Regulation of Medical Devices in Hong Kong

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Background

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Medical Device Market in Hong Kong (1)

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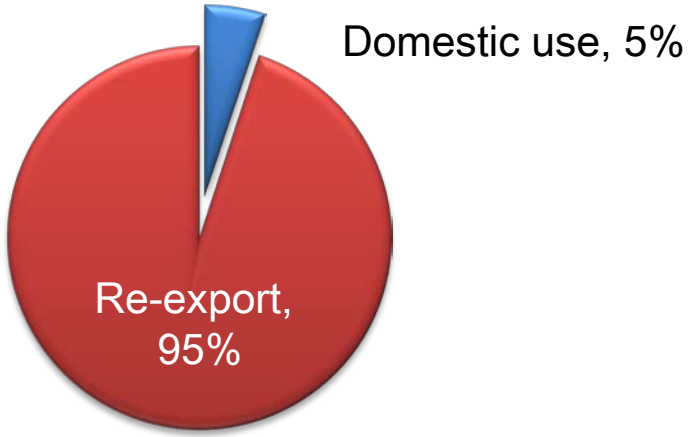
- Hong Kong is a major hub for re-export of medical devices

Imported and locally manufactured medical devices



- It is estimated that there are
  - 50+ local manufacturers
  - 3 000+ medical device suppliers, including authorised representatives, importers and distributors

Source: BIA Report

Medical Device Market in Hong Kong (2)

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Market Value	**Estimated US$ 300 million (2017)**
Market Size	**~ 40 000 medical devices** • including general medical devices and *in vitro* diagnostic medical devices (IVDMDs) • ~ 50% is Class I general medical devices
Largest end-user	**Hospital Authority (HA)** • accounts for approximately 70% - 90% of all the medical device purchased locally

Source: BIA Report & Export.gov

Latest Legislative Development

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Regulation of Medical Devices

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- Currently, there is no specific legislation that regulates the manufacture, import, sale and use of medical devices in Hong Kong
- Other related legislations

Radiation Ordinance (Cap 303)

Pharmacy and Poisons Ordinance (Cap 138)

Undesirable Medical Advertisements Ordinance (Cap 231)

Consumer Goods Safety Ordinance (Cap 456)

Telecommunications Ordinance (Cap 106)

Medical Device Legislative Progress

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Statutory Regulation of Medical Devices

2019 Listing of Class B/C IVDMDs (anticipated)

2018 Refined Legislative Proposal Focusing on Pre-market and Post-market control of MD

2015-2016 Consultancy Study on the Control of Use of Selected MD

2015 Listing of Distributors

2011-2013 Business Impact Assessment

2009 Listing of Class D IVDMD

2007–2008 Regulatory Impact Assessment

2007 Listing of Local Manufacturers and Importers

2006 Recognition of Conformity Assessment Bodies

2005 Listing of Class II/III MD

2003 Proposed Regulatory Framework comprising Pre-market Control, Post-market Control and Control on Use of High-risk MD

2004 Listing of Class IV MD

Medical Device Administrative Control System

2003 Public Consultation

Latest Regulatory Framework

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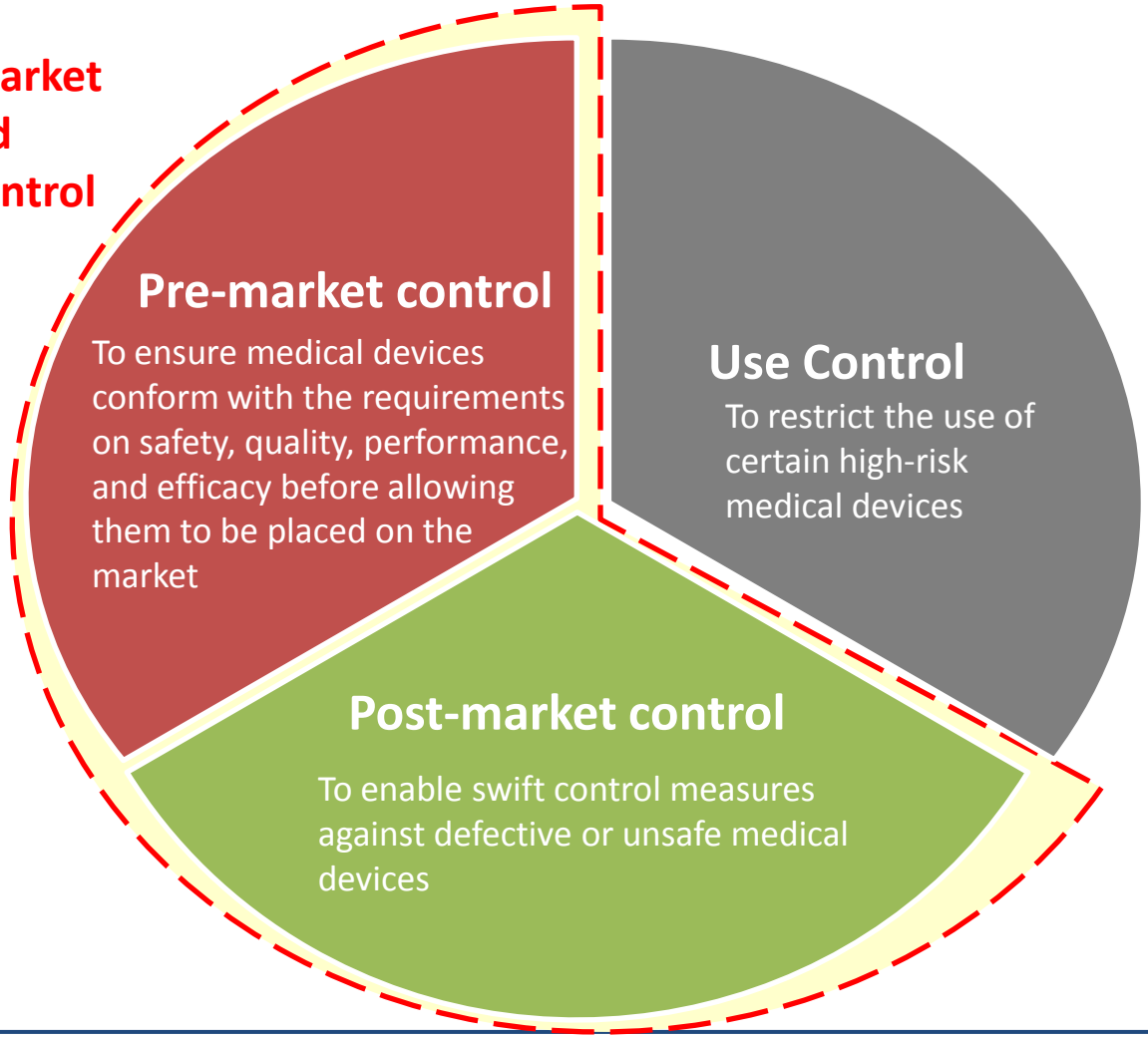
Focus on pre-market control and post-market control



Medical Device Administrative Control System (MDACS)

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Medical Device Administrative Control System (MDACS)

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- Voluntary
- Adopting a risk-based approach recommended by Global Harmonization Task Force (GHTF)
- Taking into account local situations

IMDRF International Medical Device Regulators Forum

GHTF

Aims of MDACS

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To raise public awareness on the safe use of medical devices

To provide an opportunity to collect more information and feedback from the industry as a reference to fine tune the long-term regulatory system

To enable traders to familiarise themselves with the future mandatory requirements

To prepare for smooth transition to the future statutory system

Current MDACS

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Medical Device Administrative Control System (MDACS)		
Pre-market Control		**Post-market Control**
Listing System 1. Medical Device Listing ● General medical devices (Class II, III, IV) ● IVDMDs (Class D) 2. Trader Listing ● Local Responsible Person (LRP) ● Local manufacturer ● Importer ● Distributor	**Conformity Assessment Bodies (CAB) Recognition Scheme**	**Medical Device Safety Alerts System & Adverse Incidents Reporting System**

Medical Device Listing

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Medical Device Listing Routes

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Engage

Local / Overseas Medical Device Manufacturer

Designate

bsi. SGS TÜV SÜD

Recognized CAB

Local Responsible Person (LRP)

Conformity Assessment

Apply

CAB Certificate

Referencing Marketing Approval
(Australia/Canada/EU/Japan/US/ CFDA)

Australian Government
Department of Health
Therapeutic Goods Administration

Health Canada

厚生労働省
Ministry of Health, Labour and Welfar

CE

FDA
U.S Food and Drug Administration

CFDA

Medical Device Control Office (MDCO)

Approve

12 weeks upon all supporting documents received

Listed medical device

Validity: 5 years
Application Fee: Free

Listed Medical Device

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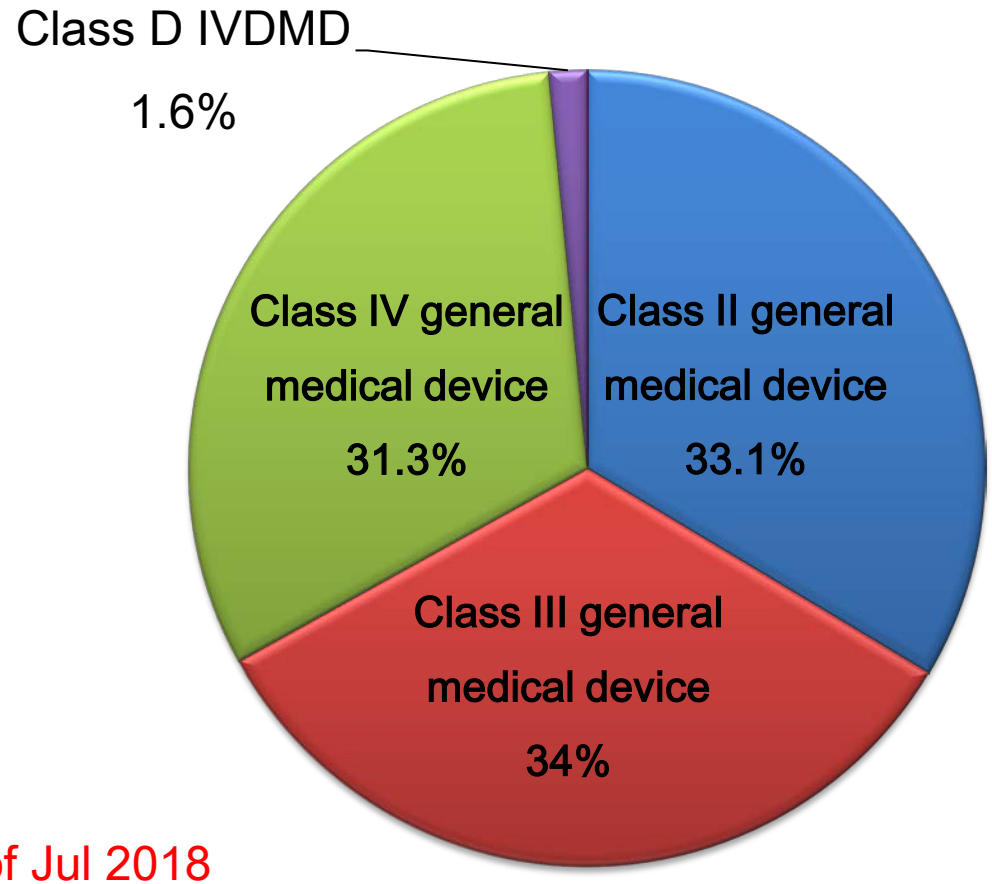
Listed medical device (active) : 3 623^



Note: ^ As of Jul 2018

Safety Alerts and Adverse Incidents Reporting

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Medical Device Safety Alert System

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- MD manufacturer, supplier & LRP
- Overseas regulatory authorities' websites
- HCPs, hospitals and healthcare institutions
- Users & Patients
- Media

Monitor / Investigate

Report

MDCO

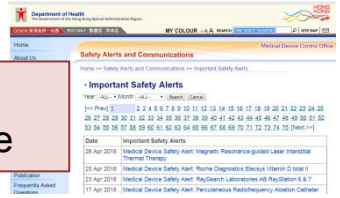
Risk Analysis

- ✓ Degree of seriousness
- ✓ Risk to different population
- ✓ Sales & distribution
- ✓ Affected users

Action

- MD manufacturer or supplier to conduct Product Recall
- Notify affected users (e.g. Hospitals)
- Letters to HCPs
- Press Release
- Messages on MDCO website

Product Recall



Adverse Incident Reporting

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The Incident led to one of the following outcomes：

- ✓ Death of a patient, user or other person
- ✓ Serious injury of a patient, user or other person
- ✓ No death or serious injury occurred by the incident might lead to death or serious injury of a patient, user or other person if the incident recurs

LRP

INCIDENT REPORT

MDCO

Other Sources

- MD Manufacturer or supplier
- HCPs, Hospitals & Healthcare Institutions
- Users & Patients
- Media

- Press Release
- Risk Communication Case Investigation
- MD manufacturer or supplier to conduct investigation & report the progress and results to MDCO
- MD manufacturer or supplier to conduct product recall

Product Recall

Useful Links

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- **Medical Device Control Office**
  www.mdco.gov.hk

  - **Issued Documents**
    (including Guidance Notes, Technical References, Code of Practice)
    https://www.mdco.gov.hk/english/mdacs/mdacs_gn/mdacs_gn.html
  - **Search Database**
    (including List of Medical Devices, List of Traders & CABs)
    https://www.mdco.gov.hk/english/sd/sd.html
  - **Information and Publication**
    (including pamphlet and Letters to Healthcare Professionals)
    https://www.mdco.gov.hk/english/emp/emp.html

Thank you

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