The Introduction of Adverse Events Report of Medical Devices

The Working Group on Medical Measurements

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Chinese Taipei

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Look Back on 2013's Presentation -1

The health agency's most concerns about Medical devices:

- Safety
- Effectiveness

Look Back on 2013's Presentation -2

Legal measures taken by health agency:

A. Registration-Products

B. Quality Management System, Good Manufacturing Practices-Manufacturers

C. Adverse Events Report-Manufacturers & User Facilities

- The standards or documents to be chosen：
  - ISO
  - GHTF
    - Global Harmonization Task Force

Definition of Medical Devices -1

ISO 14155:2011

- ✓ Any instrument, apparatus, implements, machine, appliance, implant, software, material or other similar or related article:
  - a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose of:
    1. diagnosis, prevention, monitoring, treatment or alleviation of disease,

(GHTF) SG1(PD)/N71R04

- ✓ Any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent, software, material or other similar or related article:
  - a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
    1. diagnosis, prevention, monitoring, treatment or alleviation of disease,

Definition of Medical Devices -2

ISO 14155:2011

2. diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
3. investigation, replacement, modification, or support of the anatomy or of a physiology process,
4. supporting or sustaining life,
5. control of conception,

(GHTF) SG1(PD)/N71R04

2. diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
3. investigation, replacement modification, or support of the anatomy or of a physiological process,
4. supporting or sustaining life,
5. control of conception,

Definition of Medical Devices -3

ISO 14155:2011

6. disinfection of medical devices

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

(GHTF) SG1(PD)/N71R04

6. disinfection of medical devices,
7. providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body;

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Definition of Medical Devices -4

ISO 14155:2011

- **Note** The term “medical device” is usually defined by national regulations. For the purposes of this International Standard, this definition does not list “*in vitro* diagnostic medical devices”.

(GHTF) SG1(PD)/N71R04

- **Note 1:** Products which may be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, include:
  - disinfection substances,
  - aids for persons with disabilities,
  - accessories to a medical device (see Note 2),
  - components of a medical device,
  - devices incorporating animal and/or human tissues.

Definition of Medical Devices -5

ISO 14155:2011

(GHTF) SG1(PD)/N71R04

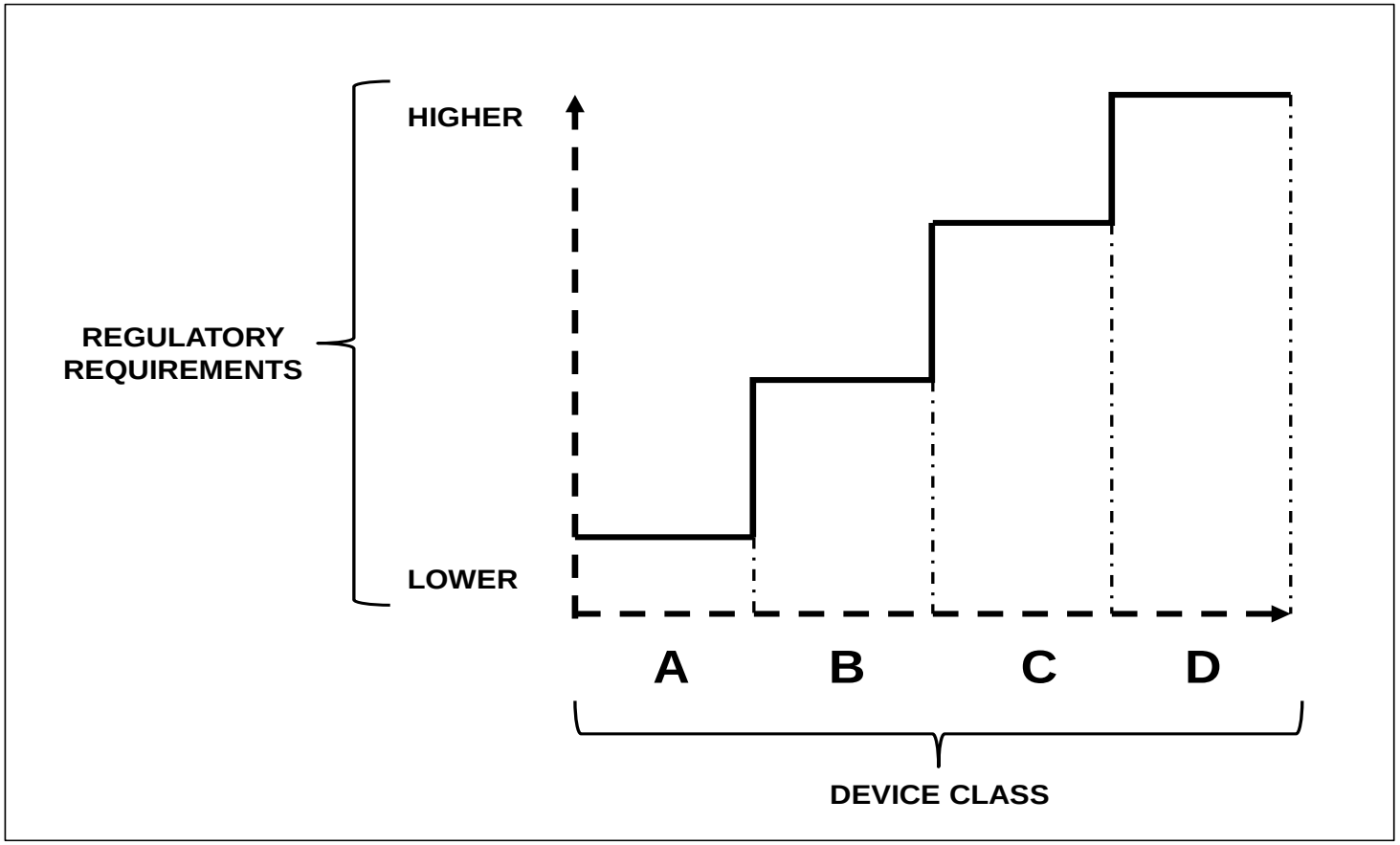
- **Note 2:** Some jurisdictions include accessories to a medical device within the definition of a medical device. Other jurisdictions do not adopt this approach but still subject an accessory to the regulatory controls (e.g. classification, conformity assessment.

Classification of Medical Devices-1

Class	Level	Device Examples
A	Low Hazard	Bandages / Tongue Depressors
B	Low-Moderate Hazard	Hypodermic Needles / Suction Equipment
C	Moderate-High Hazard	Lung Ventilator / Bone fixation Plate
D	High Hazard	Heart Valves / Implantable Defibrillator

GHTF/SG1/N77:2012

Classification of Medical Devices-2



GHTF/SG1/N77:2012

Classification of Medical Devices-3

Australia[b]	Class Ⅰ, Ⅱa, Ⅱb, Ⅲ, Active implantable medical devices
Canada	Class Ⅰ, Ⅱ, Ⅲ, Ⅳ
P.R. China	Class Ⅰ, Ⅱ, Ⅲ
Hong Kong, China[a]	Class Ⅰ, Ⅱ, Ⅲ, Ⅳ
Japan	Class Ⅰ, Ⅱ,Ⅲ, Ⅳ
Rep of Korea	Class Ⅰ, Ⅱ, Ⅲ, Ⅳ
Malaysia[a]	Class A, B, C, D
Indonesia	Class A, B, C, D
New Zealand[b]	Class Ⅰ, Ⅱa, Ⅱb, Ⅲ, Active implantable medical devices
Singapore	Class A, B, C, D
Chinese Taipei	Class Ⅰ, Ⅱ, Ⅲ
Thailand	Class Ⅰ, Ⅱ, Ⅲ
U.S.A	Class Ⅰ, Ⅱ, Ⅲ

Definition of Adverse Events -1 ISO 14155

- Any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons whether or not related to the investigational medical device.
  - Note 1 to entry: This definition includes events related to the investigational medical device or the comparator.
  - Note 2 to entry: This definition includes events related to the procedures involved.
  - Note 3 to entry: For users or other persons, this definition is restricted to events related to investigational medical devices.

Definition of Adverse Events -2 GHTF/SG2N54R8

The events which have occurred with device including:

a) A malfunction or deterioration in the characteristics or performance;

b) An incorrect or out of specification test result;

c) The discovery of a design flaw during design review;

d) An inaccuracy in the labeling, instructions for use and/or promotional materials. Inaccuracies include omissions and deficiencies. The discovery of a serious public health threat. (This can include an event that is of significant and unexpected nature such that it becomes alarming as a potential public health hazard, e.g. HIV or Creutzfeldt-Jacob Disease);

e) Use Error.

Classification of Adverse Events -1
ISO 14155

- Non-medical complaint
- Adverse Event (AE)
- Serious Adverse Event (SAE)
- Adverse Device Effect /Unanticipated Adverse Device Effect (ADE/UADE)
- Serious Adverse Device Effect/Unanticipated Serious Adverse Device Effect (SADE/USADE)

Classification of Adverse Events -2 ISO 14155

- Serious
  - Led to a death
  - Led to a serious deterioration in the health of the subject that:
    - Resulted in life-threaten illness or injury, or
    - Resulted in a permanent impairment of a body structure or a body function, or
    - Required in-patient hospitalization or prolongation of existing hospitalization, or
    - Resulted in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function,
  - Led to fetal distress, fetal death, or a congenital abnormality or birth defect

Classification of Adverse Events -3 GHTF/SG2/N54R8

- Death of a patient, User or Other Person,
- Serious Injury of a patient, User or Other Person (Serious injury is either:
  - a life-threaten illness or injury;
  - permanent impairment of a body function or permanent damage to a body structure;
  - a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure);
- No Death or Serious Injury Occurred but the Event Might Lead to Death or Serious Injury of a patient, User or Other Person if the Event Recurs.

Adverse Events Report -1

- What to report
- Who to report
- Whom to report to
- When to report

Adverse Events Report -2

What to report- GHTF/SG2/N21R8

a) A malfunction or deterioration in the characteristics or performance.

b) An inadequate design or manufacture.

c) An inaccuracy in the labeling, instruction for use and/or promotional materials.

d) A significant public health concern.

e) Other information becoming available.

Adverse Events Report -3

What to report- Annex 7 of Directives 90/385/EEC and Annex X of 93/42/EEC

a) Any SAE.

b) Any investigational Medical Devices Deficiency that might have led to a SAE if

1) suitable action had not been taken, or

2) intervention had not been made, or

3) if circumstances had been less fortunate.

c) New finding/updates in relation to already reported events.

Adverse Events Report -4

What to report-Australia

- An adverse event is an event that led to :
  - death,
  - a serious injury or deterioration to a patient, user, or other person, including:
    - a life-threaten illness or injury,
    - permanent impairment of a body function,
    - permanent damage to a body structure,
    - a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

Adverse Events Report -5

What to report-P.R. China

- Any type of event that occurs in the course of normal use of an approved medical device, which is made in accordance with quality standards, and the event causes or could cause bodily harm to humans.

Adverse Events Report -6

What to report-United States of America

- An adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious and should be reported to FDA when the patient outcome is:
  - death
  - life-threatening
  - hospitalization (initial or prolonged)
  - disability or permanent damage
  - congenital anomaly/birth defect
  - required intervention to prevent permanent impairment or damage (devices)
  - other Serious (important medical events)

Adverse Events Report -7

What to report-Chinese Taipei

- An adverse event is any undesirable experience associated with the use of a medical product in a patient that led to:
  - death
  - life-threatening
  - disability or permanent damage
  - congenital anomaly/birth defect
  - hospitalization (initial or prolonged)
  - required intervention to prevent permanent impairment or damage
  - unserious response

Adverse Events Report -8

MEDDEV 2.7/3 SAE Report Table v1															
EUDAMED - ID:															
Title of Clinical Investigation:															
CIP Number:															
Contact person (Name, Address, E-Mail, Telephone Number)										**Device type:**					
MS+NCA Reference Numbers for all participating Countries:										**Reference Member State:**					
No. of Patients enrolled to date (date of report):										**No. of Invest. Devices used to date**					
Date of Report:															
Status: a, m, u	**Date Sponsor received Report of SAE**	**Country**	**Study Center**	**Patient ID Code**	**Date of Procedure/ First Use**	**Date of Event Onset**	**Event: Organ System**	**Description of event**	**action/ treatment/patient outcome**	**Assessment of Relationship to Procedure:** Yes No Possibly	**Assessment of Relationship to Investigational Device:** Yes No Possibly	**Unanticipated SADE yes/No**	**Treatment Arm:** Investigational Device/ Control Group/ blinded/ n.a.	**Event Status:** Resolved/ Resolved with Sequelae/ Ongoing/Death	**Date of Event Resolution**

Note: Submission of this report does not, in itself, represent a conclusion by the sponsor or the competent authority that the content of this report is complete or that the device(s) listed failed in any manner and/or that the device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Adverse Events Report -9

Who to report

- Mandatory
  - Manufacturers and Importers
  - User Facilities
- Voluntary
  - Clinicians
  - Customers/Users

Adverse Events Report -10

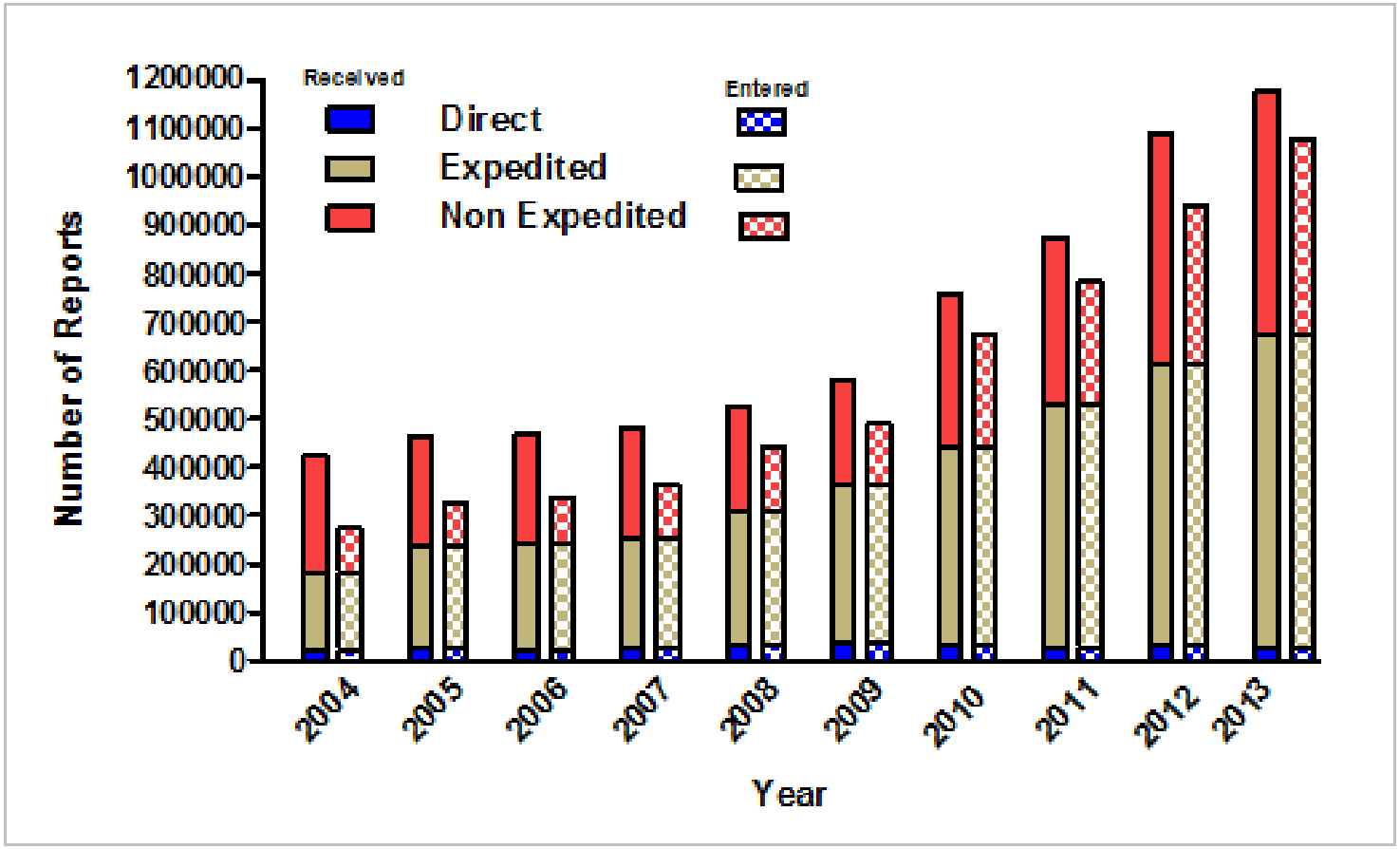
Whom to report to:

- Health Competent Agency
- Manufacturer

When to report:

- Expedited reporting
- Non-Expedited reporting

Adverse Events Report -11



This figure illustrates the number of reports received (solid bars) and entered (checkered bars) into FAERS/FDA by type of report since the year 2004 through 2013.

2016 Working Plan

- Collecting the Medical Instruments Adverse Report framework information in Asia Pacific region
  - Objects
    1) To contracture the picture of the system of adverse report of medical instruments in Asia Pacific region
    2) To address the threaten of malfunction/inaccuracy of medical measurement instruments;
    3) To bridge the dialogue between metrology authority and health authority
  - Approach
    - Design and disseminate a survey to collect the mechanisms of the system of adverse report of medical instruments in Asia Pacific region.

- Comments?
- Questions?

Thank you!