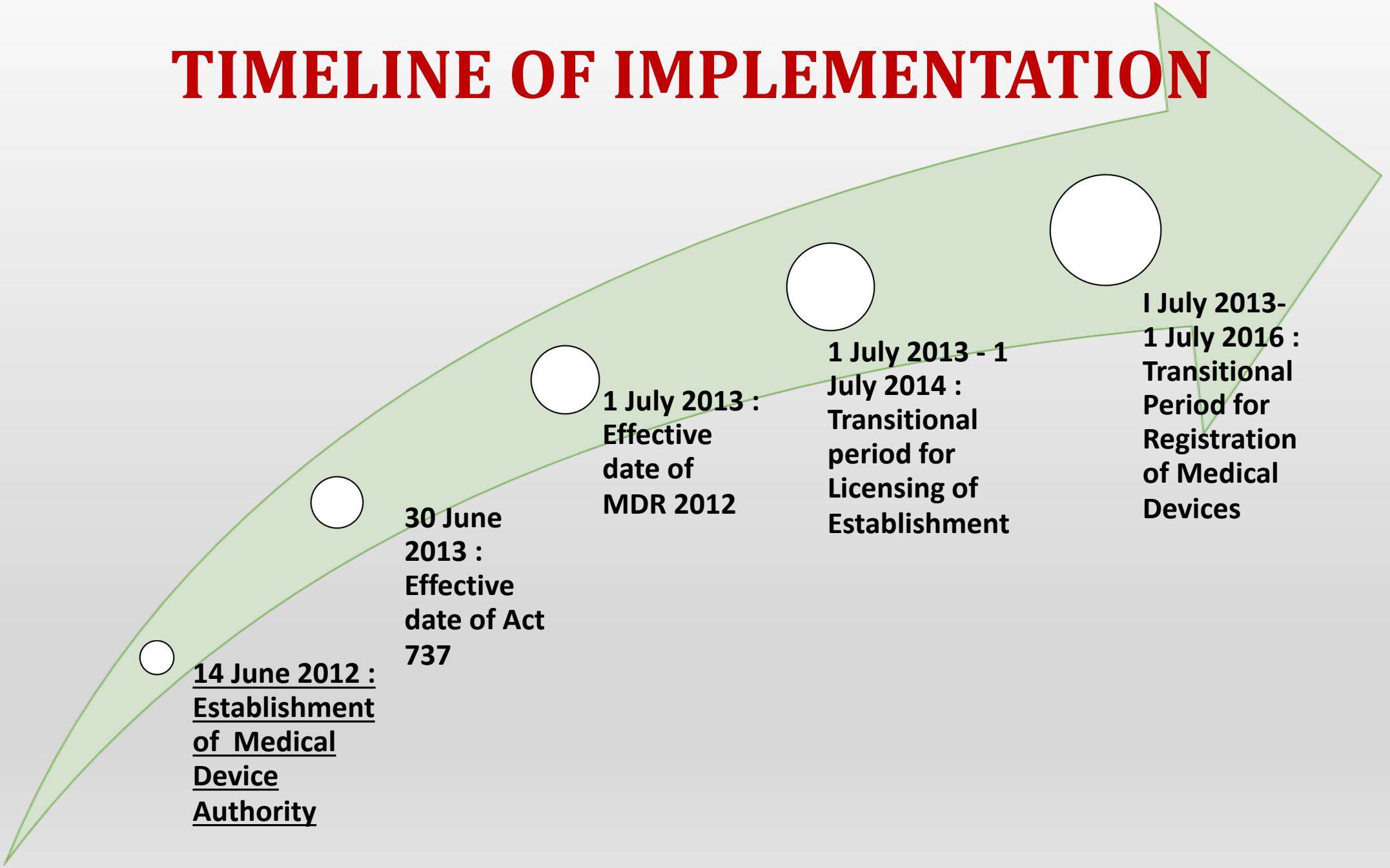
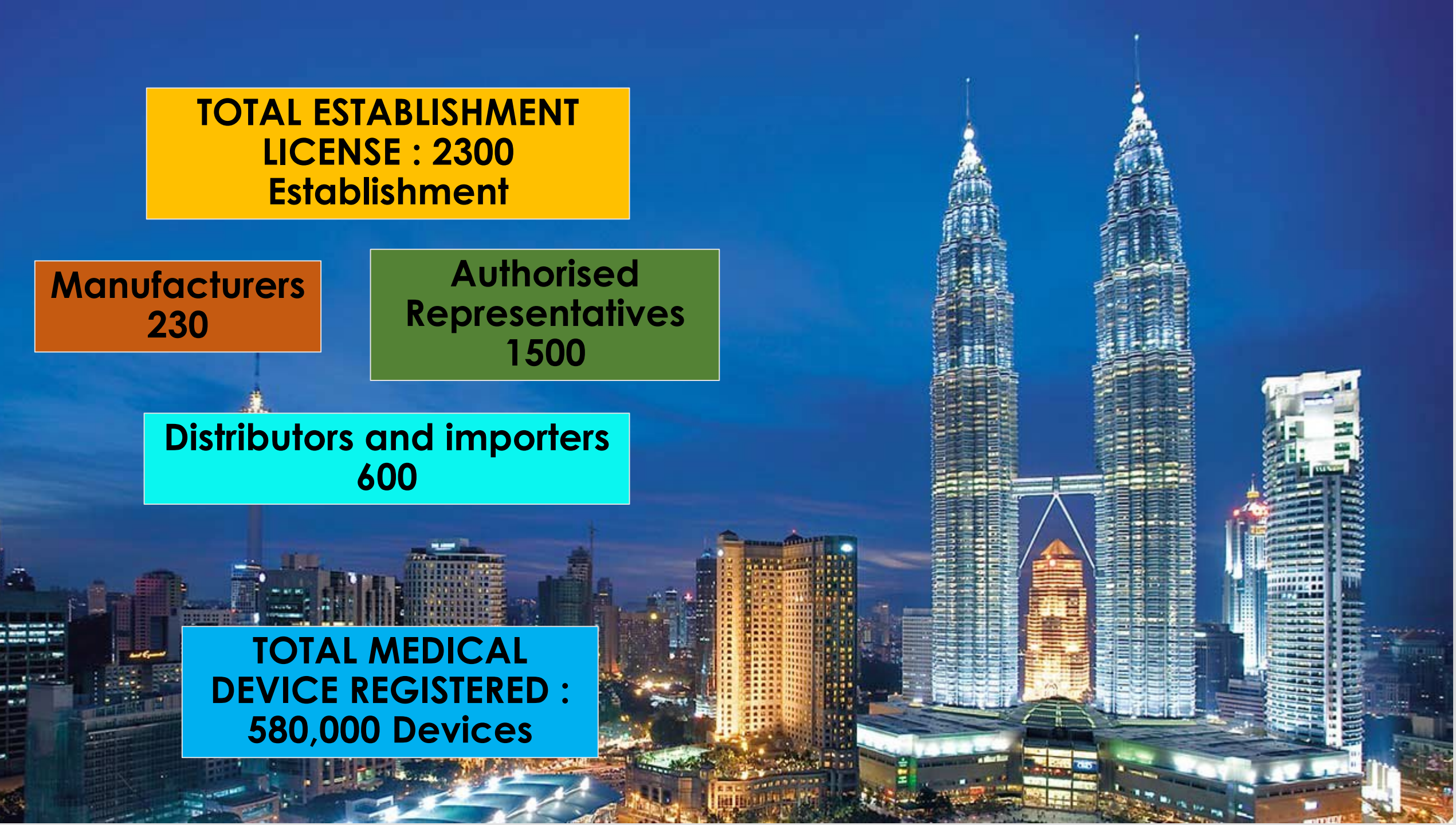
MEDICAL DEVICE REGULATORY SYSTEM



TIMELINE OF IMPLEMENTATION




TOTAL ESTABLISHMENT LICENSE : 2300 Establishment
Manufacturers 230
Authorised Representatives 1500
Distributors and importers 600
TOTAL MEDICAL DEVICE REGISTERED : 580,000 Devices

THANK YOU

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