Survey on Legal Measures Mechanism on Medical Devices

The Working Group on Medical Measurements

The 24rd Forum Meeting

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Hui-Ling Ting

Bureau of Standards, Metrology and Inspection

Chinese Taipei

Outline

- Look Back on 2015 and 2016 Investigations
- The Survey Result in 2017
- 2018 Working Plan

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Look Back on 2015 and 2016 Investigations(1/8)

2015

"*The Introduction of Adverse Events Report of Medical Devices*"

2016

"*Survey on Medical Devices Adverse Event Report* "

- Introduce adverse events : definition & classification
- In which conditions would an adverse event for a medical device be reported?
- Who must report an adverse event?
- Which authority takes responsibility for dealing with medical device adverse events?

Look Back on 2015 and 2016 Investigations(2/8)

Definition of Adverse Events (*referring to* GHTF/SG2/N54/R8)

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

e) The discovery of a serious public health threat

f) Use Error

NOTE: 1. GHTF means "Global Harmonization Task Force"

2. GHTF/SG2/N54R8:2006: Title "Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices"

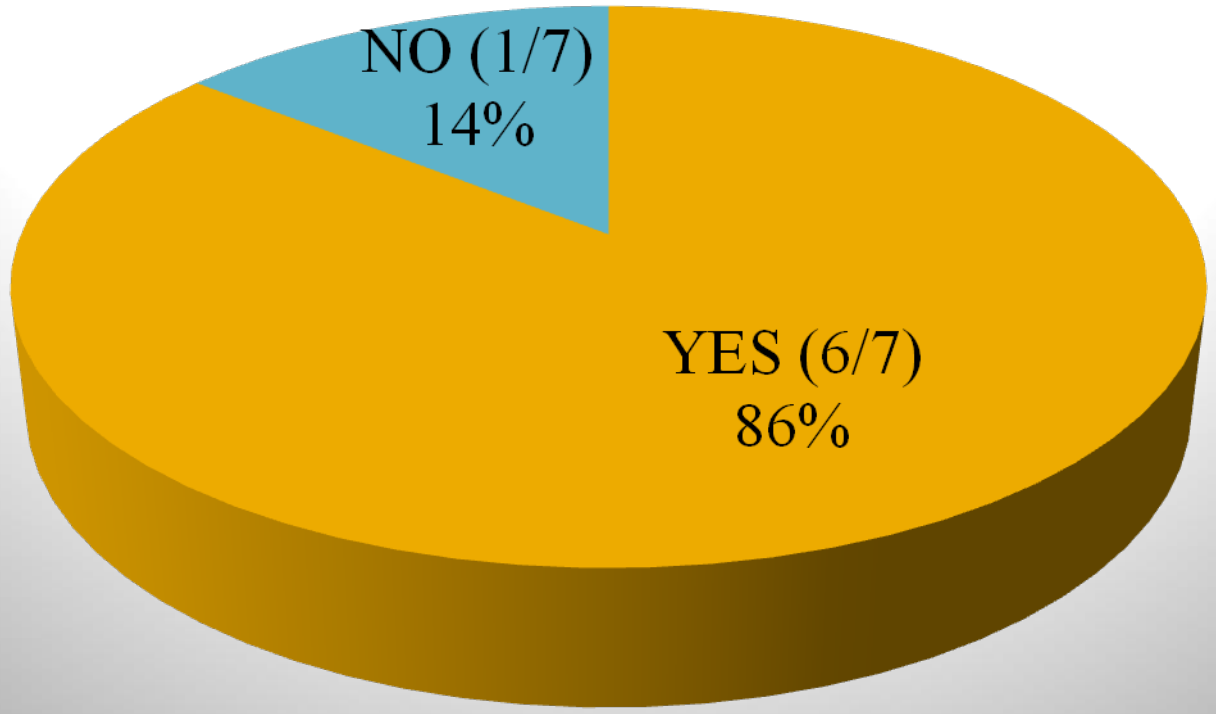
Look Back on 2015 and 2016 Investigations(3/8)

Classification of Adverse Events (*referring to* GHTF/SG2/N54/R8)

- ✓ Death of a patient, User or Other Person
- ✓ Serious Injury of a patient, User or Other Person
  - 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

Look Back on 2015 and 2016 Investigations(4/8)

Mechanisms for reporting medical device adverse events



Note: There are 7 responses totally for 2016 survey

Look Back on 2015 and 2016 Investigations(5/8)

- **In which conditions would an adverse event for a medical device be reported?**

(a) Fault with the device that caused (or could have caused) injury/death

	Canada	Indonesia	Malaysia	Mongolia	Singapore	Chinese Taipei
A malfunction or deterioration in the characteristics or performance	●	●	●		●	●
Inadequate design or manufacture	●	●	●	●	●	●
Inaccurate labeling, instruction for use and/or promotional materials	●	●	●		●	●
Other information becoming available (for example, manufacturers testing results on device are published)		●	●		●	●
Unclean/unsterile device	●	●	●	●	●	●
Incorrect assembly or use of device	●	●	●	●	●	●

Look Back on 2015 and 2016 Investigations(6/8)

- **In which conditions would an adverse event for a medical device be reported?**

(b) Fault with a device that resulted in the following outcome for a person

	Canada	Indonesia	Malaysia	Mongolia	Singapore	Chinese Taipei
Death	●	●	●	●	●	●
Serious injury or deterioration to a patient, user, or other person	●	●	●		●	●
Hospitalization (initial or prolonged)	●	●	●	●	●	●
Disability or permanent damage	●	●	●		●	●

Look Back on 2015 and 2016 Investigations(7/8)

- **Who must report an adverse event?(for example)**

	Canada	Indonesia	Malaysia	Mongolia	Singapore	Chinese Taipei
Manufacturers and Importers	●	●	●		●	●
User Facilities				●		●
Clinicians		●		●		●
Customers/Users				●		

- ***Which authority takes responsibility for dealing with medical device adverse events* : *Health authority* (almost all members)**

Look Back on 2015 and 2016 Investigations(8/8)

How many medical device adverse events occurred (2015)

Medical Device	Estimate proportions
Medical syringes (R 26)	**Medium ~ Small**
Clinical electrical thermometers with maximum device(R 115)	**Medium ~ Small**
Mechanical non-invasive sphygmomanometers (R 16-1)	**Small**
Non-invasive automated sphygmomanometer(R 16-2)	**Small**
Westergren tubes for measurement of erythrocyte sedimentation rate(R 78)	**Small**
Electrocardiographs - Metrological characteristics - Methods and equipment for verification(R 90)	**Small**
All other Devices	**Large**

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- Look Back on 2015 and 2016 Investigations
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- 2018 Working Plan

The Survey Result in 2017 (1/12)

Topic: "*Survey on Legal Measure Mechanism on Medical Devices*"

■ The related information of Legal Measures Mechanism

	Canada	Vietnam	Mongolia	Japan	Philippine	Chinese Taipei
1. *Is your economy having legal measures mechanism?*	√	√	√	√	√	√
2-1. *Which authority takes the responsibility?*	Health Canada	Department of Medical Equip-ment and Con-struction , Ministry of Health ♯1	**1.**Ministry of Healthy **2.**Department of Measuring instruments Verification, (MASM)	**1**. Ministry of Health, Labour and Welfare (MHLW) **2**. Ministry of Economy, Trade and Industry (METI)	Center for Device Regulation, Radiation Health, and Research of the Food and Drug Administration (CDRRHR FDA)	1. Ministry of Health and Welfare (MOHW) **2**. Bureau of Standards, Metrology and Inspec-tion (BSMI)

♯1 : Other agencies in coordination with Ministry of Health: Directorate for Standards, Metrology and Quality; Vietnam Agency for Radiation and Nuclear Safety

The Survey Result in 2017 (2/12)

■ The related information of Legal Measures Mechanism

	Canada	Vietnam	Mongolia	Japan	Philippine	Chinese Taipei
2-2. *Level of the competent authority*	Central/ National government	Central/ National government	Central/ National government	Central/ National government	Central/ National government	Central/ National government
3. *List the relative laws, regulations or directions (website address)*	Medical Devices Regulations (http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/)	**1.** Management of medical devices: **Decree No.36/2016/ND-CP** **2.** Measuring instruments: **No.04/2011/QH13** **3.Medical devices related to radiation**: **No.18/2008/QH12**	**1.** Mongolian Law on Guarantee of measurement uniformity **2.** Mongolian Law on Medicine and medical device	**1.** The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceutical and Medical devices **2.**Measurement Act	Republic Act 9711	**1.**Regulations for Registration of Medical Device **2.**Verification and inspection of legal measuring instruments

The Survey Result in 2017 (3/12)

■ The related information of Legal Measures Mechanism

	Canada	Vietnam	Mongolia	Japan	Philippine	Chinese Taipei
4-1. *Is there any legal measures mechanism during pre-market stage?*	√	√	√	√	√	√

◆ 4-2 Describe the legal measures mechanism during pre-market stage

Vietnam:

- Including the registration for unrestricted distribution, requirement for medical device manufacture, type approval

The Survey Result in 2017 (4/12)

■ The related information of Legal Measures Mechanism

◆ 4-2 Describe the legal measures mechanism during pre-market stage *(cont)*

Mongolia:

- Relevant medical organizations/hospitals/Health centers/ are responsible for control, check & adjustment of medical devices.
- Health development center is responsible for calibration and control of medical devices
- Mongolian General Agency for specialized inspection is responsible for control and inspection of measuring instruments and medical devices.
- MASM and it's Province centers are responsible for calibration & re-verification of measuring instruments.

NOTE: MASM :"Mongolian Agency for Standardization and Metrology"

The Survey Result in 2017 (5/12)

■ The related information of Legal Measures Mechanism

◆ 4-2 Describe the legal measures mechanism during pre-market stage *(cont)*

Japan:

- Under Measurement Act, the sphygmomanometer and clinical thermometer shall be type-approved and verified during the pre-market stage.

Philippine:

- The company who wish to import/distribute/manufacture medical device should secure first a license to operate (LTO) as medical device establishment. After the approval of the LTO, the company should apply for the certificate of product registration of individual medical devices that are regulated.

Chinese Taipei:

- Manufacturer/Importer need to obtain the medical permit license during pre-market stage.
- The regulations for registration system depend on the risk classification which refers to GHTF's standard.
- For legal metrology regulations, the sphygmomanometer and clinical electrical thermometer shall be verified.

The Survey Result in 2017 (6/12)

The related information of Legal Measures Mechanism

	Canada	Vietnam	Mongolia	Japan	Philippine	Chinese Taipei
5. *Who shall notice the competent authorities to take legal measures during pre-market stage?*	Manufacturer /Importer	Manufacturer /Importer	Manufacturer /Importer	Manufacturer /Importer	Manufacturer/ Importer	Manufacturer/ Importer
6-1. *Is there any legal measures mechanism during post-market stage?*	√	√	√	√	√	√

The Survey Result in 2017 (7/12)

■ The related information of Legal Measures Mechanism

◆ **6-2 Describe the legal measures mechanism during post-market stage?**

Vietnam:

- Including examination, inspection, verification and so on.

Philippine:

- Implementing post-market surveillance. Post market activities ensures the continuous compliance of the companies with the requirements of the FDA. Companies who violates the law will be given notice of violation.

Chinese Taipei:

- Including mechanism for adverse event report, product recall, re-modifying and so on.

The Survey Result in 2017 (8/12)

The related information of Legal Measures Mechanism

	Canada	Vietnam	Mongolia	Japan	Philippine	Chinese Taipei
7. *Who shall notice the competent authorities to take legal measures during post-market stage?*	**1.** Manufacturer /Importer **2.** Buyer/User /Patient **3.** Stakeholder association ♯1	**1.** Manufacturer /Importer **2.** Buyer/User /Patient	**2.** Buyer/User /Patient.	**1.** Manufacturer /Importer **2.** Buyer/User /Patient **3.** Stakeholder association ♯2	2.Buyer/User/ Patient. ♯3	**1.** Manufacturer /Importer **2.** Buyer/User /Patient

♯1

- Health Canada deals directly with manufacturers concerning their medical device license; however interaction post-market can include safety risk communications to the public, healthcare professionals, healthcare institutions, associations of laboratories, etc, depending on the medical device or issue.

♯2

- Competent manufacturers are allowed to conduct the initial verification after an assessment by METI under the Designated Manufacturers System specified by Measurement Act.

♯3

- This is an activity of the FDA to do post-market surveillance. However, users/patient/buyers complaint can also trigger the surveillance activity.

The Survey Result in 2017 (9/12)

■ The related information of Legal Measures Mechanism

	Canada	Vietnam	Mongolia	Japan	Philippine	Chinese Taipei
8-1. *Are there any legal requirements for manufacturers/importers*	√	√	√ (#1)	√ (#2)	√ (#3)	√ (#4)

#1

- Management of medical devices: Decree No.36/2016/ND-CP

#2

- Under Measurement Act, the manufacturers of sphygmomanometers and clinical thermometers must be registered and they shall bring the products into type approval and initial verification before sale.
- Measurement Act and related technical specifications (JIS) are applied to sphygmomanometers and clinical thermometers. There are however other regulations under MHLW.

The Survey Result in 2017 (10/12)

■ The related information of Legal Measures Mechanism

	Canada	Vietnam	Mongolia	Japan	Philippine	Chinese Taipei
8-1. *Are there any legal requirements for manufacturers/importers(cont)*	√	√	√ (#1)	√ (#2)	√ (#3)	√ (#4)

#3

- The company who wish manufacture medical device should secure first a license to operate (LTO) as medical device establishment. After the approval of the LTO, the company should apply for the certificate of product registration of individual medical devices that are regulated. Requirements for the regulation of medical devices like LTO and CPR can be downloaded from the FDA website at www.fda.gov.ph under industry corner.

#4

- Related regulation : Pharmaceutical Affairs Act

The Survey Result in 2017 (11/12)

- **Does your economy harmonize the concerned regulations with international recommendations/standards?**

  √ *Yes for all economies!!*

- **Estimated annual domestic market value of medical device in your economy**

For example:

Vietnam *: US$ 837 million*

Chinese Taipei: *US$ 2096 million*

Gross world product(GWP): *US$ 343334 million*

The Survey Result in 2017 (12/12)

Summary

- Generally, most members have the legal measures mechanism. Then the competent authority for legal measures mechanism on medical devices is national health agency in almost all member economies.
- Health agencies take on most legal measures. They have comprehensively regulatory requirements, including safety and performance for various medical devices. On the other hand, the legal metrology agencies are just in charge of small portion regarding the measurement and verification.
- Manufacturers/importers are regulated for pre- and post-market stages.
- Almost all member economies use harmonized regulations and standards established by international organization.

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2018 Working Plan

Subject:

Investigating the Regulatory System and Recognized Standards for the "Non-invasive Automated Sphygmomanometer"

- ***Regulatory Systems***
  - Health authority
  - Legal metrology authority
- ***Recognized Standards***
  - GHTF SG1-N11:2008
  - OIML R16-2
  - Others

Thanks for your attention!

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Bureau of Standards, Metrology and Inspection(BSMI)
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Appendix

Relevant Harmonized Standard(1)

GHTF (The Global Harmonization Task Force)

- Definition

  SG1(PD)/N71R04 "Definition of the Term 'Medical Device'"

- Classification

  GHTF/SG1/N77:2012 "Principles of Medical Devices Classification"

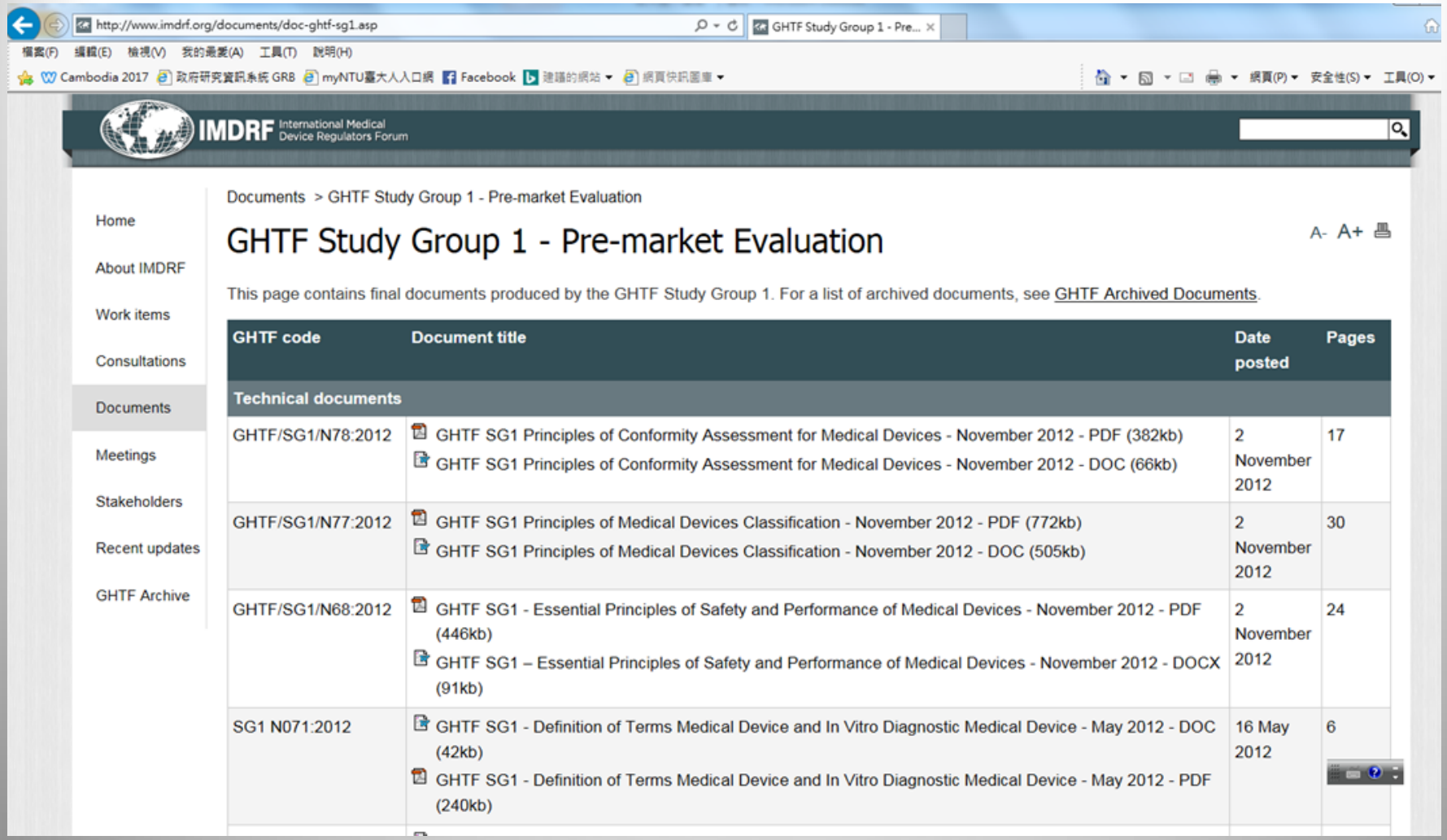
- STED & EP

  GHTF/SG1/N11:2008 "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)"

- Adverse Events

  GHTF/SG2N54R8"Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices"

Relevant Harmonized Standard(2)



International Medical Device Regulators Forum (IMDRF)

(http://www.imdrf.org/documents/doc-ghtf-sg1.asp)

Relevant Harmonized Standard(3)

- STED : (Summary Technical Documentation)

Device Description, EP Checklist, Risk Analysis and Control Summary, Product Verification and Validation

- EP : (Essential Principles)
  - Safety :chemical, physical and biological properties, EMC……
  - Performance: measuring function, diagnosis function….
- Note: Other Related Standards
  - ISO 13485 (Regarding Quality Management System(QMS) Regulation)
  - Recognized Standard Database(e.g. IEC 60601, ENISO17511…….)

Legal Measure(1)

- Measure

"Pre-Marking Notification", "Pre-Marking Approval", "Establishment License", "Declaration of Conformity" "Medical Device Reporting"…..

- Regulation Name
  - European Union Directive: MDD, AIMDD, IVMDD
  - Canada :CDMR(Canada Medical Device Regulation)
  - Japan : JPAL(Japanese Pharmaceutical Affair Law)
  - Chinese Taipei: Regulations for Registration of Medical Device

……

Classification of Medical Devices

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

Appendix-1

The health agency's most concerns about Medical devices

- Safety
- Performance

Legal measures taken by health agency:

A. Registration-Products

B. Quality Management System, Good Manufacturing Practices-Manufacturers

C. Adverse Events Report-Manufacturers & User Facilities

GHTF

- GHTF, an organization founded in 1993 by the governments and industry representatives of Australia, Canada, Japan, the European Union, and the United States of America.
- And in 2011, GHTF re-organized and replaced by IMDRF, International Medical Device Regulators Forum and introduced Brazil, P.R. China and world Health Organization into it.
- The reason we chose the organization is it is a world-wide organizations or their members share the majority of the world medical devices market.