Regulation of Medical Devices in Hong Kong

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- Latest Legislative Development

- Medical Device Administrative Control System
  - Medical Device Listing
  - Safety Alerts and Adverse Incidents Reporting
Background
Medical Device Market in Hong Kong (1)

- Hong Kong is a major hub for re-export of medical devices
  - Imported and locally manufactured medical devices
    - Domestic use, 5%
    - Re-export, 95%

- 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)

<table>
<thead>
<tr>
<th><strong>Market Value</strong></th>
<th>Estimated US$ 300 million (2017)</th>
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</thead>
<tbody>
<tr>
<td><strong>Market Size</strong></td>
<td>~ 40,000 medical devices</td>
</tr>
<tr>
<td></td>
<td>• including general medical devices and <em>in vitro</em> diagnostic medical devices (IVDMDs)</td>
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<tr>
<td></td>
<td>• ~ 50% is Class I general medical devices</td>
</tr>
<tr>
<td><strong>Largest end-user</strong></td>
<td>Hospital Authority (HA)</td>
</tr>
<tr>
<td></td>
<td>• accounts for approximately 70% - 90% of all the medical device purchased locally</td>
</tr>
</tbody>
</table>

Source: BIA Report & Export.gov
Latest Legislative Development
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)
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Medical Device Legislative Progress

Statutory Regulation of Medical Devices

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

2005 Listing of Class II/III MD

2006 Recognition of Conformity Assessment Bodies

2007 Listing of Local Manufacturers and Importers

2008 Medical Device Administrative Control System

2009 Listing of Class D IVDMD

2010-2013 Business Impact Assessment

2011-2013 Consultancy Study on the Control of Use of Selected MD

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

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

2015 Listing of Distributors

2019 Listing of Class B/C IVDMDs (anticipated)
Focus on pre-market control and post-market control

**Pre-market control**
To ensure medical devices conform with the requirements on safety, quality, performance, and efficacy before allowing them to be placed on the market.

**Use Control**
To restrict the use of certain high-risk medical devices.

**Post-market control**
To enable swift control measures against defective or unsafe medical devices.
Medical Device Administrative Control System (MDACS)
Medical Device Administrative Control System (MDACS)

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

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Aims of MDACS

- 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

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# Current MDACS

## Medical Device Administrative Control System (MDACS)

<table>
<thead>
<tr>
<th>Listing System</th>
<th>Conformity Assessment Bodies (CAB) Recognition Scheme</th>
<th>Medical Device Safety Alerts System &amp; Adverse Incidents Reporting System</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Medical Device Listing</strong></td>
<td></td>
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<tr>
<td>● General medical devices (Class II, III, IV)</td>
<td></td>
<td></td>
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<tr>
<td>● IVDMDs (Class D)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>2. Trader Listing</strong></td>
<td></td>
<td></td>
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<tr>
<td>● Local Responsible Person (LRP)</td>
<td></td>
<td></td>
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<tr>
<td>● Local manufacturer</td>
<td></td>
<td></td>
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<tr>
<td>● Importer</td>
<td></td>
<td></td>
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<tr>
<td>● Distributor</td>
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</tbody>
</table>

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Medical Device Listing

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Medical Device Listing Routes

- **Medical Device Control Office (MDCO)**
  - Listed medical device
  - Validity: 5 years
  - Application Fee: Free

**Local / Overseas**
- Medical Device Manufacturer
  - Engage
- Local Responsible Person (LRP)
  - Designate
  - Apply
  - CAB Certificate
  - Conformity Assessment
  - Referencing Marketing Approval (Australia/Canada/EU/Japan/US/CFDA)
  - Medical Device Control Office (MDCO)
    - Approve 12 weeks upon all supporting documents received
    - Validity: 5 years
    - Application Fee: Free

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Listed Medical Device

Listed medical device (active) : 3 623^ 

- Class D IVDMD: 1.6%
- Class IV general medical device: 31.3%
- Class II general medical device: 33.1%
- Class III general medical device: 34%

Note: ^ As of Jul 2018
Safety Alerts and Adverse Incidents Reporting
Medical Device Safety Alert System

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

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

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

**Monitor / Investigate**

**Report**

**Action**

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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.
Useful Links

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

  - **Issued Documents**
    (including Guidance Notes, Technical References, Code of Practice)

  - **Search Database**
    (including List of Medical Devices, List of Traders & CABs)

  - **Information and Publication**
    (including pamphlet and Letters to Healthcare Professionals)

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Thank you