# Post-market Surveillance & Vigilance Systems under MDACS

**Department of Health**
**The Government of the Hong Kong Special Administrative Region of the People's Republic of China**

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- Medical Device Safety Alert System
- Adverse Incident Reporting System

# Classes of Safety Alerts

- Classes of safety alerts
  - Class 1: reasonable chance will cause serious health problems or death
    - Urgent safety alert
  - Class 2: possibility will cause temporary or reversible health problem
    - Monthly summary
  - Class 3: little chance will cause health problems
    - No action

# Safety Alerts (1.1.~ 31.12.2006 )

- Alerts screened 907
- Affected devices sold in HK 154
  - Class 1: 54 cases
  - Class 2: 100 cases

# Types of Safety Alerts

| Types | Major User Groups | Examples |
|---|---|---|
| Household | General public | Glucometer, thermometer, pregnancy tester |
| Implant | Patients with implant | Implantable cardiac defibrillator, stent |
| Professional | Medical professionals | MRI, endoscope, pulse oximeter |
| Laboratory | Laboratories | Chemistry analyzer, blood gas analyser |
| Care Institution | Nursing homes, Auxiliary Medical Service, Fire Services Department | Automatic external defibrillator, infusion pump |

# Dissemination of Class I Safety Alerts

| | Type | MDCO Web | Hospitals/ Clinics (email) | Healthcare Professional Institutions (email) | Laboratory Institutions (email) | Press release / Newspaper |
|---|---|---|---|---|---|---|
| **Local** | Household | ✓ | ✓ | ✓ | | ✓ |
| | Implant | ✓ | ✓ | ✓ | | ✓ |
| | Professional | ✓ | ✓ | ✓ | | |
| | Laboratory | ✓ | ✓ | ✓ | ✓ | |
| | Care Institution | ✓ | ✓ | ✓ | | ✓ |
| **Overseas** | Household | ✓ | | | | |
| | Implant | ✓ | | | | |
| | Professional | | | | | |
| | Laboratory | | | | | |
| | Care Institution | | | | | |

# Classification of Adverse Incidents

- **Class 1**: reasonable chance that the incident will cause serious health problems (e.g. many users of a particular contact lens solution suffered serious eye infection within the last three months).
- **Class 2**: has caused death or serious injury, or there is a reasonable chance that the incident will cause death or serious injury if recurs (e.g. an isolated case that a patient suffered from an electric shock caused by an electrosurgical unit during an operation).
- **Class 3**: has not caused any death or serious injury, and there is a little chance that the incident will cause death or serious injury if recurs (e.g. the patient's skin became reddish after the treatment by a muscle stimulator).

# Summary of Actions

| Class of Adverse Incidents | 1 | 2 | 3 |
|---|---|---|---|
| Update Adverse Incident Database | ✓ | ✓ | ✓ |
| Acknowledge incident reporter | ✓ | ✓ | ✓ |
| Report to Management | ✓ | ✓ | X |
| May contact incident reporter for further details if necessary | ✓ | ✓ | ✓ |
| LRP/Supplier requested to conduct investigation | ✓ | ✓ | ✓ |
| Medical Device Adverse Incident Record | ✓ | ✓ | ✓ |
| May conduct preliminary investigation | ✓ | ✓ | X |
| Internal Report | Situation Report | Incident Report | X |
| May take precautionary measures | ✓ | ✓ | ✓ |
| LRP/Supplier requested to provide progress update | On need basis | On quarterly basis | On quarterly basis |
| Reporter informed of conclusions | ✓ | ✓ | ✓ |
| Case closed | Recommended actions | Recommended actions | Recommended actions |

# Adverse Incidents (2 Aug 2005~23 Apr 2007)

- Cases reported 14
  - Class 1: 3 cases
  - Class 2: 5 cases
  - Class 3: 3 cases
  - Unclassified: 3 cases

# Thank You!