

MEDICAL DEVICES AUTHORITY ACT 738



PRESENTATION TO HEALTHCARE FACILITIES

11.2.2016

IR.SASIKALA

MEDICAL DEVICES AUTHORITY

MINISTRY OF HEALTH MALAYSIA

THE MEDICAL DEVICE AUTHORITY (MDA)

- **Presentation to Healthcare Facilities**
 - 11.2.2016

CONTENT

- **Medical Devices Regulatory System**
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- **Functions of MDA**
- **Medical Device Act 2012 (Act 737)**
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MEDICAL DEVICE AUTHORITY (Act 738) 2012

- ***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***
- ***The Act may be cited as the Medical Device Authority Act (Act 738) 2012***
- ***Come into operation on the appointed date by the Minister by notification in the Gazette on the 15th March 2012***



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 **ANNOUNCEMENT**

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We are pleased to inform that

Guidance Documents

TENDER / QUOTATION

There are no tender offer at the moment.

VACANCIES

There are no vacancies at the moment.

ONLINE SERVICES



MeDC@St is a web-based Online Application System for Establishment Licensing, Medical Device Registration and Export Permit.



APPLICATION FOR
CERTIFICATE OF FREE SALE
(CFS) / MANUFACTURING



THE MEDICAL DEVICE AUTHORITY

<http://www.mdb.gov.my>

BOARD MEMBERS (MDA)

A Statutory Body with the following members

1. DG of Health as the Chairman
2. Chief Executive
3. Min of Health
4. Min of Finance
5. Not more than five persons appointed by the Minister, who have expertise and experience in medical device matters

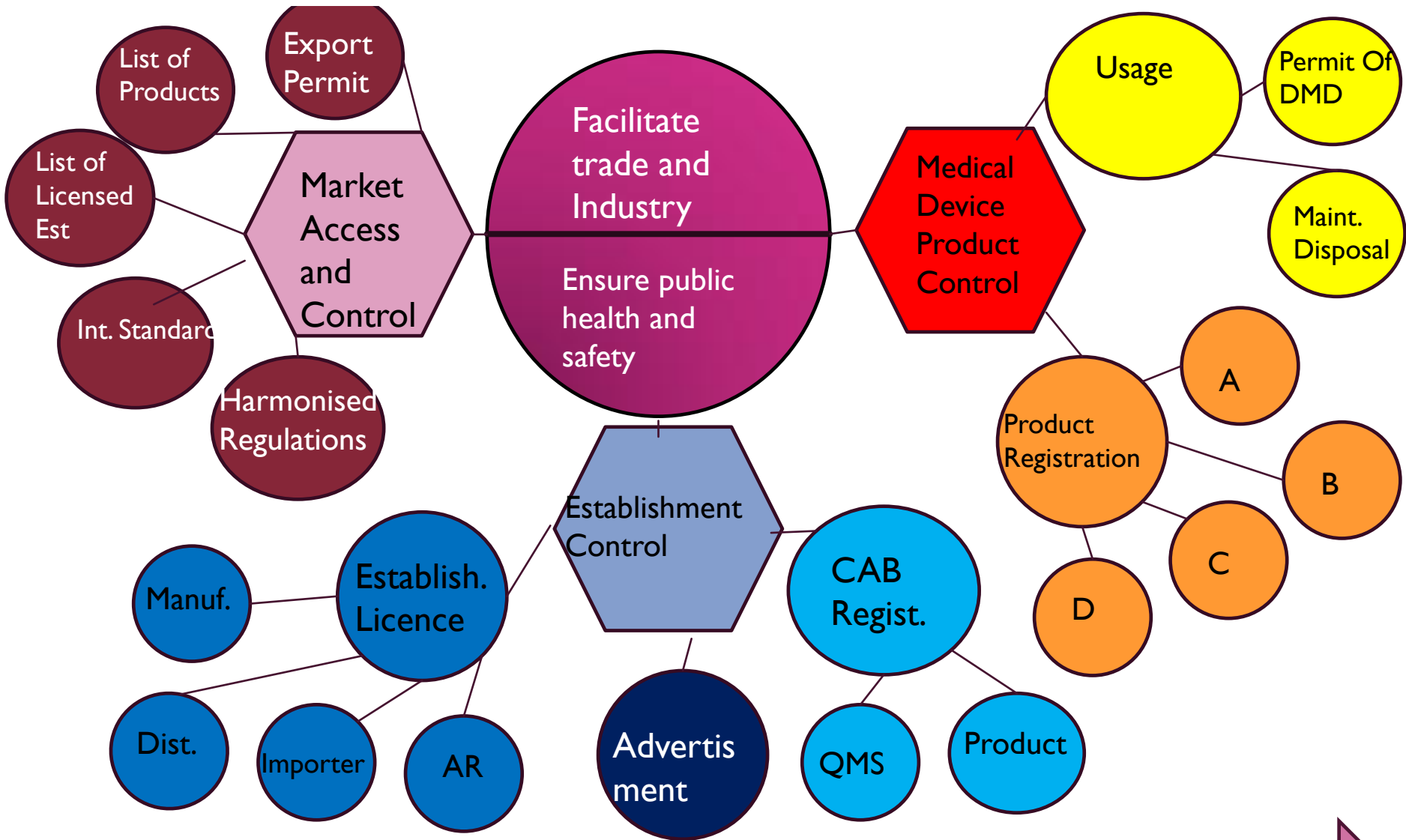
Committees appointed by MDA
- to assist it in the performance of the functions of the Authority

Functions of MDA

- To implement, enforce, consider and recommend reform to the medical device laws
- To perform the following :-
 - to regulate all matters
 - to encourage & promote the development
 - to provide consultancy & advisory service and any other services,in relation to medical device, its industries and activities

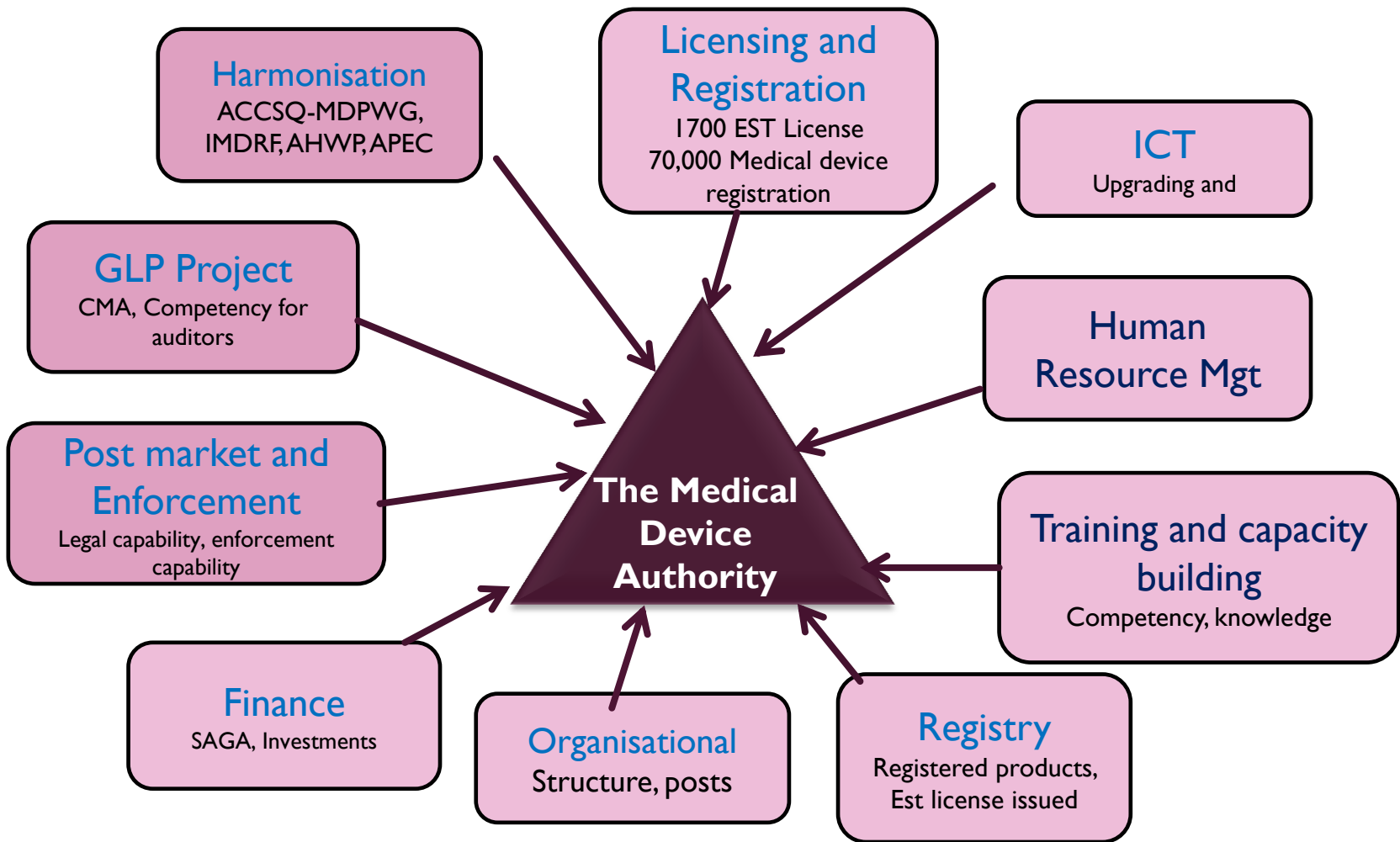
Medical Device Act 2012 (Act 737)

Objective and Control



POST-MARKET VIGILANCE AND SURVEILLANCE SYSTEMS & ENFORCEMENT

CHALLENGES TO THE AUTHORITY

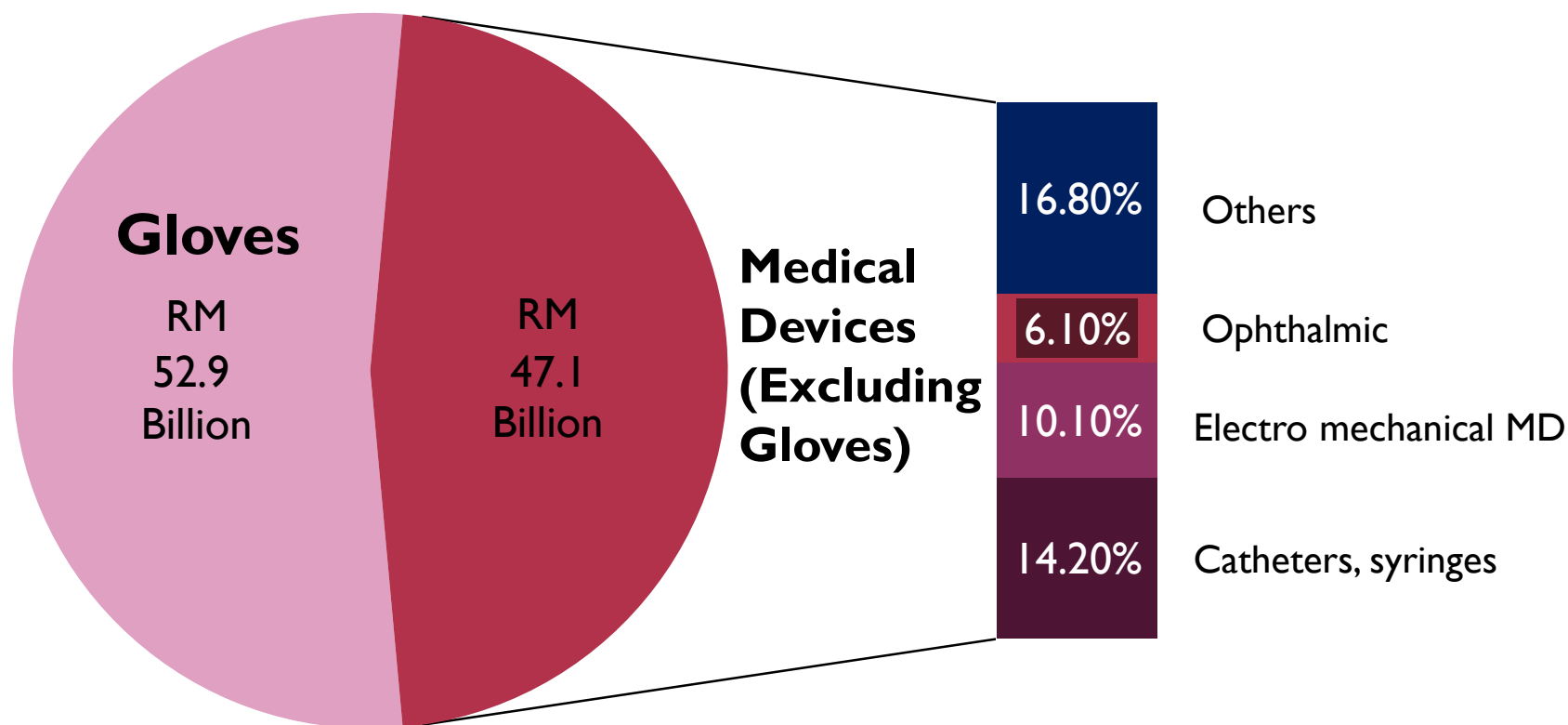


THE INDUSTRY IN MALAYSIA

- Around 1942 establishment of medical device in the country- (manufacturing, importer, exporter and distributor) extracted from MeDC@St system
- Export revenues of RM 13.49 Billion in 2014
- Export CAGR of 8 % per annum from 2005 – 2015
- Malaysia is majoring in surgical and examination gloves globally



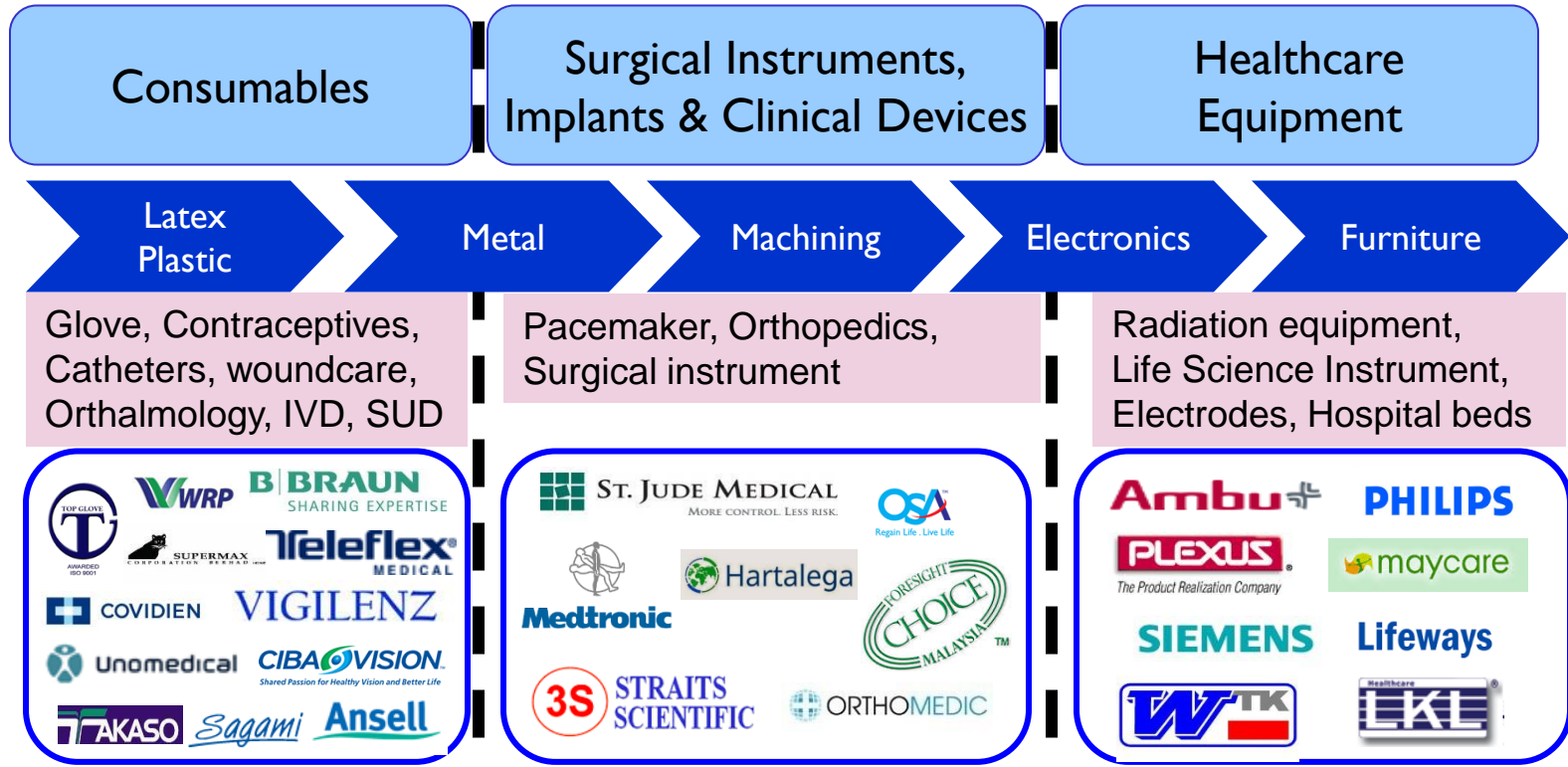
MALAYSIA EXPORTS OF MEDICAL DEVICES



Total Exports in 2014: RM13.49 Billion

Medical Device Industry Ecosystem in Malaysia

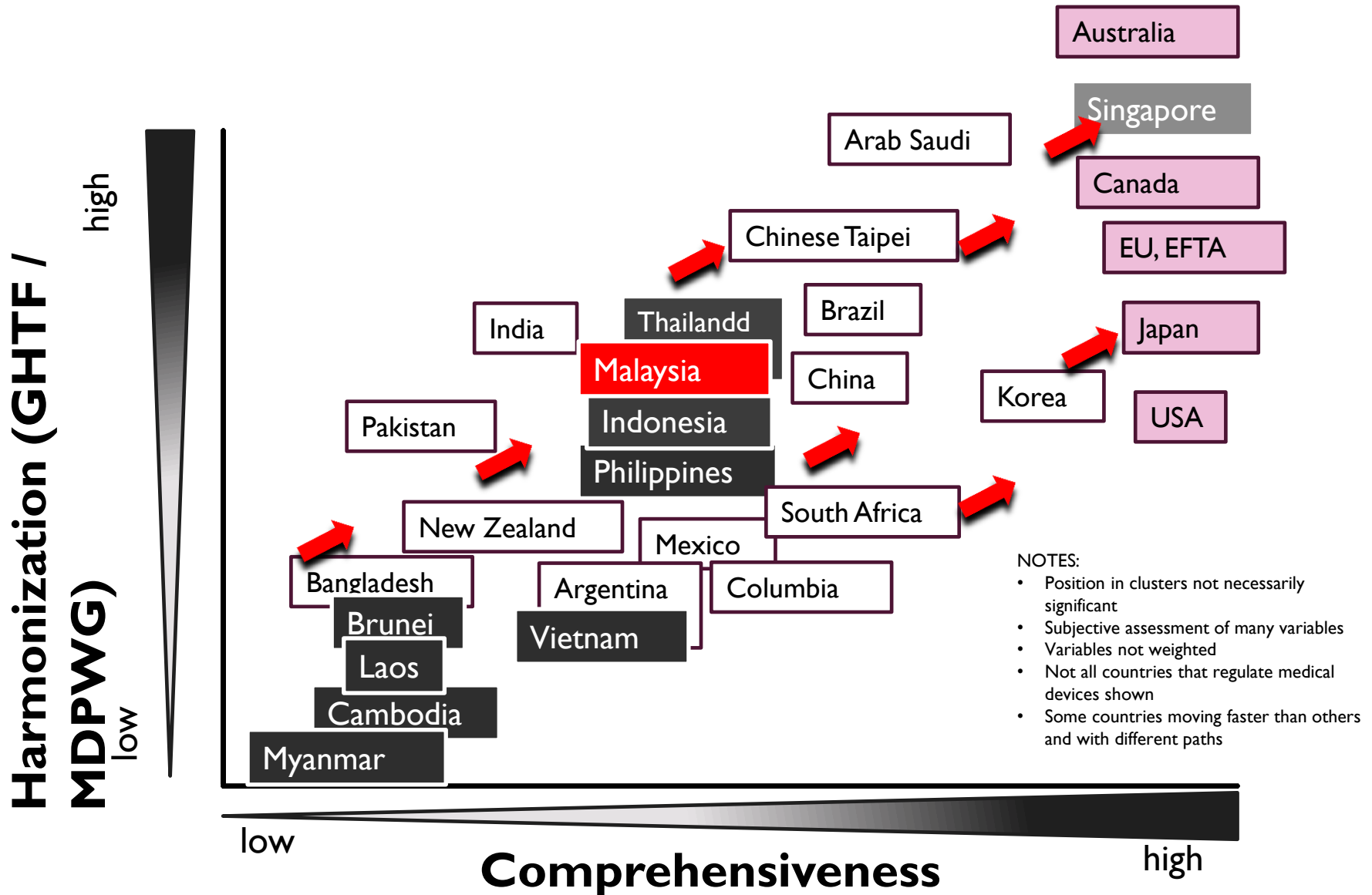
Materials: Rubber, Plastics, Steel, Electronics, etc.



Supporting Infrastructure



CONCEPTUAL QUALITATIVE OVERVIEW OF CURRENT NATIONAL MEDICAL DEVICE REGULATORY SYSTEMS - TRENDS





THANK YOU