Overview of the Medical Device Safety Alert System (MDSAS)

Medical Device Control Office (MDCO)
Department of Health
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Please refer to website www.mdco.gov.hk for details

Agenda

- Background
- Objectives
- What is Safety Information?
- Roles of Stakeholders
- Safety Management
- Examples of Safety Cases
- MDCO Website and E-mailing List
- Q & A

Please refer to website www.mdco.gov.hk for details
Background

Before Medical Device Administrative Control System (MDACS): no specific control
July 2003: Consultation Document on Regulation of Medical Devices issued
March 2004: Discussion in LegCo Panel on Health Services
26 Nov 2004: Implementation of MDACS Phase 1

Objectives of the MDACS

Raise the public’s awareness of the use of safe medical devices
Enable the trade to familiarize with the future mandatory requirements
Provide an opportunity to collect more information and feedback for fine tuning the long-term regulatory framework
Scope of MDACS

- Listing of Classes II, III and IV medical devices
- Post-market surveillance
- Adverse incident reporting system
- Webpage for information dissemination (www.mdco.gov.hk)
- Recognition of Conformity Assessment Bodies
- Listing of Local Manufacturers
- Listing of Importers

Please refer to website www.mdco.gov.hk for details

Local Responsible Person (LRP)

- LRP’s Obligations
  - Making the application for listing the medical device under the MDACS
  - Communication with users, importers, the public and the Government
  - Maintaining the list of importers and distribution records
  - Handling complaints
  - Provision of maintenance and services
  - Tracking of specific medical devices (Class IV)...

Please refer to website www.mdco.gov.hk for details
Local Responsible Person (LRP)

- Management of alerts, modifications and recalls
- Management of reportable adverse incidents in Hong Kong
- General requirements
  - reporting changes
  - provisions of records
  - advertisement requirements
  - indemnifying the Government

What are “Medical Devices”?:

- Any device, reagent or calibrator, software or material intended by the manufacturer used for:
  - Diagnosis, prevention, monitoring, treatment and alleviation of or compensation for disease/injury;
  - Investigation, replacement, modification, or support of the anatomy or of a physiological process;
  - Supporting or sustaining life;
  - Control of conception (including contraception)
  - Disinfection of medical devices; or
  - Providing information for medical purposes by means of in vitro examination of specimens;

AND

- It is not a drug

Note: see GN-01 for the formal definition of medical devices
Examples of Medical Devices

- Wheelchair
- Infusion pump
- X-ray machine
- Drug eluting stent
- Electrosurgical unit
- Patient monitor
- Autoclave
- ...

Please refer to website www.mdco.gov.hk for details

Objective of MDSAS

To efficiently safeguard public health from the use of medical devices in which their safety, efficacy and/or quality are compromised

Please refer to website www.mdco.gov.hk for details
What is “Safety Information”?  

- An announcement regarding any safety issue of a medical device that requires special attention  
- Issued in situations “where a medical device may present an unreasonable risk of substantial harm” to subjects who may use or come into contact with it  

Source: http://www.fda.gov/oc/po/firmrecalls/recall_defin.html

Types of Safety Information  

- Recalls  
- Safety alerts  
- Field corrective actions (hardware/software)  
- Important device information  
- Letters to doctors  
- Letters to patients
Causes of Safety Information

- Deviations from original specification set by the manufacturer
  - Design Error – Hardware/Software
  - Manufacturing Error
- Use Error
- Mislabelling
- Compromised product sterility / stability / efficacy
- Wrong-side or early failure
- etc, etc…

Sources of Safety Info.

- Overseas Authorities
  - United States of America: Food and Drugs Administration (FDA)
  - United Kingdom: Medicines and Healthcare products Regulatory Agency (MHRA)
  - …
- Local Responsible Persons
- Device suppliers and manufacturers
- Hospitals and healthcare institutions
- Healthcare professionals, users & patients
- News media
- Others
US FDA Safety Info.

3 Classes of Recalls:
- Class I
- Class II
- Class III

Firm Press Release
Published on the FDA Website
- http://www.fda.gov/opacom/7alerts.html

Please refer to website www.mdco.gov.hk for details

FDA Class I Recall

“...there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.”

- Issued on ad hoc basis or in weekly Enforcement Reports
- Requires immediate attention

Source: http://www.fda.gov/oc/po/firmrecalls/recall_defin.html

Please refer to website www.mdco.gov.hk for details
FDA Class II Recall

“...use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.”

Issued in weekly Enforcement Reports

Source: http://www.fda.gov/oc/po/firmrecalls/recall_defin.html

Please refer to website www.mdco.gov.hk for details

FDA Class III Recall

“...use of or exposure to a violative product is not likely to cause adverse health consequences.”

Issued in weekly Enforcement Reports

Source: http://www.fda.gov/oc/po/firmrecalls/recall_defin.html

Please refer to website www.mdco.gov.hk for details
**FDA Firm Press Release**
- Firm-initiated voluntary field actions
- Issued by Manufacturers
- Quoted by FDA
- Issued on *ad hoc* basis
- May require immediate attention → handled as Class I Recalls

**UK MHRA Safety Info.**
- 4 categories of Medical Device Alerts (MDA)
  - Immediate Action (requires immediate attention)
  - Action
  - Update
  - Information Request
- Issued on *ad hoc* basis
- www.mhra.gov.uk
Roles of MDCO

- Monitor, record and screen safety information
- Ensure prompt & appropriate remedial actions taken by suppliers
- Inform affected parties as appropriate

Actions of MDCO (1)

1. Acquire safety information from
   - overseas regulatory authorities websites
   - local suppliers
   - Hospital Authority
   - mass media
   - others
Actions of MDCO (2)

2. Contact the manufacturer or supplier for safety information details
   - Manufacturer’s letter
   - Distribution of affected devices
   - Have affected institutions been informed
   - Proposed Rectification Programme

Please refer to website www.mdco.gov.hk for details

---

Actions of MDCO (3)

3. Inform the affected parties
   - Urgent case
     - Urgent safety alert message
   - Non-urgent case
     - Monthly summary of safety alerts
   - Affects public health
     - Press release / Public announcement (by DH or suppliers)
   - Main mode of communication: e-mail

Please refer to website www.mdco.gov.hk for details
**Actions of MDCO (4)**

4. Communicates with the manufacturer / supplier

5. File closed when
   - Confirmed no affected units distributed in HK; or
   - All affected parties were informed and affected units rectified

---

**Urgent Safety Alert Message**

---

Please refer to website www.mdco.gov.hk for details
Press Release on Website

MDCO Safety Alerts in 2005

- Alerts screened: 392
- Affected devices: 134 (34%)
  - Not urgent: 89
    - Unlikely to cause major injury or death
    - Monthly summary of safety alerts
  - Urgent: 45
    - Could cause major injury or death
    - Urgent safety alert message
  - Affects public health: 11
    - Used by the general public and could cause major injury or death
    - Press release / Public announcement (by DH or suppliers)

Please refer to website www.mdco.gov.hk for details
Recipients of MDCO Safety Alert

- Depending on the distribution of the affected device:
  - Hospitals and Healthcare institutions (public and private)
  - Medical Laboratories
  - Emergency Services (Fire, Auxiliary Medical Services)
  - Medical Practitioners
  - General Public

Please refer to website www.mdco.gov.hk for details

Roles of Manufacturers

- Ensure the safety, efficacy and quality of manufactured medical devices
- Investigate complaints and adverse incidents
- Communicate to LRP/suppliers/distributors and MDCO with safety information
- Rectify the affected devices and inform MDCO upon completion (if not via suppliers)

Please refer to website www.mdco.gov.hk for details
Roles of LRP/Suppliers

- Establish an effective communication channel with the manufacturers and MDCO
- Upkeep the distribution record
- Relay the safety information to MDCO and affected parties
- Rectify the affected devices according to the instructions from manufacturers and inform MDCO upon completion

Please refer to website www.mdco.gov.hk for details

Proactive Approach by LRP/Suppliers

- Report to MDCO, in writing, any safety info. once received from manufacturers
  - via email: mdco_alert@dh.gov.hk
  - via fax: 3157 1286

Please refer to website www.mdco.gov.hk for details
**Roles of Users**

- Maintain communication with manufacturers / suppliers / MDCO
- Take appropriate actions upon the receipt of safety info.
- Report pro-actively to manufacturers / suppliers / MDCO about adverse incidents
- Maintain asset and safety management systems (healthcare institutions)

Please refer to website [www.mdco.gov.hk](http://www.mdco.gov.hk) for details

---

**Actions by Users**

- Check against inventory records to identify affected units
- Follow the advice and/or recommendations as suggested in the safety info. received
- Inform affected personnel / patients
- Remove affected units from service, if applicable
- Contact the supplier for remedial actions as soon as possible

Please refer to website [www.mdco.gov.hk](http://www.mdco.gov.hk) for details
### Safety Management (1)
- Appointment of a “Risk Manager”
- Management of safety information
- Upkeeping of asset registry
- Management of safety cases
- Management of adverse incidents

Please refer to website [www.mdco.gov.hk](http://www.mdco.gov.hk) for details.

<table>
<thead>
<tr>
<th>Safety Management (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Receive safety alert / recall messages</td>
</tr>
<tr>
<td>- Search asset registry for affected devices</td>
</tr>
<tr>
<td>- Open safety case if affected devices found</td>
</tr>
<tr>
<td>- Locate the affected devices</td>
</tr>
<tr>
<td>- Inform affected personnel / patients</td>
</tr>
<tr>
<td>- Segregate the affected device</td>
</tr>
<tr>
<td>- Communicate with the device supplier</td>
</tr>
<tr>
<td>- Monitor the field corrective actions</td>
</tr>
<tr>
<td>- Conduct safety inspection / testing</td>
</tr>
<tr>
<td>- Return the fixed device for use</td>
</tr>
<tr>
<td>- Close the safety case</td>
</tr>
</tbody>
</table>

Please refer to website [www.mdco.gov.hk](http://www.mdco.gov.hk) for details.
Management of Medical Devices

Safety Alerts

Minimum Risk

Best Performance

Technology Management

Replacement

Asset Registry

Procurement

Operations & Maintenance

Recalls

Minimum Cost

Regulatory Requirements

Adverse Events

Case 1 – Healthcare Settings

- Implantable Devices e.g. Implantable Cardioverter Defibrillators (ICDs), Pacemakers
- Purchasers – Hospitals
- End-users – Patients → Public Health Concern
- Issuance of Press Release
- Communicate with hospitals
  - contact affected patients
- Issues concerned:
  - Hazardous
  - Removal/replacement of device difficult
  - Monitoring of the patient condition
  - Tracking of patients

Please refer to website www.mdco.gov.hk for details
Case 2 – General Public

- Consumable products e.g. Blood Glucose Meters (BGMs), Thermometers
- Purchasers and End-users – General Public → Public Health Concern
- Actions
  - Public announcement
  - Enquiry hotlines
  - Communicate with patient support groups if applicable, e.g. diabetic groups for BGMs
  - Revised instructions for use / labelling

Please refer to website www.mdco.gov.hk for details

Case 3 – Health Hazard

- Polyacrylamide Gel (PAAG)
- Purchasers – Doctors / Beauticians ???
- End-users – General Public
- Public Health Hazard when use for breast augmentation
- Actions
  - Letter to doctors
  - Public announcement
  - Enquiry hotlines
  - Public Education
  - Law enforcement

Please refer to website www.mdco.gov.hk for details
Website of Department of Health

Please refer to website www.mdco.gov.hk for details

Website of Medical Device Control Office

Please refer to website www.mdco.gov.hk for details
Recalls and Alerts

Joining e-Mailing List

Please refer to website www.mdco.gov.hk for details
Questions?

Please refer to website www.mdco.gov.hk for details