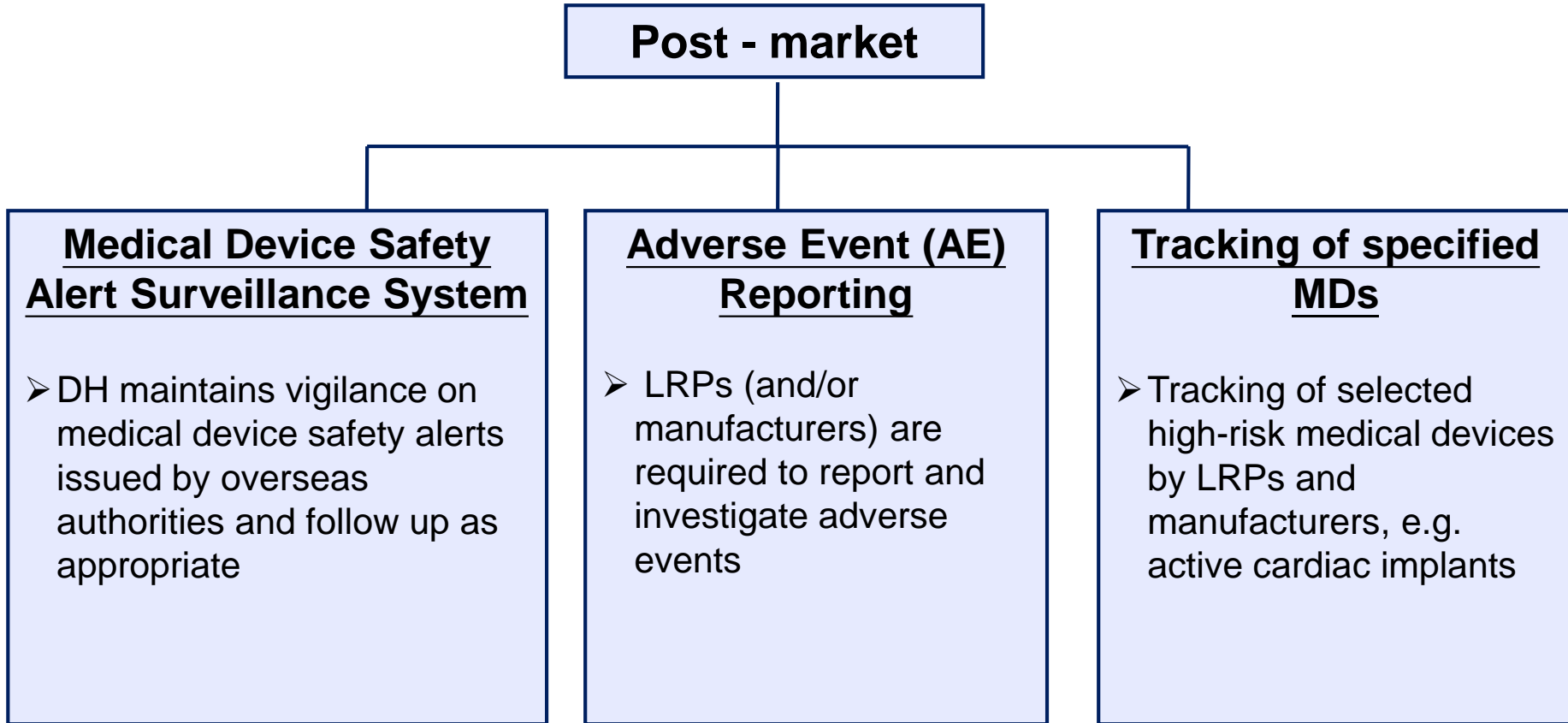

Post-market Control of Medical Device

Dr Terence CHEUNG
Medical Device Control Office
Department of Health



Post-market control



Post-market control – MD Safety Alert

Source of Information

- Website screening – US FDA / Health Canada / UK MHRA /TGA / Singapore HSA
- National Competent Authority Report (NCAR)
- Traders (Suppliers or manufacturers)

Contact the local supplier/ manufacturer

- Request necessary information
 - ❑ Local distribution of the affected products
 - ❑ Relevant field safety notice
 - ❑ Root cause analysis and proposed corrective actions & preventive actions (CAPA)

Risk Assessment

Risk Communication

- E-mail notification to relevant stakeholders
- Web message
- Letter to Healthcare Professionals
- Press Release
- Summary of safety alerts

Follow-up Actions (where appropriate)

- Monitor the manufacturer's / local supplier's progress of actions
 - ❑ Notification of affected users
 - ❑ Root cause analysis
 - ❑ CAPA e.g. software upgrade, IFU update etc.

Actions taken by MDCO

- Contact the local supplier/ manufacturer and request the following information
 - Local distribution of the affected products
 - Relevant field safety notice
 - Root cause analysis and proposed corrective actions & preventive actions (CAPA)
- Risk assessment
- Risk communication



Risk communication

- Email notification to relevant stakeholders
- Web message
- Letter to Healthcare Professionals
- Press Release
- Summary of safety alerts



MDCO website

Summary of Safety Alerts

Department of Health
The Government of the Hong Kong Special Administrative Region

Medical Device Control Office

Safety Alerts and Communications

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Summary of Safety Alerts

The following document is a summary of some medical device safety alerts and communications reported by the trade or overseas regulatory authorities. It only serves as a reference and should not be considered as exhaustive and up-to-date information. Please refer to the source of information and contact manufacturer or local supplier for details. (Updated on 26 July 2013).

Month: July | Year: 2013 | PDF | Excel

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Major Safety Alerts in July 2013

Note: FDA = Food and Drug Administration, United States of America; MHRA = Medicines and Healthcare products Regulatory Agency, United Kingdom; Health Canada = Health Canada, Canada

Date of Issue (YYYYMMDD)	Description of Product	Source of Information*	Reference No. by Source	Alert Type by Source	Local Agent	Agent Contact Telephone No.
20130702	Becton Dickinson USA BD MAX Instruments C catalogue no. 441916	FDA	RC-2013-09-00043-0	Class 0	Becton Dickinson Asia (Singapore) Pte Ltd	2577888 Ext 252
20130702	Siemens Dimension Vista SD and Dimension Vista TDS using software version 3.5.1.006.2.0	FDA	RC-2013-09-00049-1	Class 0	Siemens Healthcare Diagnostics Limited	2870 7833 / 2870 7837
20130702	Siemens PDA Adapt for use on immuno-chemiluminometric assay (ICMA) analyzers	FDA	RC-2013-09-00048-1	Class 0	Siemens Healthcare Diagnostics Limited	2870 7833 / 2870 7837
20130702	Pyralis Pylus Real Blood Cell Analysis Identification Reagent - Phlebotom U (SMA, Lot no. 9023054)	FDA	RC-2013-09-00038-1	Class II	N.A.	N.A.
20130702	Cytosol Pty Ltd Biliary Pancreatic Mast 30180020	FDA	RC-2013-09-00035-1	Class 0	N.A.	N.A.
20130702	R. Braun Medical Ltd Compress Connect Hose System	FDA	RC-2013-09-00037-1	Class 0	United Data (Hong Kong) Ltd	N.A.
20130702	RU BC Pumping Unit Lum Lock Syringe - 30000 (Product code: 30000)	MHRA	311300000000000000	FSN	King Ltd	2870 7888
20130702	Uppsal Eon Tube	MHRA	311300000000000000	FSN	N.A.	N.A.
20130702	Yook Takag O & T. This kit used on the Touch Automated Coagulation Analyzer H.C. 2228 (Catalogue no. 011324, Serial no. T200000, Lot no. T200000) (Serial no. REP 301 - REP 304, Production date 1 Dec 2012 to 15 Aug 2013)	MHRA	311300000000000000	FSN	N.A.	N.A.
20130702	Omega Lysis SMP Brain Tissue Crusher and Temperature Control Kit	MHRA	311300000000000000	FSN	N.A.	N.A.
20130702	Orion Analytical Delivery Unit, 4003, RUC FOR 40114001 Delivery Unit	MHRA	311300000000000000	FSN	N.A.	N.A.
20130702	Perk & Co. 80-HCO-ANALY-THRM 990 (Serial no. 121207, 121407)	MHRA	311300000000000000	FSN	N.A.	N.A.
20130702	Werken Group Instrumentation Laboratory Lab 600000 analyzer specific to the use of a 10013 MAHCHROMAL test no. 1001300000	MHRA	311300000000000000	FSN	Werken Hong Kong	2782 7773
20130702	Med Integri V Factor 245 Lot no. 211193, Expiry date: 31 Jan 2015	MHRA	311300000000000000	FSN	N.A.	N.A.
20130702	Pharm. Sandoz Inc. Product no. 800 001 standard insulin 400 IU high insulin, 100 IU/100 standard insulin, 100 IU/100 standard insulin	MHRA	311300000000000000	FSN	N.A.	N.A.
20130702	Siemens Healthcare PNA20 Anaesthesia System	MHRA	311300000000000000	FSN	N.A.	N.A.
20130702	Medtronic In Vivo Metric (Serial no. 9997 2204, 9997 2204)	FDA	NA	NA	Medtronic International	2870 7832
20130702	10 Yon Endologix Module Issue Pre-Clean Springs kit Catalogue no. MED0001190, Serial no. F2 1370512 and F2 1400012	FDA	RC-2013-09-00023-1	Class II	N.A.	N.A.
20130702	Hardware S.T. 504 Control Wheelchair	MHRA	MC42015040	MSA	N.A.	N.A.
20130702	Delta AI Digital Accelerators with Electronic Beam Modulator, MLCMA CC 6000 or Accelerator Upgrade	FDA	RC-2013-09-00027-1	Class I	Delta Ltd	2801 2288
20130702	Other Rapid Infrared Delivery System Kit Catalogue number 2000001, Lot number A13300A, A13300B, A13300C, A13300D	FDA	RC-2013-09-00052-1	Class 0	Styker China Ltd	2519 9910
20130702	Siemens ADIVA Central Hemocytometer (HCY) Assay used with the ADIVA Central, Central CP, 300 Central CP 300000	FDA	RC-2013-09-00025-1	Class II	Siemens Healthcare Diagnostics Limited	2870 7833 / 2870 7888
20130702	Shanklin and Phipps Ltd Software only Phipps SMP 3.0 Phipps Cliner 3.0 Phipps HPT 3.0 Phipps Plus 3.0 Phipps Suite 3.0 Phipps Mastery 3.0 (includes all Cliner Clinical Diagnostics, Inc. VITROS Chemistry Products for (Potassium) (Sodium) (Reagent), VITROS Chemistry Products CRP (Sodium) (Reagent) (REF) Catalogue no. 315 2500, 382 2740 and 400 2380)	FDA	CAPA-2013027-000008	NA	Shanklin Ltd	24171881
20130702	Yokumo Cardiovascular Systems Corporation The Same YCM-3 Temperature Control Module Catalogue Number: 4410 & Serial no.: 4000, 4002, 4005, 4009, 4001, 4002, and 4003	FDA	2-1614-2013 and 2-1615-2013	Class II	Johnson & Johnson (Hong Kong) Ltd	2738 6027
20130702	Thermo Fisher Scientific Covid Antiretroviral Susceptibility Testing Disc TMS30 (Serial no. C120000, Lot 101700)	MHRA	311300000000000000	FSN	Thermo Fisher Scientific (SRL)	2885 4010
20130702	Thermo Fisher Scientific Covid Antiretroviral Susceptibility Testing Disc AAB10 (Serial no. C120000, Lot 101700)	MHRA	311300000000000000	FSN	Thermo Fisher Scientific (SRL)	2885 4010



MDCO website

■ Web message

The screenshot shows the MDCO website home page. The header includes the Department of Health logo and navigation links. The main content area is titled "Safety Alerts and Communications" and features a list of "Important Safety Alerts" with dates and brief descriptions. A red arrow points from the list towards the right-hand screenshot.

- [20 Jul 2013] Medical Device Safety Alert: Nestle Compat Nasogastric Feeding Tube
- [25 Jul 2013] Medical Device Safety Alert: Warlen ACL TOP Family Coagulation Systems
- [25 Jul 2013] Medical Device Safety Alert: LeMaitre Abiograph Vascular Graft
- [19 Jul 2013] Medical Device Safety Alert: Tracoe Mini 3 0mm Tube
- [19 Jul 2013] Medical Device Safety Alert: DePuy LPS (Limb Preservation System) Lower Extremity Osseal Intercalary Component
- [19 Jul 2013] Medical Device Safety Alert: Medtronic Navigation StealthStation S7 and I7 Systems and Planning Station containing FrameLink Software Version 5.4
- [17 Jul 2013] Medical Device Safety Alert: SureScreen Diagnostics Oral Fluid Drug Screen Device Solvix Collector
- [17 Jul 2013] Medical Device Safety Alert: Opus Healthcare LIT Medical Adhesive Remover, 100 ml Bottle
- [9 Jul 2013] Medical Device Safety Alert: Ortho Clinical Diagnostics ORTHO BioVue System Cassettes
- [6 Jul 2013] Medical Device Safety Alert: GE Healthcare nuclear medicine systems
- [5 Jul 2013] Medical Device Safety Alert: Brainlab Plan 3.0
- [5 Jul 2013] Medical Device Safety Alert: Elekta Digital Accelerators with Electrons and Beam Modulator MLCiM/C2
- [5 Jul 2013] Medical Device Safety Alert: Handicare Ibis Comfort wheelchair
- [3 Jul 2013] Medical Device Safety Alert: Medtronic Insulin Reservoirs used with Paradigm Insulin Pump
- [2 Jul 2013] Medical Device Safety Alert: Protac SerStit Chair
- [20 Jun 2013] Medical Device Safety Alert: Thermo Fisher Scientific Remel Vibrio cholerae Inaba agglutinating serum

This screenshot shows the detailed view of the safety alert for Nestle Compat Nasogastric Feeding Tubes. It includes the title, a summary paragraph, a list of affected models, and a detailed recall notice explaining the sterility issue and the manufacturer's actions. The page also features navigation links and a "Back to Top" button.

Medical Device Safety Alert: Nestle Compat Nasogastric Feeding Tube

It has come to our attention that the medical device manufacturer, Nestle HealthCare Nutrition, Inc. has initiated a medical device field safety corrective action concerning Compat Nasogastric Feeding Tubes with universal "Y" adaptor and Stretch-Lok strap (COMPAT NG Tubes). The affected models are Compat Nasogastric Feeding Tube 8Fr, 10Fr and 12Fr. The affected lots are:

- 01413G, 02412K, 00211Z, 00712W, 14212U, 14611P, 21512Y for Compat Nasogastric Feeding Tube 8Fr;
- 00111M, 00712D, 10211E, 13712W, 21512F for Compat Nasogastric Feeding Tube 10Fr; and
- 01211AV, 01513N, 04111D, 04111P, 04111V, 05812F, 05912F, 06213N, 21512G, 23412BV, 34712V, 35411U for Compat Nasogastric Feeding Tube 12Fr.

According to the manufacturer, this recall has been initiated due to the fact that some of the COMPAT NG Tubes have been delivered in an insufficiently sealed pouch, thus compromising the sterility claimed on the label. The manufacturer assures customers that all COMPAT NG Tubes have gone through the sterilization process and there have been no complaints associated with the recalled product. However, the manufacturer is recalling the affected products because the sterility claim on the label cannot be 100% certified and verified.

Patient safety risk is considered negligible for the following reasons:

- The gastrointestinal tract normally contains many different bacteria species;
- Nasogastric tubes become non-sterile as soon as they are placed through the nasal cavity;
- If brought into a sterile environment such as an operating room because of the "sterile" labeling, standard operating procedures in those environments would minimize the chance of contamination via gloves or a similar mechanism;
- Other products on the market with the same intended use are sold non-sterile.

According to the local supplier, the affected products have been distributed in Hong Kong.

If you are in possession of the affected products, please contact your supplier for necessary actions.

Posted on 26 July 2013



MDCO website

Letter to Healthcare Professionals

香港特別行政區政府
衛生署
醫療儀器管制辦公室

香港灣仔皇后大道東 183 號
合和中心 31 樓 3101 室



THE GOVERNMENT OF THE HONG KONG
SPECIAL ADMINISTRATIVE REGION
DEPARTMENT OF HEALTH
MEDICAL DEVICE CONTROL OFFICE

Room 3101, 31/F., Hopewell Centre,
183 Queen's Road East, Wan Chai,
Hong Kong

本處傳真 OUR REF: L/M (I) 88 DH/MDCO-20-10-9
來函編號 YOUR REF:
電話 TEL: 3107 8484
圖文傳真 FAX: 3157 1286

18 January 2013

Dear Healthcare Professionals,

United States Food and Drug Administration's safety recommendations on metal-on-metal hip implants

Further to our letter sent to you on 3 April 2012 on the safety concerns over metal-on-metal (MoM) hip implants (The letter is available at our website: http://www.mdco.gov.hk/english/emp/emp_hp/files/hcp_mom.pdf), your attention is drawn to the safety information and recommendations over MoM hip implants recently issued by the United States Food and Drug Administration (FDA).

In MoM hip implants, the metal ball and the metal cup slide against each other during mobilization causing some tiny metal particles to wear off of the device around the implant, and lead to damage to bone and/or soft tissue surrounding the implant and joint. Soft tissue damage may lead to pain, implant loosening, device failure and the need for revision surgery. Besides, some of the metal ions released may enter the bloodstream causing illnesses.

Based on its latest assessment of the issue, FDA has provided updated safety information and recommendations to patients and health care providers of MoM hip implants, including their benefits and risks, and the outcome of the June 2012 Orthopaedic and Rehabilitation Devices Advisory Panel meeting.

The safety communication provides recommendations for orthopaedic surgeons before the surgery and during patient follow-up, for imaging the implant, monitoring and assessing metal ion levels and considerations for device revision. Besides, recommendations are also given for patients considering hip implants, and those with metal-on-metal hip implants. FDA also advises all healthcare providers to watch out for metal ion adverse events that may occur in patients with MoM hip implant. These events may include general hypersensitivity reaction, cardiomyopathy, neurological changes including sensory changes, psychological status change, renal impairment and thyroid dysfunction. Patients with systemic findings should be advised to consult his or her orthopaedic surgeons for further actions.

竭誠服務顧客為本素貫為先

We are committed to providing client-oriented service

Department of Health
The Government of the Hong Kong Special Administrative Region

GOVHK 香港政府一站通 TEXT ONLY 繁體版 简体版

MY COLOUR A A SEARCH Enter search keywords SITE MAP

Home Medical Device Control Office

Information and Publication

Home >> Information and Publication >> For Healthcare Professionals

* For Healthcare Professionals

General Information

- What is a Medical Device?
- Classified Examples of Medical Devices

Selected Documents

- Breast Augmentation
- Central Venous Catheter (CVC)
- Contact Lens
- Home-use Blood Glucose Meter
- Reusable Endoscopic / Laparoscopic Instruments and accessories
- TENS Machine
- Oxygen Concentrator
- Obstructive Sleep Apnea and CPAP Respirator

Letters to Healthcare Professionals

- United States Food and Drug Administration's safety recommendations on metal-on-metal hip implants (Posted on 18 Jan 2013)
- Discontinuation of "Macrolane" for use in breast augmentation (Posted on 24 Apr 2012)
- Risk of life-threatening embolism related to the use of air- or gas-pressurised spray devices for application of sprayable fibrin sealants (Posted on 12 Apr 2012)
- Safety concerns over metal-on-metal total and hip resurfacing hip replacement systems (Posted on 5 April 2012)

Useful Sites

WC WCAG 2.0 W3C HTML



www.mdco.gov.hk



MDCO website

■ Press Release

Department of Health
The Government of the Hong Kong Special Administrative Region

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Home Medical Device Control Office

Press Release

Home >> Press Release

- [8 July 2013] Press Release: Safety alert on GE Healthcare nuclear medicine systems
- [5 May 2013] Press Release: Safety alert on CoaguChek blood coagulation testing devices
- [24 April 2013] Press Release: Recall of PTS Panels Glucose Test Strips (with photo)
- [19 April 2013] Press Release: Safety alert on automated peritoneal dialysis system
- [27 Mar 2013] Press Release: Recall of Multitest Radiopaque Cu/FS intrauterine contraceptive devices (with photos)
- [25 Mar 2013] Press Release: Safety alert on two automated external defibrillators
- [21 Feb 2013] Press Release: Recall of Restylane SubQ Lidocaine 2ml dermal filler
- [15 Jan 2013] Press Release: Recall of selected lots of two brands of Acuvue contact lenses
- [17 Jul 2012] Press Release: Safety alert on ear lubricant
- [18 May 2012] Press Release: Medical device alert on a blood glucose monitoring system
- [24 Apr 2012] Press Release: Safety alert over Cameron Health SQ-RX Pulse Generators
- [6 Mar 2012] Press Release: Safety alert over certain Medtronic implantable cardioverter-defibrillators
- [5 Mar 2012] Press Release: Recall of EUKARE Blood Glucose Test Strip
- [22 Feb 2012] Press Release: Recall of Mylife Pure blood glucose strips in France
- [31 Jan 2012] Press Release: Recall of Cardiac Science automated external defibrillators
- [18 Jan 2012] Press Release: Recall of selected lots of ACUVUE® OASYS® with HYDRACLEAR® Plus Contact Lenses

Department of Health
The Government of the Hong Kong Special Administrative Region

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Home Medical Device Control Office

Press Release

Home >> Press Release

* Safety alert on GE Healthcare nuclear medicine systems

The Department of Health (DH) today (July 5) draw public attention to a safety alert concerning nuclear medicine systems manufactured by GE Healthcare

The above alert was noticed during DH's routine surveillance on medical devices safety issues. The affected systems include 1) Infinia nuclear medicine systems; 2) VG and VG Hawkley nuclear medicine systems; 3) Hela nuclear medicine systems; 4) Siva NM15; 5) Discovery NM33; 6) Optima NMCT40 and 7) Discovery NMCT670.

According to GE Healthcare, a patient in the United States has died due to injuries sustained while being scanned on an Infinia Hawkley 6, as a portion of the system has fallen onto the patient during the scan.

Investigation by the manufacturer revealed that the bolts which secured the camera to the gantry were loose, thereby stressing the support mechanism of the device and resulting in the incident.

Because of the similarities in the design of support mechanisms across many products, GE Healthcare advised healthcare facilities to cease the use of all the above-mentioned systems in addition to the Infinia system which was involved in the incident, until they have inspected all affected systems to verify that the support mechanism fasteners are secured properly.

According to the local supplier, GE Medical Systems Hong Kong Limited, 14 units of the affected nuclear medicine systems were installed at public and private hospitals in Hong Kong. The supplier has informed all affected users and will arrange inspection of the systems as soon as possible.

"So far, the DH has not received any relevant report of adverse incidents related to the devices in Hong Kong," a DH's spokesman added.

The DH has informed public and private hospitals and relevant medical associations about the alert and shall continue to liaise with the supplier on the follow-up actions.

Ends

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Follow up actions

- Monitor the manufacturer's / local supplier's progress of actions
 - Notification of affected users
 - Root cause analysis
 - CAPA e.g. software upgrade, IFU update etc.



Post-market control – AE Reporting (1)

■ Objectives

- To improve the **protection** of health and safety of patients, users and others by disseminating information that may **reduce** the likelihood of, or **prevent** repetition of adverse events associated with medical devices, or alleviated consequences of such repetition

■ Based on GHTF

■ Types of AE

- Death
- Serious Injury
- Serious public health concern
- Others



Post-market control – AE Reporting (2)

■ Adverse Incidents to be reported under the MDACS

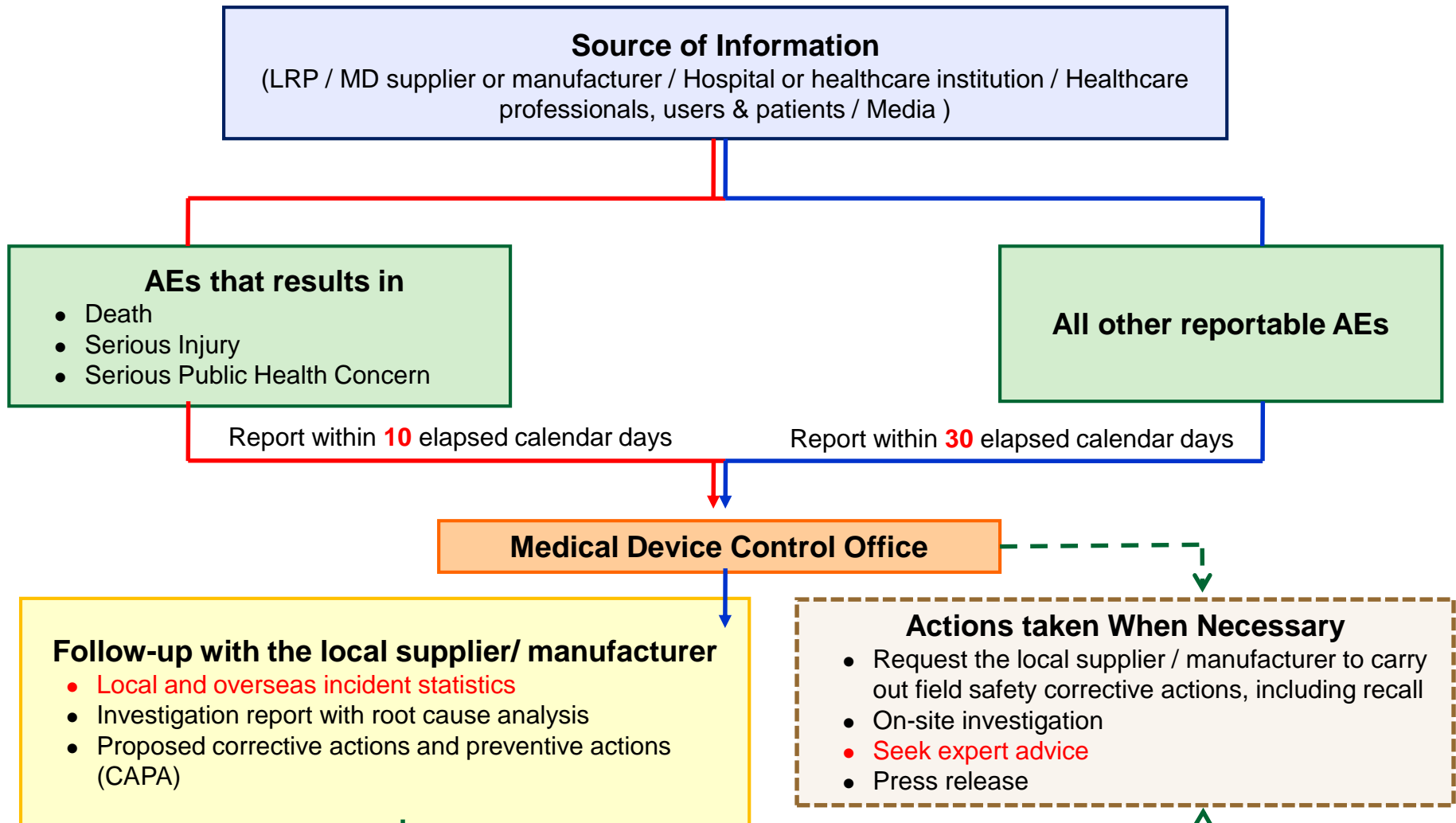
- ❑ The LRP becomes **aware** of information regarding an incident that has occurred with his listed device(s)
- ❑ The LRP's device is **associated** with the incident



Outcomes	Reportable
<u>Death</u> of a patient, user or other person	YES
<u>Serious injury</u> of a patient, user or other person	YES
No death or serious injury occurred but the incident <u>might lead to death or serious injury</u> of a patient, user or other person of the <u>incident recurs</u>	YES
<u>Use errors</u> meeting any of the following criteria	YES
◆ Results in death or serious injury/serious public health concern	
◆ A change in trend or a change in pattern of an issue that can potentially lead to death or serious injury or public health concern	
◆ When the LRP or manufacturer initiates corrective action to prevent death or serious injury or serious public health concern	



Post-market control – AE Reporting (3)



Thank you



Standard questions for safety alerts

1. Do you have any agencies in Hong Kong to represent you regarding the affected product?

2. Have this model (both affected and non-affected products) been distributed in Hong Kong? If affirmative, have the affected product been distributed in Hong Kong?

3. If you have supplied the affected products to Hong Kong, please provide us with the following information:
 - (a) The letter/information issued for the affected devices;
 - (b) The list of affected devices distributed in both the public and private healthcare service organizations in Hong Kong (such as public and private hospitals, clinics, health centres, laboratories, auxiliary medical service, etc.);
 - (c) Whether you have already notified all the affected organizations; and
 - (d) Your proposed rectification actions and programme, if any.



Standard questions for adverse incidents

To facilitate our investigation, we would be grateful if you could provide us with the following information:

1. Photo(s) of the broken device

2. Sales volume of _____

- Local
- Global

3. No. of complaints/ incidents related to _____ in the same period of time

- Local
- Global

4. Root cause of the incident

5. Relevant corrective and preventive actions, if applicable.

